



Consolidating Demographic Records and Vaccination Event Records

Recommendations of the American Immunization Registry Association (AIRA) Modeling of Immunization Registry Operations Workgroup (MIROW)

Issued on August 21, 2017

Suggested citation: AIRA Modeling of Immunization Registry Operations Workgroup (eds). Consolidating Demographic Records and Vaccination Event Records. Atlanta, GA: American Immunization Registry Association. August 2017. Available at the AIRA website: http://www.immregistries.org/resources/aira-mirow Disclaimer: This guide is not a mandatory requirements or standards document. It contains a set of guidelines that are recommended operational best practices for immunization information systems. Replacement for a portion of the MIROW 2006 Vaccine Deduplication Guidelines This guide acts as a replacement for Chapter 5: Resolution Phase and Appendix B in the MIROW 2006 Vaccine Deduplication Guidelines [1.8].

Executive Summary

Background

The American Immunization Registry Association (AIRA), in partnership with the National Center for Immunization and Respiratory Diseases (NCIRD) at the Centers for Disease Control and Prevention (CDC), formed the Modeling of Immunization Registry Operations Workgroup (MIROW) in 2005 to develop best practice guidance for immunization information systems (IIS). This document is one chapter of the guidebook produced by the workgroup. It provides consensus-based best practice recommendations to support the process of consolidating demographic and vaccination event records.

This topic addresses the most fundamental function of the IIS—consolidating information from various sources. Operational best practice recommendations support IIS Functional Standards (2013-2017) and IIS Functional Standard 1.3 (2018–2022), which states: "The IIS contains a complete consolidated demographic record and vaccination history for every child, adolescent, and adult participating in the IIS and currently residing in the jurisdiction" [2.1]. IIS use terms defined in several documents to describe demographic and immunization information, including prior and current IIS Functional Standards, MIROW guides (see Appendix B: About MIROW), Health Level Seven (HL7) specifications [2.4; 2.5], and others. Terms used in this guide are based on a domain model. Additionally, the guide references data elements that describe demographic and vaccination event concepts in terms of the prior Functional Standards (2013-2017) [2.1].

MIROW brought together experts from the IIS community, CDC, and IT vendors. The resulting best practice recommendations guide is a step toward the

alignment of consolidating records practices across IIS. The recommendations are intended for implementation at the business/operational level. As a result, they are independent from specific IIS implementations and technology solutions. Accordingly, the recommendations can support the wide variety of IIS implementation strategies on different technological platforms.

The National Vaccine Advisory Committee (NVAC) has recommended that the IIS community "promote the adoption of a guidebook and best practices for IIS as stated by the CDC/NIP [now NCIRD] and AIRA/MIROW Workgroup to adopt consistent operational guidance and quality control procedures that ensure good data quality" [2.9]. This best practices guide is one example of addressing the NVAC recommendation. It is designed to assist IIS with aligning practices through adherence to a set of common recommendations and guidelines. As a result, IIS will be able to better serve the needs of immunization programs, provider organizations, and other immunization stakeholders.

Relevance

Consolidating information from different sources about the patient or vaccination event, as well as information from multiple reports from the same source, leads to a more accurate and complete reflection of reality in the IIS. Likewise, consolidation of records helps maintain data quality within the IIS and allows for accurate evaluation of population- and vaccination-based assessments of a specified area. Immunization provider organizations rely heavily on these consolidated records for clinical decision support when providing services to their patients.

Replacement for a portion of the MIROW 2006 Vaccine Deduplication Guidelines

This guide acts as a replacement for Chapter 5: Resolution Phase and Appendix B in the MIROW 2006 Vaccine Deduplication Guidelines [1.8]. The 2006 guidelines recommended that IIS create two records for each vaccination event: a "best record" for clinical purposes and a consolidated record for both clinical and public health purposes. Due to changes in the health care landscape and technical advancements in the past 10 years, the current perspective is that providers should use an electronic health record (EHR) to maintain a clinical record for a patient. An IIS should take advantage of its

role as the repository of records from many data sources to create the most robust and comprehensive record possible via consolidation. This guide recommends the use of a single consolidated demographic record and a single consolidated vaccination event record for all IIS functions, including clinical decision support, query response, reminder/recall, Vaccines for Children program activities, and coverage assessment reports, and for viewing via direct user interface (UI). Consolidation can also provide a more complete record for patient use (i.e., consumer access).

Overview of consolidating records process

The consolidating records process begins when two records are identified as matched records during deduplication. The document does not cover the full details of the deduplication process; rather, the focus is only on the consolidating records piece. Matched records are two records that represent the same patient or the same vaccination event. Information from the two matched records should be combined into one consolidated record. Information about a patient is consolidated in a demographic record, and information about a vaccination event is consolidated in a vaccination event record. If there are more than two matched records, then the consolidation process runs repeatedly, comparing two records at a time. Once two records are matched, the best values for each data element will be selected to form a consolidated record. First, dataelement-level business rules are applied. If data-elementlevel business rules do not yield a best value, then recordlevel characteristics (e.g., confidence level and recency) are used to determine the best value for each data element of a consolidated record. This workgroup examined the comparison of only two records at a time, so, if an IIS opts to implement a process of comparing more than two records at a time, it may require the modification of processes and business rules.

This document provides best practice recommendations on how an IIS should consolidate records. While viewing this document, it may help the reader to consider the following three principles which provide a foundation for consolidation:

- The essence of consolidation is to select the best value for each data element from all available data sources. An IIS achieves this by comparing values from separate records for a single data element and selecting the better of the values. Via this process, an IIS distills and retains the best information in the consolidated record.
- The act of consolidation will create a new record or update an existing record.
- The functionality of consolidation relies on the accessibility within the IIS of certain original information submitted to an IIS by immunization providers and other data sources. Those data are vital for ongoing consolidation and for fixing incorrectly merged records.

The guidelines address the following aspects of consolidation:

- Fundamentals, including key concepts, terms, and definitions.
- Detailed descriptions of the demographic and vaccination event record consolidation processes.
- Principles that provide high-level direction and business rules for detailed guidance for the consolidation process. This includes the information that must be available from an EHR or direct UI, the information that must be in the IIS, and how to use that information to consolidate records.
- Typical and challenging operational scenarios applying the guidelines to real situations.
- Discussion of key implementation considerations: overarching themes for consolidation (e.g., education, methods of updating records, and IIS resources), data quality, and Health Level Seven (HL7) immunization messaging.

Key outcomes and recommendations

The guidelines discuss key concepts and terms for consolidating records, including:

- Three categories of records:
 - Demographic record: A group of related data elements that represent information about a patient.
 - Vaccination event record: A group of related data elements that represent information about a vaccination event.
 - Patient record: A combination of a demographic record for a patient and vaccination event record(s) for that patient. Each patient record contains one demographic record and zero, one, or more vaccination event records.
- Data element, value, data group, and data source. A data element is the general term for a component of a record. A value is the specific information submitted for that data element. Certain data elements are grouped together as a unit (data group), in which the value for each data element must come from the same data source. Data sources may include vital statistics, birthing hospitals, immunization providers, billing records, claims (e.g., Medicaid), schools, and health plans. Since trust in a specific data source varies between jurisdictions, each IIS should use its knowledge of local considerations to set business rules that reflect the confidence level in various data sources.
- Basic consolidation options: Consolidation of two existing records in an IIS results in either a new record or an update of an existing record.

- When an incoming record is matched to an existing record (demographic or vaccination event records), the existing record is updated with the value(s) from the incoming record that is determined to be "better."
- When two existing records (demographic or vaccination event records) in the IIS are determined to be matching records, consolidation can be accomplished in two different ways that are both equally acceptable.
 - The IIS creates a new record with a new IIS ID
 (i.e., IIS patient ID or IIS vaccination event ID) and
 stores a history of both IIS IDs for the two
 matched records in the new consolidated record.
 - The IIS selects either of the existing records to be updated with information from the other record and stores the IIS ID for the other existing record in history.
- Unmerging and traceability. Occasionally, two records will be erroneously matched and consolidated when the records truly represent different patients or vaccination events. When it is determined that two records were incorrectly consolidated, the IIS should be able to unmerge a consolidated record. To facilitate unmerging, the "best" practice is for an IIS to store all incoming records; however, it is a "good" practice for an IIS to be able to access sufficient information about the data source for each data element to facilitate unmerging. This is reflected in the principle that states that original information submitted by immunization providers and other data sources should be accessible by an IIS.

The guidelines provide a step-by-step description of the consolidating records process for both demographic and vaccination event records, 13 principles (high-level business rules that help to capture institutional knowledge and to guide the development of more specific business rules), 69 business rules (representing specific recommendations and decision-making logic for IIS processes and operations), 3 decision tables, and 20 operational scenarios. In addition, several implementation considerations are addressed including: education about the consolidation process, methods of updating records, IIS resources, provider profiles, data quality, data validation, vaccination action code concepts, data-type definitions in HL7 (compared with definitions in the guide), and the administered/historical indicator.

The following are examples of best practice recommendations in the guidelines.

- Examples of business rules for consolidating demographic records:
 - The IIS should make accessible the information needed to make consolidation decisions. <u>BR201</u>, <u>BR202</u>, <u>BR203</u>, <u>BR204</u>
 - Valid values should be used over invalid values in a consolidated record. BR501
 - Vital statistics is a definitive data source for certain demographic data elements. <u>BR601</u>
 - If multiple values are allowed, all unique values should be selected for the consolidated record. BR702
 - The most complete/specific data element should be selected for a consolidated record. <u>BR801</u>, <u>BR802</u>
 - If the best value cannot be selected based on characteristics of the data elements, then recordlevel characteristics (e.g., confidence level and recency) should be used to select the best value for each data element. BR901, BR902, BR903

- Examples of business rules for consolidating vaccination event records:
 - The IIS should make accessible the information needed to make consolidation decisions. <u>BR5101</u>
 - The IIS should ensure that the administered/ historical indicator contains a valid value. BR5102
 - If multiple values are allowed, all unique values should be selected for the consolidated record. BR5301, BR5302
 - If one vaccination event record is an administered record and another is a historical record, the value of the data element from the administered record should be selected over the value of the same data element from a historical record, except in the case of data elements that can have multiple values. BR5401
 - If two historical records are consolidated, a valid value should be chosen over an invalid value.
 BR5501
 - If two historical records are consolidated, a more specific/complete value should be chosen over a less specific/complete value. <u>BR5602</u>
 - If the best value cannot be selected based on characteristics of the data elements, then record-level characteristics (e.g., confidence level and recency) should be used to select the best value for each data element. <u>BR5701</u>, <u>BR5702</u>, <u>BR5703</u>

Conclusion

Consolidating information from different sources about the patient or vaccination event, as well as information from multiple reports from the same source, leads to a more accurate and complete reflection of reality in the IIS. Likewise, consolidation of records helps maintain data quality within the IIS and allows for accurate evaluation of population-and vaccination-based assessments of a specified area. Provider organizations rely heavily on these consolidated records for clinical decision support when providing services to their patients. Consolidation of records is a valuable process to ensure comprehensive and high-quality records in an IIS. This guide offers best practice recommendations to support IIS staff in implementing and sustaining the process of consolidating records.

Table of Contents

Executive Summary		Chapter 3: Fundamentals					
Background	1	Introduction to key concepts	21				
Relevance	1	Key concepts and terms	21				
Replacement for a portion of the MIROW 2006 Vaccine Deduplication Guidelines	2	Categories of records: demographic records, vaccination event records, and patient records	21				
Overview of consolidating records process	2	Data element, value, data group, and data source _	23				
Key outcomes and recommendations	3	Basic consolidation options	24				
Conclusion	4	Unmerging and traceability	26				
Table of Contents	5	Chapter 4: Consolidating Records Process	27				
		Overview of consolidating records	27				
Roster: Modeling Immunization Registry Operations Workgroup (MIROW)	9	Demographic record process: consolidating data elements for demographic record	30				
		DR-Phase 1: Select best value using data-element-level characteristics	31				
Acknowledgments	11	DR-Phase 2: Select best value using record-level characteristics	34				
Navigation	13	Vaccination event record process: consolidating data elements for vaccination event record	36				
Navigation Tips	13	VER-Phase 1: Analyze data element category	37				
Overview of this document		VER-Phase 2: Analyze records category					
Recommended reading paths	14	(administered/historical indicator)	37				
		VER-Phase 3: Select best value using data-element-level characteristics	38				
Chapter 1: Introduction	15	VER-Phase 4: Select best value using	00				
About MIROW	15	record-level characteristics	40				
About this project	15						
About this document	16	Chapter 5: Principles and Business Rules	42				
Intended audience	16						
Intended use	16	Principles					
Implementation/technology independence	16	Demographic-records-specific business rules					
Business modeling instruments		Vaccination-event-records-specific business rules _	61				
Development approach	17						
		Chapter 6: Operational Scenarios	75				
Chapter 2: Scope Overview	18	Demographic record consolidation:	7-				
Focus statements	18	selected operational scenarios	/5				
Scope	18	Vaccination event record consolidation: selected operational scenarios	80				

Chapter 7: Implementation Considerations	87
Overarching concepts for consolidation	87
Education about consolidation process	87
Methods of updating records	88
System IDs	89
IIS resources and staff time	90
Data Quality	91
Provider profile	91
Data validation process	91
HL7 Immunization Messaging	92
Vaccination action code concepts	92
Administered/historical indicator	93
Formatting of patient address	93
Conclusions	94
Selected References	95
Abbreviations	98

Appendix A: Terms and Definitions Defined via Domain Model	_ 99
Purpose of a domain model	99
Domain model for the records consolidation functional area	99
How to read and interpret the domain diagram	_ 100
Facts shown on the domain diagram	_ 102
Tables of terms and definitions	_ 103
Grouping of demographic and vaccination event data elements	_ 109
Appendix B: About MIROW	_ 113
Appendix C: 2016 MIROW Consolidating Records Workshop Participant List	_ 115
Appendix D: Confidence Level Indicator	_116
Confidence level indicator for information in a demographic record	116
Confidence level indicator for information in a vaccination event record	119

Illustrations

Figure 2-1. Context diagram for the consolidated record topic			
Figure 2-2. Scope of consolidated record topic in the context of IIS deduplication functionality	20		
Figure 3-1. Patient record, demographic record, vaccination event records	22		
Figure 3-2. Example of data elements and values in a fragment of a demographic record	23		
Figure 3-3. Option 1: Consolidate incoming data into an existing record	24		
Figure 3-4. Options 2A and 2B: Consolidate data from two existing records	25		
Figure 4-1. Consolidating records process diagram (high-level)	29		
Figure 4-2. Simplified process diagram of consolidating data elements for a demographic record	30		
Figure 4-3. Detailed illustration of consolidating data elements for a demographic record	35		
Figure 4-4. Simplified process diagram of consolidating data elements for a vaccination event record	36		
Figure 4-5. Detailed illustration of consolidating data elements for a vaccination event record	41		
Figure A-1. Domain diagram for the consolidated record topic	101		
Figure D-1. Cause-and-effect diagram—confidence level indicator	117		

Tables

Table 4-1. Decision table for process scenarios – Step DR1.1	32
Table 4-2. Decision table for Step VER3.1 process scenarios	38
Table 5-1. Principles	43
Table 5-2. Business Rules for Demographic Records	48
Table 5-3. Business Rules for Vaccination Event Records	62
Table A-1. Terms and definitions for consolidated records	103
Table A-2. Terms and definitions for consolidated records (sorted alphabetically)	108
Table A-3. Additional terms for the consolidated records topic	108
Table A-4. Grouping of demographic data elements	110
Table A-5. Grouping of vaccination event data elements	111
Table A-6. Grouping of additional data elements	112
Table B-1. MIROW: Topics/workshops overview	114
Table C-1. Workshop participant list	115
Table D-1. Data source type (who) can send what information (submission type) and how (submission method)	118
Table D-2. Decision table: simplified example of determining the confidence level indicator for demographic records	119

Roster: Modeling Immunization Registry Operations Workgroup (MIROW)

Co-Chairs

Warren Williams, MPH

MIROW Steering Committee Co-chair

Branch Chief

Immunization Information Systems Support Branch /

Centers for Disease Control and Prevention

Phone: (404) 639-8867 E-mail: <u>wxw4@cdc.gov</u>

Elaine Lowery, JD, MSPH

MIROW Steering Committee Co-chair

Public Health Consultant

AIRA

Phone: (303) 881-2440

E-mail: elaine.lowery@comcast.net

Amanda Harris

MIROW Steering Committee Co-chair

Nevada WeblZ Manager

Nevada State Immunization Program

Phone: (775) 684-4258 E-mail: asharris@health.nv.gov

American Immunization Registry Association (AIRA)

Rebecca Coyle, MSEd

Executive Director

AIRA

Phone: (202) 527-7000, ext. 2

E-mail: coyler@immregistries.org

Nichole Lambrecht, MSc

Senior Project Manager

AIRA

Phone: (202) 470-0026

E-mail: nlambrecht@immregistries.org

Business Analysis

David Lyalin, PhD

Public Health Analyst

Immunization Information Systems Support Branch /

Centers for Disease Control and Prevention

Phone: (404) 718-4594 E-mail: <u>dil8@cdc.gov</u>

Subject Matter Experts

Rae Barr

Senior Implementation Specialist

Scientific Technologies Corporation (STC)

Phone: (602) 832-3431

E-mail: rae_barr@stchome.com

Kathleen Blaney, MPH, RN

Adult Outreach Coordinator

New York City Department of Health and Mental Hygiene

Phone: (347) 396-2544

E-mail: kblaney@health.nyc.gov

Amanda Harris

Nevada WeblZ Manager

Nevada State Immunization Program

Phone: (775) 684-4258

E-mail: asharris@health.nv.gov

Baskar Krishnamoorthy

Business Analyst

Florida SHOTS, Immunization Section

Florida Department of Health Phone: (850) 245-4444 ext. 2351

E-mail: baskar.krishnamoorthy@flhealth.gov

Nichole Lambrecht, MSc*

Senior Project Manager

AIRA

Phone: (202) 470-0026

E-mail: nlambrecht@immregistries.org

Elaine Lowery, JD, MSPH*

Public Health Consultant

AIRA

Phone: (303) 881-2440

E-mail: <u>elaine.lowery@comcast.net</u>

Craig Newman, PhD

Health Research Analyst Northrop Grumman/CDC Phone: (608) 345-3606 E-mail: yuo9@cdc.gov

Elizabeth Parilla, MPH*

Vaccine Management and Improvement Unit Supervisor

Minnesota Department of Health

Phone: (651) 201-5532

E-mail: elizabeth.parilla@state.mn.us

Katie Reed, MPA

Project Manager DXC Technology

Phone: (315) 263-7324

E-mail: catherine.reed@dxc.com

Loren Rodgers, PhD

Acting Evaluation Team Lead

Immunization Information Systems Support Branch /

Centers for Disease Control and Prevention

Phone: (404) 718-4835 E-mail: lrodgers@cdc.gov

Kim Salisbury-Keith

KIDSNET Development Manager Rhode Island Department of Health

Phone: (401) 222-5925

E-mail: kim.salisburykeith@health.ri.gov

MIROW Steering Committee:

- Warren Williams, Co-chair, CDC
- Elaine Lowery, Co-chair, AIRA
- Amanda Harris, Co-chair, NV
- Brandy Altstadter, STC
- Baskar Krishnamoorthy, FL
- Nichole Lambrecht, AIRA

- Tracy Little, OR
- David Lyalin, CDC
- Megan Meldrum, NY
- Amy Metroka, NYC
- Katie Reed, DXC
- Elizabeth Parilla, MN

^{*} Panel included three paid public health consultants. Refer to the <u>Development Approach</u> section in <u>Chapter 1: Introduction</u> for more information.

Acknowledgments

Members of the Modeling of Immunization Registry Operations Workgroup (MIROW) appreciate and acknowledge the following:

- External reviewers for their willingness to read and constructively comment on the materials. Their efforts benefited this document significantly:
 - Brandy Altstadter, Senior Technical Architect and Account Executive, STC
 - Noam Arzt, President, HLN Consulting, LLC
 - Assiatou Bah, Epidemiologist, Tennessee Immunization Program
 - Nathan Bunker, Senior Technical Project Manager, AIRA
 - Tricia Charles, Program Coordinator, Massachusetts Immunization Information System
 - Brad Couse, Software Developer and Consultant, Envision Technology Partners, Inc.
 - Michael Flynn, Technical Manager, New York State Immunization Information System
 - Kristin Hardy, Epidemiologist, Minnesota Department of Health
 - Nathalie Hartert, IIS Director, Tennessee
 - Therese Hoyle, Senior Public Health Advisor, Michigan Department of Health & Human Services
 - Mary Beth Kurilo, Policy and Planning Director, AIRA
 - Eric Larson, Senior Technical Project Manager, AIRA
 - Marlene Lugg, Assistant Investigator, Kaiser Permanente Southern California
 - Karen McGettigan, MCIR Project Manager, Michigan Public Health Institute
 - Clark Oelrichs, IIS Coordinator, Missouri Department of Health and Senior Services
 - Laura Pabst, Deputy Director, Immunization Information Systems Support Branch / Centers for Disease Control
 and Prevention
 - Vassiliki Papadouka, Director of Research and Evaluation, New York City Department of Health and Mental Hygiene
 - Sharon Polek, Region 5 MCIR Coordinator, Michigan Department of Health & Human Services
 - Veronica Rodriquez, Data Manager, Puerto Rico Health Department
 - Sue Salkowitz, Health Information Systems Consultant, Salkowitz Associates, LLC
 - Jody Schweitzer, IIS Programmatic Coordinator, Kentucky Immunization Program
 - Alexandra Ternier, City Research Scientist, New York City Department of Health & Mental Hygiene
 - Cherie Thomas, Trey Industries, Inc.
 - Mary Woinarowicz, IIS Manager, North Dakota Department of Health Immunization Program

- Facilitation support provided during the in-person meeting in Decatur, Georgia (August 16-18, 2016), by the team from Advanced Strategies, Inc—Kahil Branton, Gail DeCosta, and Faith Bradberry.
- Editorial support—**Ginger Redmon,** Writer/Editor at the Centers for Disease Control and Prevention (CDC)), and **Maureen Brody**, copy/editing services contracted through AIRA.
- Administrative support of the AIRA staff for organizing modeling sessions—Amanda Dayton and Amanda Branham.
- Contributions of the following organizations, which provided materials on consolidating records issues to help frame the topic and prepare for the modeling sessions:
 - Alaska Immunization Information System (VacTrAK)
 - Nevada Immunization Information System (Nevada WebIZ)
 - New Jersey Immunization Information System (NJIIS)
 - New York Citywide Immunization Registry (CIR)
 - Scientific Technologies Corporation
- Contributions from the following individuals during various stages of the workgroup who were not available for the complete project:
 - Tanzil Choudhury, Business Analyst, Berry Technology Solutions, Contractor for Centers for Disease Control and Prevention
 - Andrew Luker, WebIZ Coordinator and Technical Lead, Arkansas Department of Health
 - Judy Merritt, Director of Data, Scientific Technologies Corporation
 - Miriam Muscoplat, MIIC Manager, Minnesota Department of Health
 - Cindy Scullion, Business Analyst, Business Rules Solutions, Contractor for Centers for Disease Control and Prevention

Navigation

Navigation Tips

- For a convenient navigation through chapters and sections, activate the navigation pane for this document (e.g., for MS Word via the following menu selections: "View → Navigation Pane <check box>", for Adobe Acrobat via the Bookmarks button).
- After navigating from the Table of Contents or via a hyperlink to a location within this document, use "Alt + ←" keystroke to return to the page where you started (for Adobe Acrobat and MS Word).

Overview of this document

- Executive Summary Describes the background, relevance to the immunization community, and key recommendations.
- Chapter 1: Introduction
 Introduces MIROW efforts, the current topic under development, analysis instruments used, intended audience, and principles of the workgroup's collaborative consensus-based development approach.
- Chapter 2: Scope Overview Presents an overview of the scope of this topic as well as inclusion and exclusion designations.
- Chapter 3: Fundamentals Introduces the topic of consolidated records, defines the key concepts and terms needed to describe the process of consolidating records, and provides fundamental principles.
- <u>Chapter 4: Consolidating Records Process</u>

 Describes the process of consolidating records.
- Chapter 5: Principles and Business Rules Provides operational decision-making recommendations for the process of consolidating records.
- Chapter 6: Operational Scenarios Describes typical and challenging operational scenarios that illustrate implementation of best practice recommendations.

- Chapter 7: Implementation Considerations Contains implementation considerations, including overarching concepts (education, methods for updating records, IIS resources, staff time), data quality (provider profiles and data validation process), and HL7 immunization messaging (vaccination action codes, administered/historical indicator, and patient address formatting) concepts.
- Appendix A: Terms and Definitions Defined via <u>Domain Model</u>
 Contains terms and definitions for consolidated records captured through a domain model.
- Appendix B: About MIROW Describes MIROW and previously published MIROW guidelines.
- Appendix C: 2016 MIROW Consolidating Records Workshop Participant List List of participants in the MIROW consolidating records workshop held during the 2016 AIRA National Meeting.
- Appendix D: Confidence Level Indicator Describes the confidence-related considerations that are used to select between values for a data element.

Recommended reading paths

Several reading paths are recommended for a minimalist approach. A reader that is new to using MIROW documents is encouraged to read Chapter 1: Introduction, and anyone unclear about the scope should read Chapter 1: Introduction, and anyone unclear about the scope should read Chapter 2: Scope
Overview. A reader interested in detailed understanding of the "who, what, why, where, when, how" aspects of consolidated records should read the entire document, starting with Appendix A: Terms and Definitions Defined via Domain Model.

Program Managers:

- Executive Summary
- Chapter 3: Fundamentals
- Chapter 5: Principles and Business Rules
- Chapter 7: Implementation Considerations

Immunization Program Staff:

- Executive Summary
- Chapter 3: Fundamentals
- Chapter 4: Consolidating Records Process
- Chapter 5: Principles and Business Rules
- Chapter 6: Operational Scenarios
- Chapter 7: Implementation Considerations

Technical Developers:

- Executive Summary
- Appendix A: Terms and Definitions Defined via Domain Model
- Chapter 4: Consolidating Records Process
- Chapter 5: Principles and Business Rules
- Chapter 6: Operational Scenarios
- <u>Chapter 7: Implementation Considerations</u>

Chapter 1: Introduction

About MIROW

The American Immunization Registry Association (AIRA), in partnership with the National Center for Immunization and Respiratory Diseases (NCIRD) at the Centers for Disease Control and Prevention (CDC), formed the Modeling of Immunization Registry Operations Workgroup (MIROW) in 2005 to develop best practice guidance for functional aspects of immunization information systems (IIS). For more information about MIROW and its work products, please see Appendix B: About MIROW.

About this project

This topic addresses the most fundamental function of the IIS—consolidating information from various sources into a consolidated record. Operational best practice recommendations support IIS Functional Standards (2013-2017) and IIS Functional Standard 1.3 (2018-2022), which states: "The IIS contains a complete consolidated demographic record and vaccination history for every child, adolescent, and adult participating in the IIS and currently residing in the jurisdiction." [2.1] IIS use terms defined in several documents to describe demographic and immunization information, including the IIS Functional Standards, MIROW guides (see Appendix B: About MIROW), HL7 specifications [2.4; 2.5], and other materials. This guide uses a set of terms that are defined in the domain model (Table A-1 and Table A-2). Additionally, <u>Table A-4</u>, <u>Table A-5</u>, and <u>Table A-6</u> contain data elements that describe demographic and vaccination event concepts in terms of core data elements developed in connection with prior Functional Standards (2013-2017) [2.1]. Cross-references between terms used in the domain model and terms used in Table A-4, Table A-5, and Table A-6 are provided in Table A-1.

Ultimately, development of operational best practice recommendations should enable IIS:

- To improve quality (accuracy and completeness) of a patient's information by creating a consolidated demographic record that incorporates information from various sources about a single patient.
- To improve quality (accuracy and completeness) of a patient's immunization information by creating a consolidated vaccination event record that incorporates information from various sources about a single vaccination event.

The development process consisted of a preliminary phase that included web-based teleconferences held June–August 2016, a face-to-face meeting held August 16–18, 2016, in Decatur, Georgia, and post-meeting activities (August 2016–August 2017) to finalize the recommendations.

About this document

This document provides consensus-based best practice recommendations for consolidating records.

Intended audience

The recommendations outlined in this guide are designed for use by programmatic, technical, and operational personnel involved in creating or maintaining an IIS, awardee immunization program staff, health care information system vendors, and immunization service providers. One goal of this guide is to bridge the gap between IIS technical and program staff, IIS and awardee immunization program staff, and IIS and their partners. Bridging these gaps will help create a mutual understanding of common issues and identify actions to implement/apply these recommendations.

Intended use

This guide contains a set of recommended operational best practices (including principles and business rules) that are intended as a basis for standardizing IIS applications and operations. In addition, this guide can be used for staff training, operational documentation, and communication purposes and for providing guidance for electronic health record (EHR) applications.

The implementation of best practice recommendations will vary based on the specifics of an IIS and its interaction with EHR vendor technology and application architecture, as well as local laws, regulations, and policies. Additionally, resource constraints and required changes to existing functionality may result in incremental adoption of these guidelines.

Implementation/technology independence

MIROW best practice recommendations are intended to be implemented at the business/operational level and, thus, are independent from specific IIS implementations and technology solutions. Since this process incorporates an industry-wide strategic approach to capturing and maintaining business knowledge, requirements, and policies/constraints that are independent of implementation architecture and technical solutions, these best practice recommendations will be able to support the wide variety of IIS implementation strategies on different technological platforms.

Business modeling instruments

The recommended best practices were formulated using business modeling instruments:

- Domain model (Appendix A: Terms and Definitions) documents agreed-upon terms and definitions for the project. Establishes a foundation and a reference source (common vocabulary) for other project materials (e.g., principles, business rules).
- Process model (<u>Chapter 4: Consolidating Records</u>
 <u>Process</u>) provides a step-by-step description of the consolidating records process and related processes.
- Principles (<u>Chapter 5: Principles and Business Rules</u>)
 provide a high-level direction and help to guide the development of more specific business rules.
- Business rules (<u>Chapter 5: Principles and Business Rules</u>) represent specific requirements and decision-making logic for consolidating records.
- Operational scenarios (<u>Chapter 6: Operational Scenarios</u>) use brief user stories to describe how to apply best practice recommendations in typical and challenging situations.

The following assumptions reflect the MIROW approach to the development of principles and business rules and associated best practices presented in this document:

- The focus should be on recommendations and business rules that have the greatest potential for providing value and use across all IIS.
- The business rules represent an attempt to balance ideal practices with pragmatic considerations of what can be implemented in an IIS.
- Specific implementation of business rules (and associated best practices) may vary based on resources, goals, needs, and unique implementation concerns.
- The set of business rules and other recommendations presented here is not exhaustive. Each individual IIS may choose to implement additional rules based on its unique requirements and insights.
- Finally, the business rules and associated best practices are not static and will need to change and evolve over time as business requirements change.

Development approach

MIROW used business engineering and facilitation techniques to analyze IIS processes and develop recommendations. It used a pragmatic, results-oriented approach that has been effective for modeling of IIS and cancer registration operations. Business analysts, public health consultants, and subject matter experts (SMEs) conducted initial preparatory off-line work (assembling pertinent materials, producing preparatory notes, analyzing processes, and developing preliminary drafts). During a subsequent face-to-face facilitated modeling session held on August 16-18, 2016, in Decatur, Georgia, the workgroup of SMEs used the preparatory materials to frame and scope resources and began developing and formulating consensus-based recommendations. The post-session work finalized the development of recommendations. The SMEs addressed a set of remaining issues during a series of teleconferences. The goal was a consensus among SMEs regarding best practice recommendations, which did not require 100%

agreement but meant, "I can live with that and support it." The first part ("can live with that") allowed the group to focus on achieving a consensus in principle, avoiding prolonged discussions on minor issues (when at least no one disagreed strongly enough to veto the agreement). The second part ("support it") provided a due-diligence check to ensure there were no serious disagreements left among the experts, assuring that experts agreed with the recommendation sufficiently to stand behind it and support it.

Starting in 2015, the MIROW Steering Committee added a small group of public health consultants to the development process. The goal was for the small group to be able to research, review, and assimilate information from the full SME panel, thereby reducing the amount of time required by SMEs to review and develop content during the development process.

Chapter 2: Scope Overview

Focus statements

The consolidation of a demographic record for a patient (i.e., selecting the best value for each demographic data element for a patient from all available sources).

The consolidation of a vaccination event record (i.e., selecting the best value for each data element for a vaccination event from all available sources).

Scope

Consolidating records is an important step in the broader process of deduplication of records. There are several IIS community documents on deduplication of demographic records, including merging/consolidating considerations, for example [2.10; 2.11]. The vaccination event deduplication process is also described in depth in the MIROW 2006 Vaccine Deduplication Guidelines [1.8]. While the 2006 MIROW guidelines [1.8] address only vaccination event records, the concepts are broadly applicable to demographic records as well. Although the concepts discussed in this document may apply to other public health programs (e.g., lead, maternal child health, etc.) that utilize the immunization registry demographic records, the concepts of consolidating records were discussed through the immunization program and related sources lens.

The vaccination event deduplication process includes the following three phases: Selection, Evaluation, and Resolution. The Selection and Evaluation phases are not in the scope of this guide and the Resolution phase is partially in scope. This guide acts as a replacement for Chapter 5 "Resolution phase," as it describes vaccination event records consolidation and Appendix B of the MIROW 2006 Vaccine Deduplication Guidelines [1.8].

Phase 1. Selection (not in scope): In Phase 1, the IIS identifies and groups potential duplicate records from incoming and existing records. Incoming records are records that have been received by the IIS from an IIS-authorized organization (IIS-AO) via an electronic data exchange (EDE) or the direct user interface (UI). An IIS-AO is any organization that has an agreement with the IIS that allows submittal and/or retrieval of the IIS data. Existing records are records that are stored within the IIS. The process of identifying and grouping potential duplicate records can happen: 1) when an incoming record arrives in the IIS via an electronic message or the UI or 2) during analysis of existing records in the IIS. For an illustration of these two pathways, see Figure 2-1.

A duplicate record exists when there is more than one record representing a patient or vaccination event. Duplicate demographic records represent the same patient. Duplicate vaccination event records represent the same vaccination event. While duplicate records represent the same patient or vaccination event, they are not identical to each other. Identical records have exactly the same data values for each corresponding data element (i.e., the same record was submitted by the same data source twice).

Phase 2. Evaluation (not in scope): In Phase 2, the IIS evaluates pairs of potential duplicate records to determine if the records match each other or if the records represent different patients or vaccination events. Possible outcomes are to:

- Determine the pair is a duplicate (i.e., both vaccination records represent the same patient or vaccination event).
- Determine the pair is not a duplicate (i.e., vaccination records represent different patients or vaccination events).
- Determine the pair of records requires manual evaluation to decide if records are duplicates or not.

Two records that have been identified as duplicate records are called "matched records." The consolidation process begins at the point in the deduplication process when records are matched and proceeds through the Resolution phase. Accordingly, the scope of this guide starts when records are matched. Management of records that are not identified as a match or that require additional examination to determine if there is a match are not considered in scope.

18

Phase 3. Resolution (partially in scope): The Resolution phase of the deduplication process has two possible outcomes:

- If records are found to be duplicates during the Evaluation phase, then a record event must be produced by merging information from duplicate records into a consolidated record. This is in scope.
- If records are found not to be duplicates during the Evaluation phase, then a new record must be added to the registry. This is not in scope.

<u>Figure 2-1</u> presents a context diagram for consolidating records based on the results of determination of whether records match.

If it has been determined that a consolidated record needs to be unmerged, then any records that were previously merged should go back through the consolidation process. This is in scope (see Figure 2-2 for illustration).

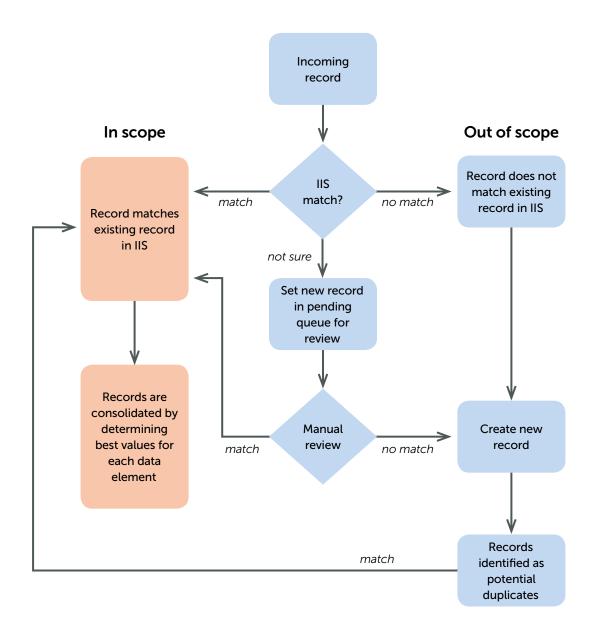


Figure 2-1. Context diagram for the consolidated record topic

The scope for the current topic includes (i.e., in scope):

- Determining the best option(s) for the consolidated record process (i.e., merging information in an existing record versus merging information in a new record versus selecting the best record, etc.).
- Selecting the best value for each data element in a consolidated record.
- Identifying and grouping data elements to be considered for consolidation.
- Determining the level of confidence in information to be consolidated (e.g., information from different data sources).
- Handling of original submissions after consolidation (i.e., retaining all information versus retaining some information and discarding other information).
- Unmerging (i.e., correcting an incorrect merge).

The scope of the current topic excludes (i.e., out of scope):

- Identifying matching records.
- Creating a new record (i.e., patient, demographic, vaccination event).
- Combining multiple vaccination events into one patient record. Consolidating the same vaccination event for the same patient would be in scope, but combining different vaccination events for the same patient would be out of scope. For example, Tommy Smith receives two separate doses of vaccine at his two-month appointment and three separate doses at his four-month appointment. It would be in scope for this document to consolidate information about each one of these vaccination events into five individual vaccination event records. It would be out of the scope for this document to discuss how the five separate vaccination events are combined in a vaccination history for a patient within an IIS.

Figure 2-2 provides a diagram of the scope of a consolidated record topic in the context of IIS deduplication functionality.

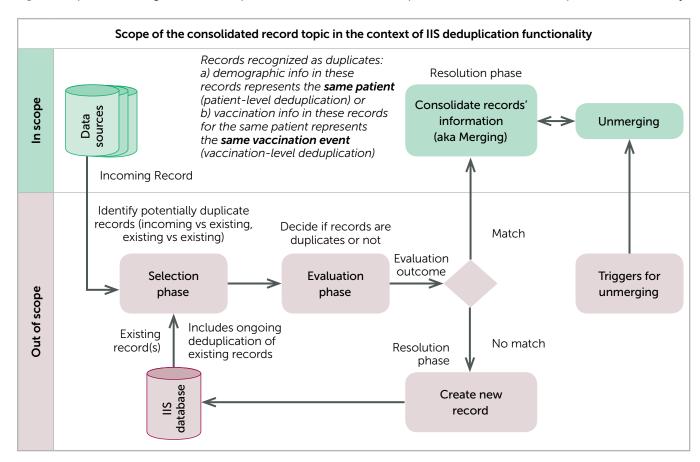


Figure 2-2. Scope of consolidated record topic in the context of IIS deduplication functionality

Chapter 3: Fundamentals

Introduction to key concepts

One of the core functions of an IIS, per the Functional Standards, is to provide "consolidated demographic and immunization records for persons of all ages in its geopolitical area, except where prohibited by law, regulation, or policy" [2.1]. Consolidating information from different sources about the patient or vaccination event from different sources, as well as information from multiple reports from the same source, leads to a more accurate and complete reflection of reality in the IIS, if done correctly. Likewise, consolidation of records helps maintain data quality within the IIS and contributes to accurate evaluation of population- and vaccination-based assessments of a specified area. Immunization provider organizations rely heavily on consolidated records for clinical decision support when providing services to their patients. Consolidation of records is a valuable best practice to ensure comprehensive and high-quality records in an IIS.

This guide acts as a replacement for Chapter 5: Resolution Phase and Appendix B of the MIROW 2006 Vaccine Deduplication Guidelines [1.8]. The 2006 guidelines recommended that an IIS should create two records for each vaccination event: a "best record" for clinical purposes and a consolidated record for both clinical and public health purposes. Due to the technical advancements of the past 10 years, the current perspective is that providers should use an EHR system to maintain the clinical record for a patient. An IIS should take advantage of its role as the repository of information from many data sources to create the most robust and comprehensive record possible via consolidation. This guide recommends the use of a single consolidated

demographic record and a single consolidated vaccination event record for all IIS functions, including clinical decision support, query responses, reminder/recall, Vaccines for Children (VFC) program activities, and coverage assessment reports, and for viewing via direct UI (<u>P01</u> and <u>P02</u>). Consolidation also provides a more complete record for consumer access.

The key concepts used in the process of consolidating records are defined in this section. For a more comprehensive set of terms and definitions, refer to Appendix A: Terms and Definitions Defined via Domain Model. For an overview of deduplication that occurs prior to the consolidating records process, refer to Chapter 2: Scope Overview.

Key concepts and terms

This section provides a brief introduction of the four key concepts for consolidating records:

- Categories of records
- Data element, value, data group, and data source
- Basic consolidation options
- Unmerging and traceability

Categories of records: demographic records, vaccination event records, and patient records

There are three categories of records that will be discussed in this guide: demographic, vaccination event, and patient records (Figure 3-1).

- A demographic record is a group of data elements that represent information about a patient.
- A vaccination event record is a group of data elements that represent information about a vaccination event.
- A patient record is a combination of a demographic record for a patient and vaccination event record(s) for that patient. Each patient record contains one demographic record and zero, one, or more vaccination event records.

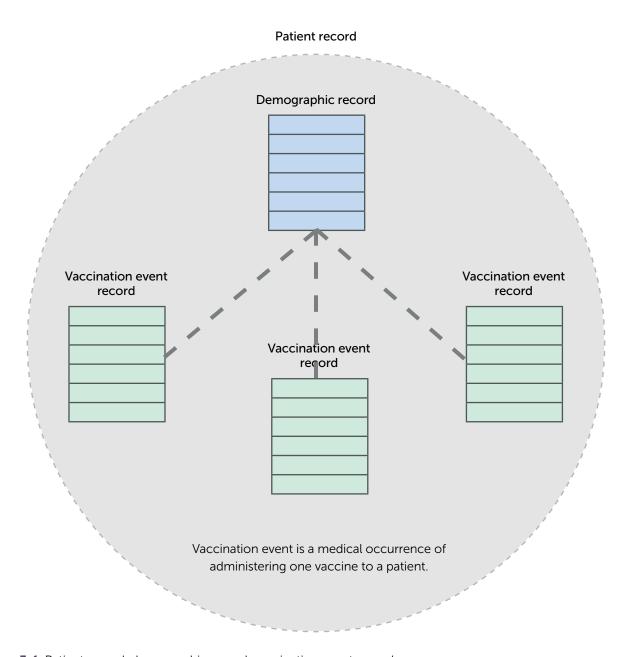


Figure 3-1. Patient record, demographic record, vaccination event records

Data element, value, data group, and data source

The goal in the process of consolidating a demographic record or vaccination event record is to select the best value for each data element (P05). A data element is the general term for a component of a record. For example, patient first name, patient date of birth, and patient gender are all data elements in a demographic record, while vaccine type and vaccination date are data elements in a vaccination event record. A value is the specific information contained in that data element. For example, in Figure 3-2, "Robert" is the value for the data element of patient first name. Figure 3-2 provides additional examples of these terms and how they relate to each other.

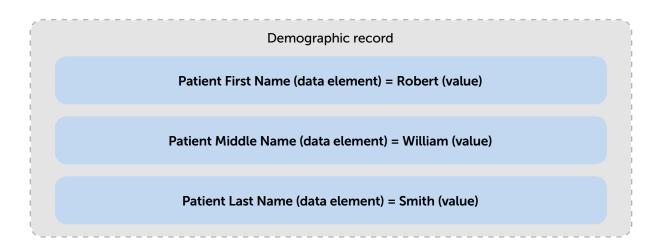


Figure 3-2. Example of data elements and values in a fragment of a demographic record

Certain data elements are grouped together and treated as one data group in which the values for all data elements must come from the same data source. It is important to select values for all data elements in a data group from the same data source because mixing values from different data sources would result in incorrect interpretation of the values. For example, the "Patient Telephone" data group includes the data elements, "Patient Telephone Number" and "Patient Telephone Number Type." If each of the two records contains a different "Patient Telephone Number Type" (e.g., home and cell), allowing a combination of values from the two data sources would potentially lead to a phone number being assigned to the incorrect telephone number type. Some of the identified data groups are:

- alternate patient ID
- patient multiple birth
- responsible person name
- patient telephone
- patient status
- vaccine dose volume and unit

The section <u>Grouping of demographic and vaccination</u> <u>event data elements</u> in <u>Appendix A: Terms and</u> <u>Definitions Defined via Domain Model</u> provides more detail about data groups.

An important characteristic of a data element is its data source. The data source is indicated by the IIS-AO ID. Data sources may include vital statistics, birthing hospitals, immunization provider, schools, and health plans. Since the confidence level in a specific data source is based on the IIS local knowledge, each IIS will want to develop rankings that reflect the confidence level in data from different data sources.

Basic consolidation options

The two options described in this section illustrate approaches to consolidation depending on whether the matching records are: 1) an incoming record and an existing record or 2) two existing records. The following options reflect the principle that consolidation of two existing records in an IIS should result in either a new record or an update of an existing record (P04). These options are tied to management of IIS patient IDs. IIS patient IDs uniquely identify patient records in an IIS. The first time an IIS receives information about a patient, a patient record is created and an IIS patient ID is assigned. Patient ID is in the demographic record, not in the patient record. Once it has been determined that the information is for the same patient, the two records need to be consolidated using the consolidation process (Chapter 4: Consolidating Records Process).

Option 1: An incoming record is determined to match an existing record.

When new information is received about a patient from an incoming record, the IIS determines through the consolidation process whether values in the newly received record are "better" than the information currently in the demographic record or vaccination event record, respectively. The existing record will be updated with the value(s) that have been determined to be "better" In accordance with the guidelines in this document. Since the incoming record has not yet been assigned an IIS ID (IIS patient ID for a demographic record and IIS vaccination event ID for a vaccination event record), the IIS ID for the existing record is used for the consolidated record. In Figure 3-3, it was determined that data element 3 from the incoming record should be added to the existing record as shown in the consolidated record. The updated existing record is then used for the consolidated record.

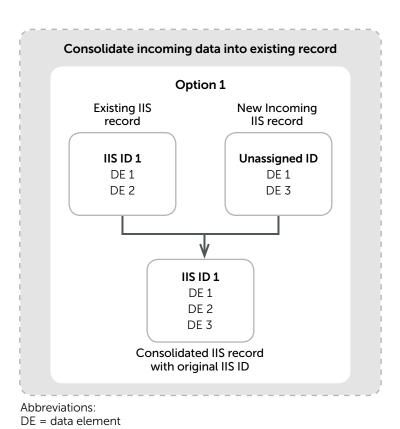


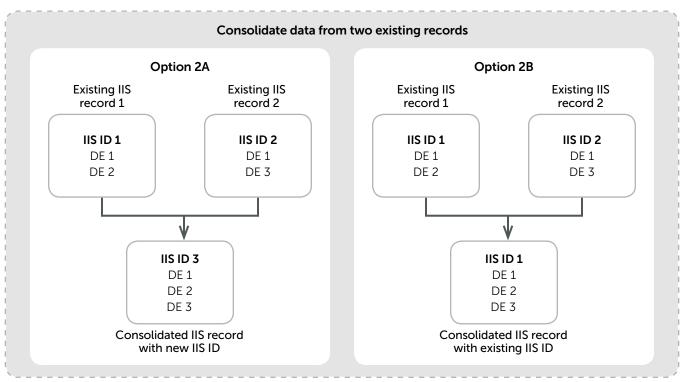
Figure 3-3. Option 1: Consolidate incoming data into an existing record

Option 2: Two existing records are determined to match.

Two existing records (demographic or vaccination event) in the IIS may be determined to be matching records and require consolidation. This can happen when an existing record has information added or corrected and, due to the new information in the record, the two records are determined to match. Since the records were not initially matched, each record will have its own IIS ID: an IIS patient ID for a demographic record and an IIS vaccination event ID for a vaccination event record. Consolidation can be accomplished in two different ways that are both equally acceptable.

- Option 2A: Create a new record with a new IIS ID (i.e., IIS patient ID or IIS vaccination event ID) and store a history of both IIS IDs for the two matched records in the new consolidated record.
- Option 2B: Select either of the existing records to be updated with information from the other record. In Figure 3-4, Record 1 is selected to be the base record. The IIS ID from the selected record is used for the consolidated record and the IIS ID from the other record is stored in a history of the IIS ID.

Consolidation of two demographic records should trigger consolidation of vaccination event records as well. When patient records are consolidated, their vaccination history must also be consolidated.



Abbreviations: DE = data element

Figure 3-4. Options 2A and 2B: Consolidate data from two existing records

Unmerging and traceability

Occasionally two records may be erroneously matched and consolidated while truly representing different patients or vaccination events. When it is determined that two records were incorrectly consolidated, the IIS should be able to unmerge a consolidated record (P10). There is variation in how different programs manage the process of unmerging. As the best practice, an IIS would store all incoming records and document which records were merged. However, it may not be practical to store all incoming records in perpetuity. There is also a manual

component to unmerging records, since IIS staff will likely need to contact the relevant provider(s) and determine/confirm which data belong to which patients. Therefore, while the "best" practice is for an IIS to store all incoming records, it is a "good" practice for the IIS to be able to access sufficient information for each data element to facilitate unmerging. This is reflected in the principle that states that an IIS should have access to original information (P03).

Summary

The benefits of consolidation rest on the belief that the whole is greater than each of its parts. By creating consolidated records, information from a variety of sources can be combined to tell a more complete story. As stated at the beginning of this chapter, IIS should create and use consolidated records (P01 and P02). Consolidation allows the information in an IIS to better reflect reality by representing the patient and vaccination events in a complete and accurate way. Likewise, the process of creating consolidated records supports data quality (i.e., completeness) and leads to better data for public health purposes. By providing a single consolidated demographic record and a single consolidated vaccination event record for all IIS functions, the IIS offers the most complete and accurate information to providers and the public. The processes in the next chapter describe best practice recommendations for how an IIS should consolidate records. While learning about these processes, it may help the reader to consider the following three principles, which are foundational to consolidation:

- The essence of consolidation is to select the best value for each data element/data group from all available data sources. An IIS achieves this by comparing values from separate records for a single data element and selecting the better of the values. Via this process, an IIS distills and retains the best information into the consolidated record (P05).
- The act of consolidation will create a new record or update an existing record (P04).
- Consolidation relies on certain original information being accessible in the IIS. Certain data are vital for ongoing consolidation and for fixing incorrectly merged records. An IIS should have access to those data (P03).

These three principles shape the processes and business rules described throughout the remainder of this guide.

Chapter 4: Consolidating Records Process

This guide recommends that an IIS create a single consolidated record for the demographic record or vaccination event record when there are matching records for a patient or a vaccination event (P01). The consolidated record should be used in all IIS functions, including clinical decision support, query response, reminder/recall, VFC activities, and coverage assessment reports, and for viewing via direct UI (P02). The consolidation process achieves that goal by merging information from multiple data submissions about a patient into a consolidated demographic record and information about a vaccination event into a consolidated vaccination event record. This chapter provides a description of the consolidating records process in diagrammatic and textual (step-by-step process description) formats. Decision-making logic for this process is presented in Chapter 5: Principles and Business Rules.

Chapter 3: Fundamentals and Appendix A: Terms and Definitions Defined via Domain Model provide background material and context for this chapter.

This chapter is organized as follows:

- An overview of the consolidating records process.
- A description of the consolidating records process for demographic records.
- A description of the consolidating records process for vaccination event records.

The step-by-step description of the consolidating records process uses references to process diagrams, principles and business rules (<u>Chapter 5: Principles and Business Rules</u>), operational scenarios (<u>Chapter 6:</u> Operational Scenarios), and other materials.

Overview of consolidating records

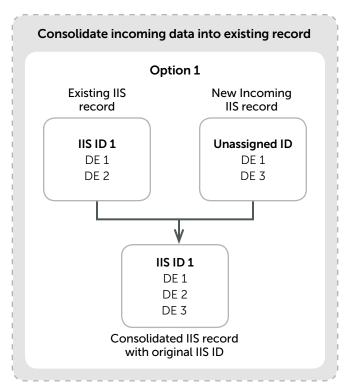
The consolidating records process begins when two records are identified as matched records (Figure 2-1 and Figure 2-2). Information from the two matched records must be consolidated into one record. Consolidating records can occur for both demographic records and vaccination event records. For an overview of deduplication process activities that occur prior to the consolidating records process, refer to Chapter 2: Scope Overview, Figure 2-2. If there are more than two matched records, then the process will be run repeatedly, comparing two records at a time. Ideally, the

result of the consolidating records process is that each patient in the jurisdiction is represented by a single demographic record and each vaccination event is represented by a single vaccination event record (P01).

The consolidating records process can be initiated from two different pathways: 1) arrival of an incoming record in the IIS as an electronic message, direct UI, or electronic file or 2) analysis of existing records in the IIS. For an illustration of the two pathways, see <u>Figure 2-1</u> and <u>Figure 2-2</u> in <u>Chapter 2: Scope Overview</u>.

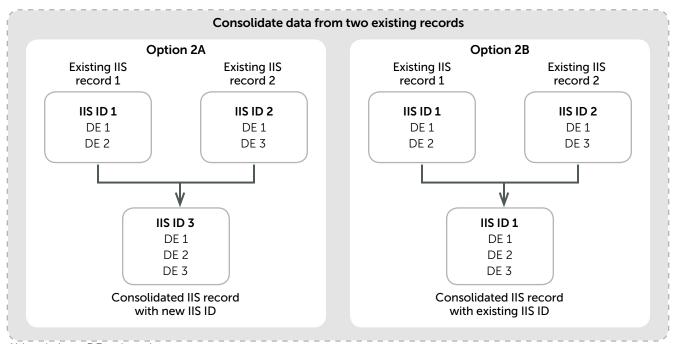
In the first pathway, a patient record is submitted to the IIS by an external data source. The record contains patient demographic information and information on zero or more vaccination event(s) for that patient. Once the incoming patient record is matched to an existing patient record in the IIS, the consolidation process selects what value should be used for each data element in a consolidated record (consolidated demographic record or consolidated vaccination event record). The existing record will remain in the IIS and values from data elements in the incoming record will be used to update the existing record. The updated record in this case is a consolidated record. This option is illustrated in detail in Figure 3-3 (also seen here for easy reference) in Chapter 3: Fundamentals.

In the second pathway, two distinct existing patient records in the IIS are found to be matching records. This situation could occur when one or more data elements in a record are updated after an IIS record was added to the IIS, resulting in a match to another existing record. An IIS can follow one of two options to produce a consolidated record: 1) create a third record with a new IIS ID (different from the two existing matched records) and deactivate IIS IDs from both matched records, or 2) update one of the existing records (the IIS ID from that record remains active and the IIS ID from the matched record is deactivated).



Abbreviations: DE = data element

In both options, best values for a consolidated record are chosen from both matched records. These options are illustrated in further detail in <u>Figure 3-4</u> (also seen here for easy reference) in <u>Chapter 3: Fundamentals</u>.



Abbreviations: DE = data element

The specific process and business rules that should be applied when determining the best value per data element for these two pathways are detailed in the chapter sections Demographic record process: consolidating data elements for vaccination event record, respectively.

<u>Figure 4-1</u> illustrates the high-level activities involved in consolidating matched records. The grayed items are out of scope for this topic.

Once two records are matched, the best values for each data element will be selected. First, data-element-level business rules are applied. If data-element-level business rules do not yield a best value, then record-level characteristics (e.g., confidence level and recency) are used to determine the best value for each data element.

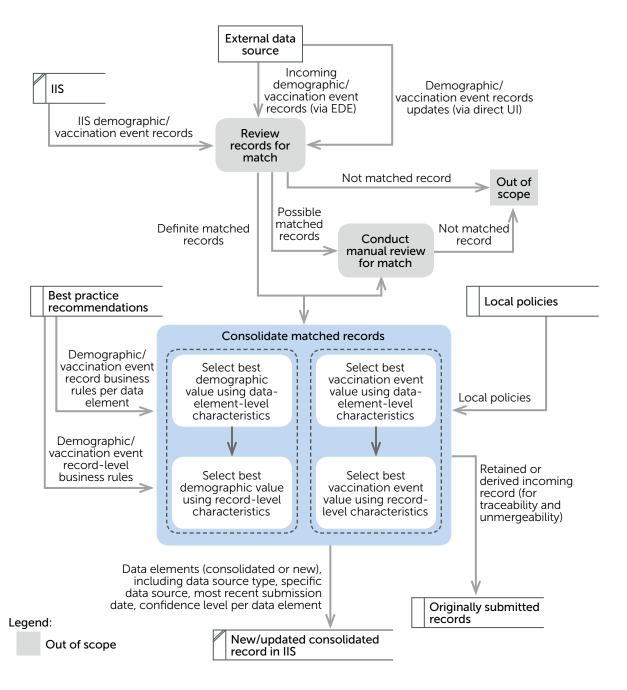


Figure 4-1. Consolidating records process diagram (high-level)

Demographic record process: consolidating data elements for demographic record

This process compares two demographic records, one data element at a time, to determine the best value for each data element for inclusion in a consolidated demographic record. One of the records is used as a base record to update with information from another record (see <u>BR101</u> and <u>BR102</u>).

The process (Figure 4-2) starts when the same data element (e.g., first name) from two records is selected for

comparison. First, data-element-level business rules are applied. If a best value cannot be identified using data-element-level business rules, record-level characteristics (e.g., data source for each data element) are used to identify the appropriate value. Once a value has been selected for use in the consolidated demographic record, the process ends for that data element. This process is repeated for each demographic record data element being consolidated.

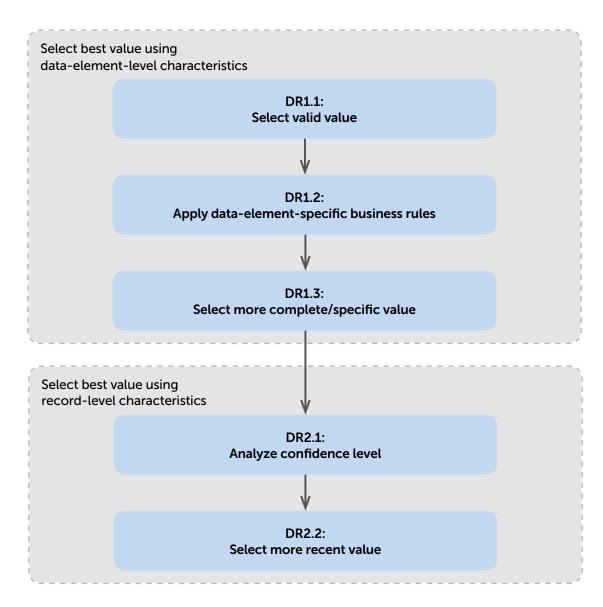


Figure 4-2. Simplified process diagram of consolidating data elements for a demographic record

In the process description and in the process diagram (Figure 4-3), the value for the data element from the first record is referred to as "value A" and the value for the data element from the second record is referred to as "value B."

Note that the term "data element" in this chapter is used to describe both data elements and data groups (i.e., a set of data elements that must be from the same data source); see items 4 and 9 in <u>Table A-1</u> in <u>Appendix A:</u> <u>Terms and Definitions Defined via Domain Model</u>.

DR-Phase 1: Select best value using data-element-level characteristics

Phase 1 of the consolidating records process selects the best value for demographic record data elements based on valid/invalid considerations, data-element-specific business rules, and completeness/specificity considerations.

Step DR1.1: Check for valid values

During this step, the best value for a data element is selected based on analysis of values A and B for being valid, invalid, or empty, as well as these values being the same or different and required or not required.

An IIS should perform system validations, including HL7 format conformance testing and data validation checks, before the consolidating records process begins (see the Data Quality section in Chapter 7: Implementation Considerations). Therefore, the term "invalid value" for a data element in the consolidating records process means an irregular value that did not result in a rejection during the IIS validation process. Usually, invalid values that occur in the consolidating records process result from the requirement that a data element must have a value. Examples for demographic data elements include a patient name of "Baby Boy" or patient date of birth that is "01/01/1900."

Table 4-1 illustrates decision-making logic for all process scenarios. Process Scenario 1 corresponds to the main scenario described and Process Scenarios 2 through 10 correspond to alternate scenarios described. Each column in this table represents a process scenario: conditions (attributes of the data being compared) and outcomes (i.e., whether value A or value B should be selected). The process scenarios are different from operational scenarios (Chapter 6: Operational Scenarios). Process scenarios relate to the main and alternate steps in the process model. Operational scenarios describe typical and challenging day-to-day situations that illustrate implementation of best practice recommendations.

Table 4-1. Decision table for process scenarios – Step DR1.1

Process Scenarios										
Scenario ID	1	2	3	4	5	6	7	8	9	10
	Main	DR1.1A	DR1.1B	DR1.1C	DR1.1D	DR1.1E	DR1.1F	DR1.1G	DR1.1H	DR1.11
Conditions										
Value A: Valid (V), Invalid (I), Empty (E)	V	V	V	V	I	I	I	I	I	E
Value B: Valid (V), Invalid (I), Empty (E)	1	V	V	E	I	I	I	Е	E	E
Same (S) vs. Different (D)	_	S	D	_	S	_	D	_	_	_
Required (R) vs. Not Required (N)	_	_	_	_	R	N	R	R	N	_
Outcomes										
Select value A	Х			Х				Χ		
Select either value A or B		Х			Х					
Local implementation							Х			
Assign blank (empty) value						Х			Χ	Х
Move to the next step (Step DR1.2)			Х							
Business Rules										
	BR501	BR502	ı	BR503	BR504	BR505	BR506	BR507	BR508	BR509

Notes:

- Symmetrical scenarios are not shown in this decision table. For example, the symmetrical scenario for Step DR1.1C is value A is empty and value B is valid. In this scenario, value B is selected as the best value.
- IIS should consider the following when selecting between values A or B (Scenarios 2 and 5): what the base record is and recency.

Main scenario: If one value is valid and the other value is invalid, the valid value is selected for the consolidated demographic record. For example, in <u>Table 4-1</u> Process Scenario 1, value A is valid and value B is invalid, so value A is selected. The process ends for that data element.

Decision support references: $\underline{\mathsf{BR501}}$, Process Scenario 1 in Table 4-1

Alternate paths:

Step DR1.1A: If values A and B are the same valid value, either value can be selected. The process ends for that data element.

Decision support references: <u>BR502</u>, Process Scenario 2 in Table 4-1

Step DR1.1B: If values A and B are different valid values, the consolidating records process moves on to Step DR1.2.

Decision support references: Process Scenario 3 in Table 4-1

Step DR1.1C: If value A is valid and value B is empty, value A is selected. A valid value is selected over an empty value. The process ends for that data element.

Decision support references: <u>BR503</u>, Process Scenario 4 in <u>Table 4-1</u>

Step DR1.1D: If values A and B are the same invalid value and a value for that data element is required, either value can be selected. The process ends for that data element.

Decision support references: <u>BR504</u>, Process Scenario 5 in <u>Table 4-1</u>

Step DR1.1E: If values A and B are invalid values and a value for the data element is not required, a blank value is assigned. The process ends for that data element.

Decision support references: <u>BR505</u>, Process Scenario 6 in <u>Table 4-1</u>

Step DR1.1F: If values A and B are different invalid values and the value for that data element is required, the value is selected based on the local implementation of the consolidating records process. The process ends for that data element.

One of the examples for this scenario: value A is "Baby Boy Smith" and value B is "Unknown Smith."

Decision support references: <u>BR506</u>, Process Scenario 7 in <u>Table 4-1</u>

Step DR1.1G: If value A is invalid, value B is empty, and the value for the data element is required, then value A is selected. An invalid value for a data element is selected over an empty value if the value of the data element is required. The process ends for that data element.

Decision support references: <u>BR507</u>, Process Scenario 8 in <u>Table 4-1</u>

Step DR1.1H: If value A is invalid, value B is empty, and a value for the data element is not required, then a blank value is assigned. The process ends for that data element.

Decision support references: <u>BR508</u>, Process Scenario 9 in <u>Table 4-1</u>

Step DR1.1I: If values A and B are empty, then a blank value is assigned. The process ends for that data element.

Decision support references: <u>BR509</u>, Process Scenario 10 in Table 4-1

Step DR1.2: Apply business rules specific for a data element

At this point in the consolidating records process, it has been determined that values A and B are different valid values. During this step, the consolidating records process applies business rules that are specific for the data element under consideration. Based on <u>BR701</u>, certain data elements must have a single value.

Main scenario: If a best value is identified based on the business rules specific for the data element, that value is selected for the consolidated demographic record. For example, if the data element under consideration is patient date of birth and record A was submitted by Vital statistics and record B was submitted by a provider organization, the value for the data element in record A is selected for the consolidated demographic record. The process ends for that data element.

Decision support reference: <u>BR601</u>

Alternate paths:

Step DR1.2A: If the data element allows for multiple values, then all unique values are selected. The process ends for that data element.

Decision support reference: BR702

Step DR1.2B: If the best value is not identified and the data element does not allow for multiple values, then the consolidating records process moves on to Step DR1.3.

Step DR1.3: Select more complete/specific value

The consolidating records process selects the more complete/specific value of the data element for consolidation when available.

Main scenario: If a best value is identified based on which value is more complete or more specific, the value is selected for a consolidated demographic record (for example, a full name versus an initial or a more complete street address). The process ends for that data element.

Decision support references: <u>BR801</u>, <u>BR802</u>

Alternate path:

Step DR1.3A: If the best value is not identified, the consolidating records process moves on to Phase 2, <u>Step DR2.1</u>.

DR-Phase 2: Select best value using record-level characteristics

If the best value cannot be selected during Phase 1, then the consolidating records process continues with Phase 2 and selects the best demographic value using recordlevel characteristics.

Step DR2.1: Analyze confidence level

The consolidating records process selects the best value for a data element based on the confidence level. If one record has a higher confidence level, the data element value from that record is selected for the consolidated demographic record. Appendix D: Confidence Level Indicator describes how to determine the confidence level for a demographic record. The process ends for that data element

Main scenario: If a best value is identified based on confidence level in the record, the value is selected for the consolidated demographic record. The process ends for that data element.

Decision support references: BR901, P08

Alternate path:

Step DR2.1A: If the best value is not identified, the consolidating records process moves on to Step DR2.2.

Step DR2.2: Select more recent value

The consolidating records process selects the value from the most recent record. If one value is from a more recent record, that value is selected for the consolidated demographic record. The process ends for that data element.

Recency considerations are used twice during Phase 2. In <u>Step DR2.1</u>, recency is one of the factors for determining the confidence level indicator for data elements. In <u>Step DR2.2</u>, recency serves as a tiebreaker if value A and B have the same level of confidence. For example, the data source for value A has a higher data quality than the data source for value B, but the date for value A is less recent than the date for value B, resulting in the same level of confidence for values A and B. In that case, value B is selected as the most recent one.

Main scenario: If a best value is identified based on recency, that value is selected for the consolidated demographic record. The process ends for that data element.

Decision support references: BR902, P09

Alternate path:

Step DR2.2A: If the best value has not been identified, the IIS should use locally developed policies to determine how to select a value.

Decision support reference: BR903

After the best value for the data element is determined, the process moves on to the next data element until all data elements are consolidated.

<u>Figure 4-3</u> illustrates the details of consolidating data elements for a demographic record.

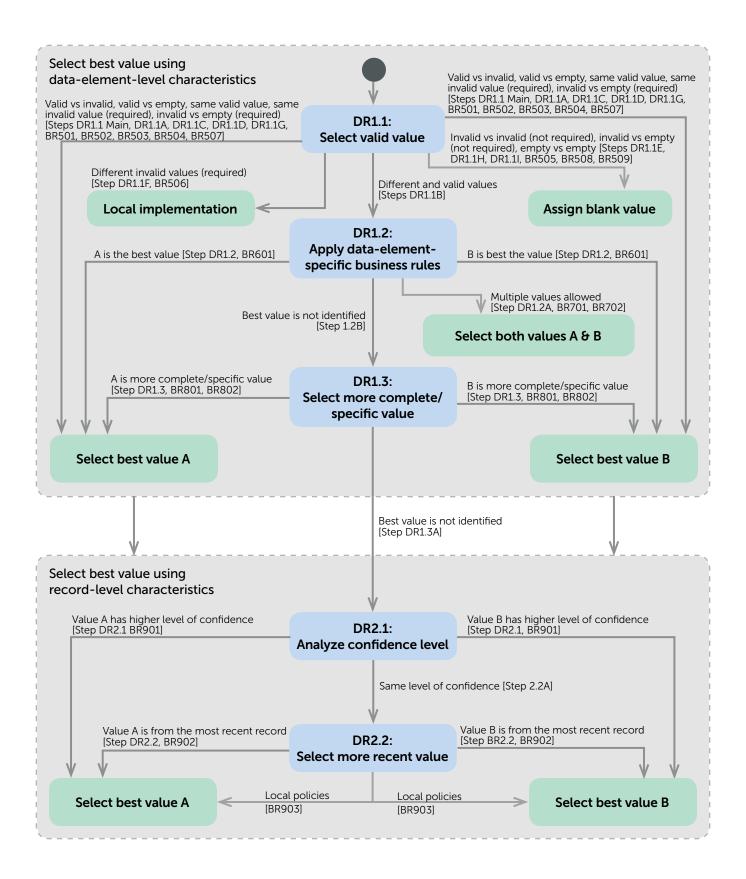


Figure 4-3. Detailed illustration of consolidating data elements for a demographic record

35

Vaccination event record process: consolidating data elements for vaccination event record

This section describes the process of comparing two vaccination event records, one data element at a time, to determine which value will be selected for each data element for inclusion in a consolidated vaccination event record.

The process (Figure 4-4 and Figure 4-5) starts when the same data element (e.g., vaccine lot number) from two records is selected for comparison. First, data-element-level business rules are applied. If a best value cannot be identified using data-element-level business rules, record-level characteristics (e.g., data source for each data element) are used to identify the appropriate value. Once a value has been selected for use in the consolidated vaccination event record, the process ends for that data element. This process is repeated for each vaccination event record data element being consolidated.

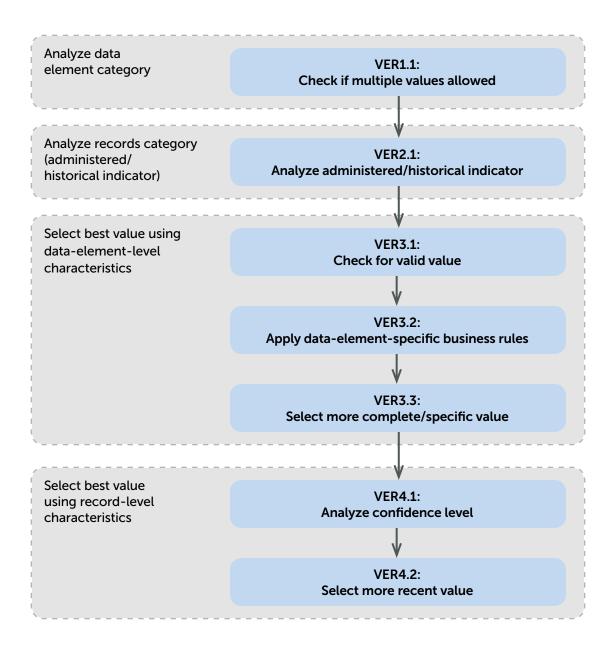


Figure 4-4. Simplified process diagram of consolidating data elements for a vaccination event record

In the process description and in the process diagram (Figure 4-5), the value for the data element from the first record is referred to as "value A," and the value for the data element from the second record is referred to as "value B."

Note that the term "data element" in this chapter is used to describe both data elements and data groups (i.e., a set of data elements that must be from the same data source); see items 4 and 9 in <u>Table A-1</u> in <u>Appendix A:</u> <u>Terms and Definitions Defined via Domain Model.</u>

VER-Phase 1: Analyze data element category

Phase 1 of the consolidating records process checks to determine whether multiple values are allowed for the data element under consideration. Vaccine reaction, (aka adverse reaction) is an example, and multiple values associated with various vaccine reactions can be captured in a vaccination event record (or in a demographic record—see <u>BR5302</u>).

Step VER1.1: Check to determine whether multiple values allowed

Certain data elements can have multiple current values.

Main scenario: If multiple values are allowed for the data element, then all unique values are selected in the consolidated vaccination event record. The process ends for that data element.

Decision support reference: BR5302

Alternate path:

Step VER1.1A: If multiple values are not allowed for the data element, then the consolidating records process moves on to VER-Phase 2, <u>Step VER2.1</u>.

VER-Phase 2: Analyze records category (administered/historical indicator)

Phase 2 of the consolidating records process analyzes the vaccination event records based on values of administered/historical indicator.

Step VER2.1: Analyze administered/historical indicator

Main scenario: If the administered/historical indicator for one of the records is administered and for another record is historical, then the value of the data element from the administered record is selected. The process ends for that data element.

Decision support reference: BR5401

Alternate paths:

Step VER2.1A: If the administered/historical indicator for both records is administered and the records are from different data sources, no additional data elements are examined. The situation requires further investigation.

Decision support references: BR5402

Step VER2.1B: If the administered/historical indicator for both records is administered and the records are from the same data source, then the value from the most recent record is selected for the consolidated vaccination event record. The process ends for that data element.

Decision support references: <u>BR5403</u>, <u>P09</u>

Step VER2.1C: If the administered/historical indicator for both records is historical, then the consolidating records process continues to Phase 3, <u>Step VER3.1</u>.

VER-Phase 3: Select best value using data-element-level characteristics

At this phase, the consolidation process examines values A and B for a data element from two historical records to select the best value for a consolidated vaccination event record.

Step VER3.1: Check for valid values

During this step, the best value for a data element is selected based on whether analysis of values A and B determines that they are valid, invalid, or empty, as well as whether the values are the same or different and required or not required.

An IIS should perform system validations, including HL7 format conformance testing and checking for data validation, before the consolidating records process begins (see the <u>Data Quality</u> section in <u>Chapter 7:</u> <u>Implementation Considerations</u>). Therefore, the term "invalid value" for a data element in the consolidating

records process means an irregular value that did not result in a rejection during the IIS validation process. Usually, invalid values that occur in the consolidating records process result from the requirement that a data element must have a value. An example of an invalid value for a vaccination event record data element is a vaccine lot number with extraneous characters.

Table 4-2 illustrates decision-making logic for all process scenarios. Scenario 1 corresponds to the main process scenario and Scenarios 2 through 10 correspond to alternate scenarios described. Each column in this table represents a process scenario. The process scenarios are different from operational scenarios (Chapter 6: Operational Scenarios). Process scenarios relate to the main and alternate steps in the process model. Operational scenarios describe typical and challenging day-to-day situations that illustrate implementation of best practice recommendations.

Table 4-2. Decision table for Step VER3.1 process scenarios

Process Scenarios										
Scenario ID	1	2	3	4	5	6	7	8	9	10
	Main	VER3.1A	VER3.1B	VER3.1C	VER3.1D	VER3.1E	VER3.1F	VER3.1G	VER3.1H	VER3.11
Conditions										
Value A: Valid (V), Invalid (I), Empty (E)	V	V	V	V	I	I	I	I	I	E
Value B: Valid (V), Invalid (I), Empty (E)	1	V	V	E	1	1		E	E	E
Same (S) vs. Different (D)	-	S	D	_	S	_	D	_	_	_
Required (R) vs. Not Required (N)	-	-	_	_	R	N	R	R	N	_
Outcomes										
Select value A	Х			Х				Х		
Select either value A or B		Х			Х					
Local implementation							Х			
Assign blank (empty) value						Х			Х	Х
Move to the next step (Step VER3.2)			Х							
Business Rules										
	BR501	BR502	ı	BR503	BR504	BR505	BR506	BR507	BR508	BR509

Notes:

- Symmetrical scenarios are not shown in this decision table. For example, in the symmetrical scenario for <u>Step VER3.1C</u>, value A is empty and value B is valid. In this scenario, value B is selected as the best value.
- IIS should consider the following when selecting between values A or B (Scenarios 2 and 5): what the base record is and recency.

Main scenario: If one value is valid and the other value is invalid, the valid value is selected for the consolidated vaccination event record. For example, in <u>Table 4-2</u>, Process Scenario 1, value A is valid and value B is invalid, so value A is selected. The process ends for that data element

Decision support references: <u>BR5501</u>, Process Scenario 1 in Table 4-2

Alternate paths:

Step VER3.1A: If values A and B are the same valid value, either value can be selected. The process ends for the data element.

Decision support references: <u>BR5502</u>, Process Scenario 2 in <u>Table 4-2</u>

Step VER3.1B: If values A and B are different valid values, the consolidating records process moves on to Step VER3.2.

Decision support reference: Process Scenario 3 in Table 4-2

Step VER3.1C: If value A is valid and value B is empty, value A is selected. A valid value is selected over an empty value. The process ends for that data element.

Decision support references: <u>BR5503</u>, Process Scenario 4 in <u>Table 4-2</u>

Step VER3.1D: If values A and B are the same invalid value and a value for that data element is required, either value can be selected. The process ends for that data element.

Decision support references: <u>BR5504</u>, Process Scenario 5 in <u>Table 4-2</u>

Step VER3.1E: If values A and B are invalid values and a value for the data element is not required, a blank value is assigned. The process ends for that data element.

Decision support references: <u>BR5505</u>, Process Scenario 6 in <u>Table 4-2</u>

Step VER3.1F: If values A and B are different invalid values and the value for that data element is required, the value is selected based on the local implementation for the consolidating records process. The process ends for that data element.

Decision support references: <u>BR5506</u>, Process Scenario 7 in <u>Table 4-2</u> Step VER3.1G: If value A is invalid, value B is empty, and the value for the data element is required, then value A is selected. An invalid value for a data element is selected over an empty value if the value of the data element is required. The process ends for that data element.

Decision support references: <u>BR5507</u>, Process Scenario 8 in <u>Table 4-2</u>

Step VER3.1H: If value A is invalid, value B is empty, and a value for the data element is not required, then a blank value is assigned. The process ends for that data element.

Decision support references: <u>BR5508</u>, Process Scenario 9 in <u>Table 4-2</u>

Step VER3.1I: If values A and B are empty, then a blank value is assigned. The process ends for that data element.

Decision support references: <u>BR5509</u>, Process Scenario 10 in <u>Table 4-2</u>

Step VER3.2: Apply business rules specific for a data element

At this point in the consolidating records process, it has been determined that values A and B are different valid values. During this step, the consolidating records process applies business rules that are specific for the data element under consideration.

Main scenario: If a best value is identified based on the business rules specific for the data element, that value is selected for the consolidated vaccination event record. The process ends for that data element.

Decision support references: No business rules were identified for <u>Step VER3.2</u>. Accordingly, IIS should skip <u>Step VER3.3</u> until applicable business rules are identified.

Alternate path:

Step VER3.2A: If a best value cannot be identified based on the data-element-level business rules, then the consolidating records process moves on to <u>Step VER3.3</u>.

Step VER3.3: Select more complete/specific value

The consolidating records process selects the more complete/specific value of the data element for consolidation when available.

Main scenario: If a best value is identified based on which value is more complete or more specific, the value is selected for a consolidated vaccination event record. For example, a more specific vaccine type (e.g., HIB-

PRP-T) should be selected over the more generic vaccine type (e.g., HIB-Unspecified). The process ends for that data element.

Decision support references: <u>BR5601</u>, <u>BR5602</u>

Alternate path:

Step VER3.3A: If the best value is not identified, the consolidating records process moves on to Phase 4 of the process, <u>Step VER4.1</u>.

VER-Phase 4: Select best value using record-level characteristics

Consolidating records process continues using recordlevel characteristics to select the best value for a data element under consideration.

Step VER4.1: Analyze confidence level

The consolidating records process selects the best value for a data element based on the confidence level. If one record has a higher confidence level, the data element value from that record is selected for the consolidated vaccination event record. <u>Appendix D: Confidence Level Indicator</u> describes how to determine the confidence level in a vaccination event record. The process ends for that data element.

Main scenario: If a best value is identified based on confidence level in the record, the value is selected for the consolidated vaccination event record. The process ends for that data element.

Decision support references: BR5701, P08

Alternate path:

Step VER4.1A: If the best value is not identified, the consolidating records process moves on to Step VER4.2.

Step VER4.2: Select more recent value

The consolidating records process selects the value from the most recent record. If one value is from a more recent record, that value is selected for the consolidated vaccination event record. The process ends for that data element.

Recency considerations are used twice during Phase 4. In Step VER4.1, recency is one of the factors for determining the confidence level indicator for data elements. In Step VER4.2, recency serves as a tiebreaker when value A and B have the same level of confidence. For example, the data source for value A has a higher data quality than the data source for value B, but the date for value A is less recent than the date for value B, resulting in the same level of confidence for values A and B. In that case, value B is selected as the most recent one.

Main scenario: If a best value is identified based on recency, the value is selected for the consolidated vaccination event record. The process ends for that data element.

Decision support references: BR5702, P09

Alternate path:

Step VER4.2A: If the best value is not identified, the IIS should use locally developed policies to determine how to select a value.

Decision support reference: BR5703

After the best value is determined based on the steps described above and local policies, the process moves on to the next data element until all data elements have been consolidated.

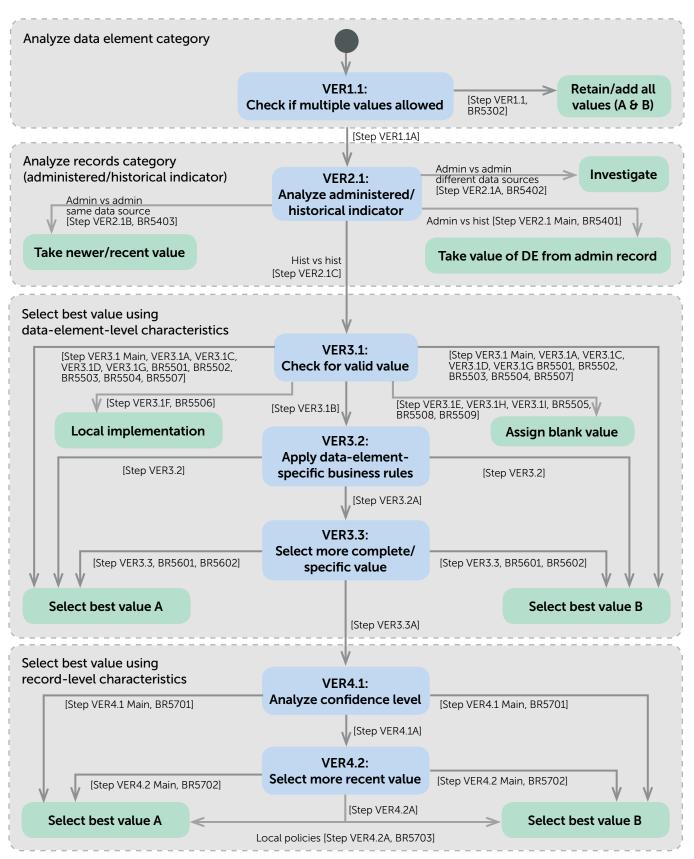


Figure 4-5. Detailed illustration of consolidating data elements for a vaccination event record

Chapter 5: Principles and Business Rules

Principles and business rules describe recommended decision-making logic to accomplish a task. Principles reflect business guidelines, practices, or norms that we choose to follow. They are high-level directions that help guide the development of more specific business rules. For example, "IIS should establish and use a confidence ranking for data sources" is a general principle. Business rules represent specific requirements and decision-making logic for IIS processes and operations. An example of a business rule is "Information received from a data source with a higher confidence level should be selected over information received from a data source with a lower confidence level."

<u>Table 5-1</u> contains principles, and <u>Table 5-2</u> (demographic record) and <u>Table 5-3</u> (vaccination event record) contain business rules. The tables are organized in the following manner:

- Each principle (P) and business rule (BR) has a reference number.
- The Remarks column provides additional explanation, alternate (good) practices in some cases, and examples.
- Related principles, business rules, and other material in this document are referenced in the Remarks column.

Principles

<u>Table 5-1</u> presents principles in the following order:

- P01. Create consolidated record.
- P02. Use consolidated record.
- <u>P03</u>. Make original information accessible.
- P04. Consolidation results.
- P05. Use best value for each data element.
- P06. Order for applying business rules.
- P07. Accuracy over completeness.
- P08. Confidence ranking for data sources.
- P09. Recency.
- <u>P10</u>. Unmerge.
- P11. Specific local laws control.
- P12. Business routines should not be counterproductive.
- P13. Principles and business rules apply regardless of method of transmission.

Table 5-1. Principles

Para dalah	Dd.
Principles P01. Create consolidated record.	Remarks This document provides best practices for consolidating demographic
The IIS should create a single consolidated demographic record for each patient and a single consolidated vaccination event record for each vaccination event.	 This document provides best practices for consolidating demographic records and vaccination event records. References: Chapter 3: Fundamentals Chapter 4: Consolidating Records Process Chapter 5: Principles and Business Rules P02: Use consolidated record.
P02. Use consolidated record. A consolidated record should be used for all IIS functions.	 The consolidated demographic record for each patient and consolidated vaccination event record for each vaccination event should be used for all IIS functions, including clinical decision support, query responses, reminder/recall, VFC activities, and coverage assessment reports, and for viewing via direct UI. References: Chapter 3: Fundamentals Chapter 7: Implementation Considerations P01: Create consolidated record.
P03. Make original information accessible. Original information should be accessible by an IIS.	The words "retain," "store," and "keep" are used to indicate the IIS should save originally submitted data values. The term "accessible" in this principle implies that the originally submitted values can be kept, stored, or retained and that they can be derived from other values. Chapter 7: Implementation
	 Considerations discusses these terms. Original information consists of the data values as originally submitted to an IIS and information about the data elements containing those values. For a demographic record, original information consists of: data source type specific data source (vaccinator IIS-AO) date of submission to the IIS confidence level For each vaccination event record, original information consists of: data source type specific data source (vaccinator IIS-AO) date of submission to the IIS confidence level value of the administered/historical indicator alternate vaccination event ID Original information is necessary to make future consolidation decisions as new information becomes available for consolidation and for unmerging incorrectly merged records. The subset of original information necessary to make consolidation decisions is listed in BR201 for demographic record and in BR5101 for vaccination event record. The subset of original information required to consolidate records is not sufficient to unmerge records. References:
	P10: Unmerge. BR201: Information needed to make consolidation decisions. BR1201: Prevent remerging of previously unmerged records. BR5101: Information needed to make consolidation decisions. BR6001: Prevent remerging of previously unmerged records.

Principles	Remarks
P04. Consolidation results. Consolidation should result in either a new record or an updated base record.	References: Chapter 3: Fundamentals Chapter 4: Consolidating Records Process BR101: Base record: existing record over incoming record. BR102: Base record: two existing historical records. BR5001: Base record: existing record over incoming record. BR5002: Base record: two existing records.
P05. Use best value for each data element. The best value for each data element from all available data sources should be selected for a consolidated record.	 This principle should not be applied to data elements that can have multiple values. For example, all unique values for adverse reactions should be selected and retained in a consolidated record. References: Chapter 3: Fundamentals Chapter 4: Consolidating Records Process Chapter 5: Principles and Business Rules BR501. Use valid values. BR5501. Use populated values over empty values. BR5503. Use populated values over empty values.
P06. Order for applying business rules. Business rules for selecting a best value for a data element should be applied in a specific order.	 Process diagrams in <u>Chapter 4: Consolidating Records Process</u> present business rules in a specific order. <u>Table 5-2</u> in <u>Chapter 5: Principles and Business Rules</u> presents business rules for consolidating demographic records in the order in which the business rules are to be applied. <u>Table 5-3</u> in <u>Chapter 5: Principles and Business Rules</u> presents business rules for consolidating vaccination event records in the order in which the business rules are to be applied. References: <u>Chapter 4: Consolidating Records Process</u> <u>Chapter 5: Principles and Business Rules</u>
P07. Accuracy over completeness. Accurate information should be used over more complete information in a consolidated record.	 This principle indicates that accurate information is preferable over more complete inaccurate information. With respect to a vaccination event record, the administering provider has the most knowledge of vaccination event information. BR5401 provides that, if multiple values are not allowed, the value from an administered vaccination event record should be chosen over the value from a historical vaccination event record. Note: This is a different recommendation from that in the MIROW 2006 Vaccine Deduplication Guidelines [1.8]. In consolidating demographic records, an IIS could implement this principle as one aspect of local considerations for confidence level of a data source. Appendix D: Confidence Level Indicator discusses confidence level. References: BR901: Use information with highest confidence level. BR5401: Use administered vaccination event information over historical. BR5701: Use information with highest confidence level. Appendix D: Confidence Level Indicator

Principles Remarks P08. Confidence ranking for data sources. ■ The consolidating records process may result in selection of a value before consideration of confidence level. A confidence ranking for data sources ■ Using local considerations, the confidence ranking is specified at the should be established and used by the IIS. record level. References: Chapter 4: Consolidating Records Process Chapter 7: Implementation Considerations Step DR2.1 Step VER4.1 BR901: Use information with highest confidence level. BR5701: Use information with highest confidence level. Appendix D: Confidence Level Indicator P09. Recency. ■ Exceptions to this principle are stated in BR101, BR102, BR5001, and BR5002 regarding choosing a base record. More recent information should be used Recency is used in determining the confidence level for a data source. over older information in a consolidated record when all other factors are equal. References: Step DR2.2 Step VER2.1B Step VER4.2 BR902: Use information that has most recent submission date. BR5403: Use information that has most recent submission date. BR5702: Use information that has most recent submission date. Appendix D: Confidence Level Indicator P10. Unmerge. Implementation will differ among IIS. ■ Unmerging may involve both manual and automated methods. An IIS should be able to unmerge a ■ BR1201 and BR6001 describe unmerging considerations. consolidated record. An unmerge can be triggered when: Records that were deemed to be a match are later deemed not to be a match • An incoming vaccination event record contains a delete code and the vaccination event record had been previously consolidated. Chapter 7: Implementation Considerations discusses the delete action code. When considering historical vaccination event records, an unmerge triggered by a delete action code may result in more than one remaining vaccination event record that will then be reconsolidated. For unmerging records: Best practice: To facilitate unmerging, all original records should be retained. • Good practice: To facilitate unmerging, data source information for all data elements and data groups selected for a consolidated record should be accessible by the IIS. References: Chapter 3: Fundamentals <u>Chapter 7: Implementation Considerations</u> P03: Make original information accessible. BR1201: Prevent remerging of previously unmerged records. BR6001: Prevent remerging of previously unmerged records.

Principles	Remarks
P11. Specific local laws control.	References:
Local laws, regulations, and policies regarding opt-out, foster care, protective custody, and adoption supersede all other principles and business rules.	Chapter 7: Implementation Considerations BR1101: Local laws, regulations, and policy control. BR5901: Local laws, regulations, and policy control.
P12. Business routines should not be counterproductive.	■ An IIS should ensure that its consolidating records process does not result in overwriting validated data.
IIS business routines such as data quality/validation and consolidation should not be counterproductive.	References: Chapter 7: Implementation Considerations BR1002: Prevent overwriting validated data. BR1003: No conflict with existing data. BR5802: Prevent overwriting validated data. BR5803. No conflict with existing data.
P13. Principles and business rules apply regardless of method of transmission.	Data transmission methods include: Direct UI, HL7 messages, and electronic files.
The Ps and BRs in this guide should be applicable to all methods of data transmission.	References: Chapter 7: Implementation Considerations

Demographic-records-specific business rules

<u>Table 5-2</u> presents business rules for consolidating demographic records in the order in which the business rules are to be applied. <u>BR101</u> to <u>BR304</u> and <u>BR1001</u> to <u>BR1101</u> apply throughout the process of consolidating demographic records. <u>BR501</u> to <u>BR903</u> follow the order of the steps in the process model in <u>Chapter 4: Consolidating Records Process</u>.

Base Record

- BR101. Base record: existing record over incoming record.
- <u>BR102</u>. Base record: two existing records.

Information needed to make consolidating records decisions

- BR201. Information needed to make consolidation decisions.
- BR202. Retain all past IIS patient IDs.
- BR203. Use current (i.e., active) IIS patient ID.
- BR204. Retain past values.

Data group

- <u>BR301</u>. Data elements considered to be a data group.
- <u>BR302</u>. Data group values are from same data source.
- <u>BR303</u>. Treat elements of data group as one.
- <u>BR304</u>. Values within a data group must be consistent.

Data element of same type

■ <u>BR401</u>. Compare data elements of same type.

■ Valid/invalid value (Step DR1.1)

- <u>BR501</u>. Use valid values.
- <u>BR502</u>. Use either of two identical valid values.
- <u>BR503</u>. Use populated values over empty values.
- BR504. Use either invalid value for required data elements.
- BR505. Use empty value instead of invalid value of nonrequired data element.
- BR506. Use local implementation rules for invalid values for required data element.
- <u>BR507</u>. Use invalid value in certain cases.
- BR508. Use empty value over invalid value for non-required data element.
- BR<u>509</u>. Use either value when both values are empty.

■ Vital statistics supremacy (Step DR1.2)

■ <u>BR601</u>. Supremacy of vital statistics.

■ Single/multiple values (Step DR1.2A and Step DR1.2B)

- <u>BR701</u>. Data elements with a single value.
- BR702. Retain all unique values from data elements with multiple values.

■ Completeness/specificity (Step DR1.3)

- <u>BR801</u>. Use more complete information.
- BR802. Use more specific information.

Record-level considerations (<u>Step DR2.1</u> and <u>Step DR2.2</u>)

- BR901. Use information with highest confidence level.
- BR902. Use information that has most recent submission date.
- BR903. Use local policies if no selection made based on another business rule.

■ Data Validation

- <u>BR1001</u>. Data validation.
- <u>BR1002</u>. Prevent overwriting validated data.
- <u>BR1003</u>. No conflict with existing data.

■ Local laws

■ <u>BR1101</u>. Local laws, regulations, and policy control.

Unmerge

BR1201. Prevent remerging of previously unmerged records.

Proceed to <u>Table 5-3</u> for vaccination event record business rules.

Table 5-2. Business Rules for Demographic Records

Business Rules	Remarks
Base record	
BR101. Base record: existing record over incoming record. Consolidation of an existing record with an incoming record should result in an update of the existing record.	 An existing record should be used as the base record to consolidate information from an incoming record. A base record is a record to be updated with information from another record during the consolidating records process. Consolidation of two demographic records should trigger consolidation of associated vaccination records as well. References:
	Chapter 3: Fundamentals, Figure 3-3 in Option 1: Incoming record with no IIS ID Chapter 4: Consolidating Records Process P04: Consolidation results. P13: Principles and business rules apply regardless of method of transmission. S101: Base record: incoming and existing demographic records. Appendix A: Terms and Definitions Defined via Domain Model
BR102. Base record: two existing records. Consolidation of two existing records (i.e., with two IIS patient IDs) should result in one of the following outcomes: ■ A new consolidated record with a new IIS patient ID. ■ An updated consolidated record with one of the existing IIS patient IDs.	 A base record is a record to be updated with information from another record during the consolidating records process. If one of two existing records is updated during consolidation, either of the two existing records may be chosen to be updated with the best information from the other record. Local implementation will determine which one of the two existing patient IDs to use. Factors to consider when determining which of two existing records to use as the base record in consolidation: The initial date each record was added to the IIS (may want to use the earliest record added to the IIS) Confidence level in each record (established by each IIS) (BR901). Completeness of the record Association of a demographic record with one or more vaccination event records Consolidation of two demographic records should trigger consolidation of associated vaccination records as well.
	References: Chapter 3: Fundamentals, Figure 3-4 in Option 2: Two existing IIS records are determined to match section. Chapter 4: Consolidating Records Process P04: Consolidation results. P13: Principles and business rules apply regardless of method of transmission. S102: Base record: two existing demographic records. Appendix A: Terms and Definitions Defined via Domain Model

Business Rules Remarks

Information needed to make consolidating records decisions

BR201. Information needed to make consolidation decisions.

The following information should be known for each data element and data group to make consolidation decisions:

- Data source type
- Specific data source
- Most recent submission date
- Confidence level

- This business rule may be implemented in multiple ways—for example, storing or inferring (i.e., making accessible) the required information.
- The information required by this business rule is sufficient to consolidate records, but not to unmerge records. Additional information may be required to unmerge records. Unmerging may also require manual intervention. BR1201 provides unmerging considerations.
- BR301 lists data elements that form data groups.
- Appendix A: Terms and Definitions Defined via Domain Model defines data source and discusses use of IIS-AO to identify a specific data source.
- <u>BR901</u> discusses local considerations that influence determination of the confidence level in reported data.
- Best practice: The IIS should keep an audit trail of all changes made, especially a subset for each data element that includes original data source, data source for the last modification, and, for data elements from a vaccination event record, administered/historical indicator. The IIS will be able to access the audit trail to know if the record originally came from a record that was changed later by the IIS (for example, data validation or address cleansing [2.8]) or by a provider through a UI.
- Data retention laws and policies differ. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.

References:

P03: Make original information accessible.

BR301: Data elements considered to be a data group.

BR901: Use information with highest confidence level.

BR1201: Prevent remerging of previously unmerged records.

Appendix A: Terms and Definitions Defined via Domain Model

Business Rules	Remarks
BR202. Retain all past IIS patient IDs. All past IIS patient IDs associated with a consolidated demographic record should be retained by the IIS.	 IIS patient ID has a unique single value per record. When existing records are consolidated, their IIS patient IDs need to be retained. For example, if a patient had two records with different IIS patient IDs (i.e., the ID assigned by the IIS for each patient) and the records are consolidated, both IIS patient IDs should be retained. Local laws, regulations, and policies control and may restrict retention of some IIS patient IDs (e.g., adoptions). Data retention laws and policies differ. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records. References: Chapter 7: Implementation Considerations P11: Specific local laws control. BR203: Use current (i.e., active) IIS patient ID. BR1101: Local laws, regulations, and policy control.
BR203. Use current (i.e., active) IIS patient ID. The current IIS patient ID should be included in all IIS- originated communications about a patient.	 In response to a query (either electronic or verbal), an IIS should communicate a change in association of an IIS patient ID to an IIS-AO that submitted information for that patient. The IIS does not have an affirmative obligation to communicate a change in association of an IIS patient ID. An IIS should be prepared to respond to queries for IIS patient IDs that no longer exist (e.g., an adoption). A patient has only one current (active) ID at any point in time. BR202 states that all IIS patient IDs should be retained by the IIS as historical IIS patient IDs. References: Chapter 7: Implementation Considerations BR202: Retain all past IIS patient IDs.
BR204. Retain past values. IIS should make accessible past values for the following data elements and data groups: Alternate patient ID Patient address Patient alias name Patient telephone Patient e-mail address	 Making past values accessible facilitates IIS functions such as matching and unmerging. In bidirectional data exchanges, challenges caused by changing IIS patient IDs can be mitigated if original medical record patient IDs (i.e., alternate patient IDs) are preserved. Alternate patient ID and patient telephone are data groups. All values in a data group should be made accessible as a unit. Patient address and patient alias name are not data groups because their component data elements can come from multiple data sources. All data elements that comprise patient address and patient alias name should be made accessible. Date of birth history may be retained by some IIS. Data retention laws and policies differ among IIS jurisdictions. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.
	References: Chapter 7: Implementation Considerations BR202: Retain all past IIS patient IDs. BR203: Use current (i.e., active) IIS patient ID. BR301: Data elements considered to be a data group. BR303: Treat elements of data group as one.

Business Rules Remarks

Data Group

BR301. Data elements considered to be a data group.

All of the following collections of data elements should be considered as data groups:

- Patient multiple birth (patient birth order and patient multiple birth indicator)
- Patient telephone (patient telephone number and patient telephone number type)
- Alternate patient ID (patient ID; patient ID: assigning authority ID; patient ID: type)
- Responsible person name (first, middle, and last and relationship to patient)
- Patient status (patient status indicator— provider facility level and provider facility IIS-IO)
- Contraindication(s)/precautions(s) (contradiction(s)/ precautions(s), contraindication(s)/precautions(s) observation date(s))
- Exemptions(s) (exemption(s)/parent refusal(s) of vaccine, date of exemption/parent refusal of vaccine)
- History of vaccine-preventable disease (history of vaccine-preventable disease and date of history of vaccine-preventable disease)
- Vaccine adverse reaction(s) (adverse reaction(s) and date of adverse reaction observation)
- Original submission data (original submission date and data source ID for original submission)
- Most recent submission data (most recent submission date and data source ID for most recent submission date)

- Certain data elements are grouped together and treated as one data group in which the value for each data element must come from the same data source. It is important to select all values for data elements in data groups from the same data source because mixing values from different data sources would incorrectly change the interpretation of the values.
 - For example, the patient telephone data group includes data elements patient telephone number and patient telephone number type. If the two records contain different "patient telephone number type" (e.g., home and cell), then allowing a combination of values from the two data sources would potentially lead to a phone number being assigned to the incorrect telephone number type.
- The <u>Grouping of demographic and vaccination event data elements</u> section in <u>Appendix A: Terms and Definitions Defined via Domain Model</u> provides more detail about data groups.

References:

BR302: Data group values are from same data source.

BR303: Treat elements of data group as one.

BR304: Values within a data group must be consistent.

S103: Patient first name: two invalid values.

Grouping of demographic and vaccination event data elements section of Appendix A: Terms and

Definitions Defined via Domain Model

Business Rules	Remarks
BR302. Data group values are from same data source. The value for each data element in a data group must come from the same data source.	 Example: First, middle, and last name and relationship to patient must come from the same source for responsible person. References: BR301: Data elements considered to be a data group. BR303: Treat elements of data group as one. BR304: Values within a data group must be consistent. S103: Patient first name: two invalid values.
BR303. Treat elements of data group as one.	Data elements within a group are treated together as one.
All data elements within a data group should be treated as a single data element.	Example: patient telephone and patient telephone number type. References: BR301: Data elements considered to be a data group. BR302: Data group values are from same data source. BR304: Values within a data group must be consistent.
BR304. Values within a data group must be consistent.	If all elements in a data group are not internally consistent, the IIS should reject all values in the
Values of all data elements within a data group should be consistent with each other.	data group. Example: For the data group "patient multiple birth," birth order and multiple birth indicator must be consistent. If multiple birth indicator is twins, birth order cannot be three.
	References: BR301: Data elements considered to be a data group. BR302: Data group values are from same data source. BR303: Treat elements of data group as one.
Data element of same type	
BR401. Compare data elements of same type. Only data elements of the same type should be compared for consolidation purposes.	 In some cases, a concept of "type" can be applied to some sets of demographic data elements that do not constitute a data group (e.g., patient address contains six data elements: street, city, state, country, zip code, and county of residence). Example: For consolidation purposes, compare a street address to a street address, but do not compare a street address to a PO Box. Categorization of data elements/groups into types is determined by local implementation. Examples of types of patient address are: Physical (for example, street) and mailing (for example, PO Box or street) Primary (home) and secondary References:
	Chapter 7: Implementation Considerations S105: Address: same type. S107: Phone number: same type. Appendix A: Terms and Definitions Defined via Domain Model

Business Rules	Remarks
Valid/invalid value (Step DR1.1)	
BR501. Use valid values. A valid value for a data element or data group should be used over an invalid value.	 An IIS should maintain an "invalid value" list for some data elements to be used for data validation purposes. A list of known invalid values should be maintained for fields that do not have valid value code tables (e.g., phone number "999-999-999" or city "Anytown"). An invalid value in a data element or data group may not be sufficient to reject the entire incoming record; however, the data may be flagged as invalid. An IIS should perform system validations, including testing for HL7 format conformance and checking for data validation, before the consolidating records process begins (see Data Quality section in Chapter 7: Implementation Considerations). Therefore, the term "invalid value" for a data element in the consolidating records process means an irregular value that did not result in a rejection during the IIS validation process. Usually, invalid values that occur in the consolidating records process result from the requirement that a data element must have a value. Examples of invalid demographic data elements include a "Baby Boy" patient name, a patient date of birth that is "01/01/1900," and an address with a PO Box number in the street field. In special cases, an empty value should be used instead of other submitted values (BR508). References: Step DR1.1 Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 1 P05: Use best value for each data element. BR507: Use invalid value in certain cases. S104: Patient first name: one valid, one invalid value.
BR502. Use either of two identical valid values.	References:
A data element value from either one of two records under consideration should be selected as the best value for a consolidated record when all of the following are true: Values are valid. Values are the same.	Step DR1.1A Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 2
BR503. Use populated values over empty values.	■ In special cases, an empty value should be used instead of other submitted values.
A valid value for a data element or data group should be chosen over an empty value.	A known valid value should be chosen over an unknown (empty, blank) value. References: Step DR1.1C Table 4.1 in Chapter 4: Consolidating Records Process Scenario 4.
	Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 4 P05: Use best value for each data element. BR507: Use invalid value in certain cases

Business Rules	Remarks
BR504. Use either invalid value for required data elements.	A data element is required because it is a software minimum field required to save the data element.
A data element value from either one of two records under consideration should be selected as the best value for a consolidated record when all of the following are true: Values are invalid. Values are the same. Data element is required to have a value.	References: Step DR1.1D Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 5
BR505. Use empty value instead of invalid value for non-required data element.	A data element is required because it is a software minimum field required to save the data element. References:
The value of a data element or data group in a consolidated demographic record should be empty if all of the following are true: The data element is not required by the IIS. The values in both matched records are invalid.	Step DR1.1E Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 6
BR506. Use local implementation rules for invalid values	A data element is required because it is a software minimum field required to save the data element.
for required data element. Local policies should be implemented for choosing between two different invalid values for a required data element in a consolidated record.	References: Step DR1.1F Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 7 S103: Patient first name: two invalid values
BR507. Use invalid value in certain cases.	A data element is required because it is a software minimum field required to save the data element.
An invalid value should be selected over an empty value for a data element that is required to have a value.	 For example, an IIS may require a patient first name. The only value submitted is "Baby Boy" in one record and an empty value in a second record. "Baby Boy" may be flagged as invalid but must be chosen for a consolidated record because the data element is required. Application of this business rule requires that the value be flagged as invalid, which is crucial. References: Step DR1.1G Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 8
BR508. Use empty value over invalid value for non-required data element.	A data element value is required because it is a software minimum field required to save the data element. References:
An empty value for a data element should be used over an invalid value when the data element is not required.	Step DR1.1H Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 9
BR509. Use either value when both values are empty.	■ IIS may have data quality procedures to assign values.
The value of a data element in a consolidated record should be empty when the values in both matched records are empty.	References: Step DR1.1l Table 4-1 in Chapter 4: Consolidating Records Process, Process Scenario 10

Business Rules Remarks Vital statistics supremacy (Step DR1.2) BR601. Supremacy of vital statistics. Some IIS do not receive data from vital statistics. ■ Local law, regulations, or policy may provide that vital statistics is a definitive source of information for Vital statistics is a definitive source of information for the patient name. In this case, the IIS could store the patient name from vital statistics in a separate field in following data elements: addition to a consolidated patient name. Even though vital statistics is a definitive source of Patient date of birth information, they may be incorrect in some instances. For example, a change of gender may be Patient gender communicated to the IIS by a call from a provider. BR1003 provides guidance on investigating Patient multiple birth indicator incoming data that are inconsistent with existing data. Patient birth order ■ Vital statistics is a definitive source for birth certificate number. A birth certificate number is one value Birthing facility name for Alternate Patient ID: Type. Patient birth state ■ The 2013 MIROW guide [1.3] Data Quality Assurance in Immunization Information Systems: Selected Mother's name: maiden last Aspects also discusses vital statistics as being the authoritative source for some data elements (see ■ Birth certificate number BR104 in the 2013 guide, items 7.2, 7.3 in the Table 3 Domain model - terms and definitions). References: Step DR1.2 BR1003: No conflict with existing data. BR1101. Local laws, regulations, and policy control. S103: Patient first name: two invalid values. S108: Patient last name: vital statistics compared with later provider submission. \$109: Patient last name: provider submission compared with later vital statistics submission. S110: Address: vital statistics compared with later provider submission. S111: Patient date of birth: vital statistics compared with later provider submission. Appendix A: Terms and Definitions Defined via Domain Model, Table A-4 Single/multiple values (Step DR1.2A and Step DR1.2B) BR701. Data elements with a single value. An alias date of birth should be stored separately from the date of birth. The following data elements must have a single value: References: Patient date of birth Step DR1.2B Patient multiple birth indicator Appendix A: Terms and Definitions Defined via Domain Model, Table A-4 Patient birth order Birthing facility name Patient birth state ■ IIS patient ID Original submission date Most recent submission date

Business Rules

BR702. Retain all unique values from data elements with multiple values.

All unique values should be retained for data elements that can have multiple current values.

Remarks

- A demographic record may have multiple values for the following data elements/groups:
 - Alternate patient ID (but only one per type and data source)
 - Patient address
 - Patient alias name
 - Responsible person name (can have multiple per type)
 - Patient telephone (can have multiple per type)
 - Race
 - Mother's name
 - Patient e-mail address
 - Patient active/inactive status indicator (PAIS) (but only one per provider)
 - Contraindication(s)/precaution(s)
 - History of vaccine-preventable disease
 - Exemption(s)
 - Vaccine adverse reaction(s)
- For example, there may be multiple patient home addresses if a child lives at multiple homes.
- IIS may have different implementations for capturing race.
- See MIROW 2015 Management of Patient Active/Inactive Status Guidelines [1.2] for a discussion of PAIS.
- Each of four data groups (contraindication(s)/precautions(s), history of vaccine-preventable disease, exemption(s), and vaccine adverse reaction(s)) may be associated by the data source with a vaccination event or with a patient or encounter date. For example, a vaccine adverse reaction may be submitted to the IIS through a UI and associated with a specific vaccination. Future modifications to HL7 may also allow association of an adverse event with a specific vaccination. Alternatively, a data source may not know the date of vaccination or the specific vaccinations given and may submit a vaccine adverse reaction with an observation date or date of vaccination encounter (but not a specific vaccine). The IIS should associate contraindication(s)/precautions(s), history of vaccine-preventable disease, exemption(s), and vaccine adverse reaction(s) with a demographic record, vaccination event record, patient, or encounter as reported by the data source.

References:

Chapter 7: Implementation Considerations

Step DR1.2A

S107: Phone number: same type.

Table A-4 and Table A-6 in Appendix A: Terms and Definitions Defined via Domain Model

MIROW 2015 Management of Patient Active/Inactive Status Guidelines [1.2]

Business Rules	Remarks
Completeness/specificity (Step DR1.3)	
BR801. Use more complete information. More complete information should be used over less complete information.	 Examples: 123 Main St. vs. 123 Main St. Apt 20—an address with an apartment number is more complete than one without. "E." vs. "Elizabeth"—a full first name is more complete than an initial.
	References: Step DR1.3
BR802. Use more specific information.	■ Example:
More specific information should be used over less specific information.	A person listed with a relationship of "Parent" versus the same person listed as "Mother." References: Step DR1.3
Record-level considerations (Step DR2.1 and Step DR2.2)	
BR901. Use information with highest confidence level.	■ The confidence level indicator aggregates factors that impact selection of the best value for a
The value with the higher confidence level should be used in a consolidated record.	 demographic data element from multiple data sources; it reflects the level of confidence or trust regarding quality of data. These factors include: How a record containing the data element/data group is submitted to an IIS (submission method). What type of information the record containing the data element/data group represents (submission type). Who submitted the record containing the data element/data group (data source type). When the record containing the data element/data group is submitted (recency). Any specific knowledge of the data source submitting the record containing the data element/data group. Confidence level is discussed in detail in Appendix D: Confidence Level Indicator.
	References: Chapter 7: Implementation Considerations Step DR2.1 P07. Accuracy over completeness. P08: Confidence ranking for data sources. S101: Base record: incoming and existing demographic records. S106: Patient first name: demographic record recency. Appendix D: Confidence Level Indicator

Business Rules	Remarks
BR902. Use information that has most recent submission date. The value with the most recent submission date should be selected for a consolidated record.	 Dates associated with data elements and/or records are important for determinations in addition to consolidating records. For example, for timeliness calculations, an IIS should make accessible 1) the date a record was originally created (loaded) in the IIS and 2) the date a record was first created (loaded) in the IIS if two existing records are consolidated. See BR1002 for exceptions to this general rule.
	References: Step DR2.2 P09: Recency. S105: Address: same type. S106: Patient first name: demographic record recency. S107: Phone number: same type. S108: Patient last name: Vital statistics compared to later provider submission. S109: Patient last name: Provider submission compared to later vital statistics submission. S110: Address: Vital statistics compared to later provider submission.
BR903. Use local policies if no selection made based on another business rule. An IIS should consistently implement local policies to select a value for the consolidating records process if other BRs do not result in selection of a value.	 If no value is selected for consolidation after application of another BR, the IIS should develop a policy to consistently choose one of the two values. Considerations for local policies could include the date of the most recent vaccination event record submitted with a demographic record, if any. References: Step DR2.2A
Data validation	
BR1001. Data validation. Data validation should occur within each demographic record and between each demographic record and all associated vaccination event records.	 Consolidated records should be subject to regular IIS data validation rules. Best practice: Validate incoming data using the same rules as existing data to prevent a cycle of overwriting validated data. Good practice: Perform regular data validation on existing data. If the IIS has limited resources, incoming data may be subject to less stringent validation rules.
	References: Chapter 7: Implementation Considerations BR1002. Prevent overwriting validated data. BR1003: No conflict with existing data.

Pusinasa Pulas	Describe
Business Rules	Remarks
BR1002. Prevent overwriting validated data. The consolidating records process should not result in overwriting validated data.	 BR902 states the general rule that the most recent information should be chosen for a consolidated record. This business rule, BR1002, is an exception to the general rule stated in BR902. If an IIS changes a value through data validation, the value can be locked/flagged for the same value from the same data source. Example: IIS changes an address through data cleansing/validation and the data source submits the same "bad" address. The IIS should make accessible the value that was replaced.
	References: Chapter 7: Implementation Considerations P12: Business routines should not be counterproductive. BR902: Use information that has most recent submission date. BR1001. Data validation. BR1003: No conflict with existing data.
BR1003. No conflict with existing data.	■ This BR applies to existing data.
The value of any data element should be consistent (i.e., in agreement) with other values in the patient record.	 Incoming data that are inconsistent with existing data will be used in a consolidated record in accordance with these guidelines and, after consolidation, will be subject to regular data validation. Cross-field validation should be performed across vaccination event record and demographic record. Examples: Existing record is marked as "deceased patient," but incoming record has "administered vaccination." Vaccine type administered is inconsistent with age recommendations. DOB mismatch between two records. Gender mismatch between two records. Inconsistent data should be flagged and investigated.
	References:
	Chapter 7: Implementation Considerations
	P12: Business routines should not be counterproductive.
	BR1001. Data validation.
	BR1002. Prevent overwriting validated data.

Business Rules	Remarks
Local laws	
BR1101. Local laws, regulations, and policy control. Information should not be used in a consolidated record if local laws, regulations, or policies prohibit utilizing that information.	 IIS should consult with local authorities about opt-out, foster care, protective custody, and adoption. For example, local laws, regulations, or policies may prohibit use of an address for a child in protective custody in a demographic record. Local laws, regulation, or policies may differ in implementation. For example, some IIS may limit access to certain information for some or all entities, but allow the information to be stored in the IIS. Other IIS may prohibit inclusion of information in the IIS (e.g., Social Security number).
	References:
	P11: Specific local laws control.
Unmerge	
BR1201. Prevent remerging of previously unmerged records.	Unmerging and remerging happens often with twins.
Consolidation of previously unmerged records should	A special indicator may be used to prevent remerging.
be prevented.	References:
	Chapter 7: Implementation Considerations
	P03: Make original information accessible.
	P10: Unmerge.

Vaccination-event-records-specific business rules

<u>Table 5-3</u> presents business rules for consolidating vaccination event records in the order in which the business rules are to be applied. <u>BR5001</u> to <u>BR5202</u> and <u>BR5801</u> to <u>BR5901</u> apply throughout the process of consolidating vaccination event records. <u>BR5301</u> to <u>BR5703</u> follow the order of the steps in the process model in <u>Chapter 4:</u> <u>Consolidating Records Process</u>.

Base record

- BR5001. Base record: existing record over incoming record.
- <u>BR5002</u>. Base record: two existing records.

Information needed to make consolidating records decisions

- BR5101. Information needed to make consolidation decisions.
- <u>BR5102</u>. Administered/historical indicator.
- <u>BR5103</u>. Retain all past IIS vaccination event IDs.
- BR5104. Use current (i.e., active) IIS vaccination event ID.
- <u>BR5105</u>. Retain past values.

■ Data element of same type/data groups

- BR5201. Compare data elements of same type.
- BR5202. Data elements considered to be data groups.
- BR5203. Data group values are from same data source.
- <u>BR5204</u>. Treat elements of data group as one.
- BR5205. Values within a data group must be consistent.

■ Single/multiple values (Step VER1.1)

- <u>BR5301</u>. Data elements with a single value.
- BR5302. Retain all unique values from data elements with multiple values.

Administered/historical (Step VER2.1)

- BR5401. Use administered vaccination event information over historical.
- <u>BR5402</u>. Two administered vaccination event records (different data sources).
- BR5403. Use information that has most recent submission date.

■ Valid/invalid value (Step VER3.1)

- BR5501. Use valid values.
- BR5502. Use either of two identical valid values.
- <u>BR5503</u>. Use populated values over empty values.
- BR5504. Use either invalid value for required data elements.
- BR5505. Use empty value instead of invalid value for non-required data element.
- BR5506. Use local implementation rules for invalid values for required data element.
- BR5507. Use invalid value in certain cases.
- BR5508. Use empty value over invalid value for non-required data element.
- BR5509. Use either value when both values are empty.

■ Completeness/specificity (Step VER3.3)

- <u>BR5601</u>. Use more complete information.
- BR5602. Use more specific information.

■ Record-level considerations (Step VER4.2)

- BR5701. Use information with highest confidence level
- BR5702. Use information that has most recent submission date.
- <u>BR5703</u>. Implement local policies to select value.

■ Data validation

- BR5801. Data validation.
- <u>BR5802</u>. Prevent overwriting validated data.
- <u>BR5803</u>. No conflict with existing data.

Local laws

■ <u>BR5901</u>. Local laws, regulations, and policy control.

Unmerging

■ <u>BR6001</u>. Prevent remerging of unmerged records.

Table 5-3. Business Rules for Vaccination Event Records

Business Rules	Remarks
Base record	
BR5001. Base record: existing record over incoming record. Consolidation of an existing record with an incoming record should result in an update of the existing record.	 The result is the same regardless of the method of submission. An existing record should be used as the base record to consolidate information from an incoming record. Base record is a record to be updated with information from another record during the consolidating records process. Consolidation of two demographic records should trigger consolidation of associated vaccination records as well.
	References: Chapter 3: Fundamentals, Figure 3-3 in Option 1: Incoming record with no IIS ID Chapter 4: Consolidating Records Process P04: Consolidation results. P13: Principles and business rules apply regardless of method of transmission. S1101: Base record: Existing administered and historical vaccination event records. S1102: Base record: Existing versus incoming historical vaccination event records. S1106: Two historical vaccination event records: Valid value versus blank/invalid value. Appendix A: Terms and Definitions Defined via Domain Model
 BR5002. Base record: two existing records. Consolidation of two existing records (i.e., with two IIS vaccination event IDs) should result in one of the following outcomes: A new consolidated record with a new IIS vaccination event ID. An updated consolidated record with one of the existing IIS vaccination event IDs. 	 Base record is a record to be updated with information from another record during the consolidating records process. If one of two existing records is updated during consolidation, either of the two existing records may be chosen to be updated with the best information from the other record. Local implementation will determine which one of the two existing vaccination event IDs to use. Factors to consider when determining which of two existing records to use as the base record in consolidation: The initial date each record was added to the IIS (may want to use the earliest record added to the IIS). Confidence level for each record (established by each IIS) Consolidation of two demographic records should trigger consolidation of associated vaccination records as well.
	References: Chapter 3: Fundamentals, Figure 3-4 in Option 2: Two existing IIS records are determined to match section. Chapter 4: Consolidating Records Process P04: Consolidation results. P13: Principles and business rules apply regardless of method of transmission. Appendix A: Terms and Definitions Defined via Domain Model

Business Rules Remarks

Information needed to make consolidating records decisions

BR5101. Information needed to make consolidation decisions.

The following information should be known for each data element to make consolidation decisions:

- Data source type
- Specific data source
- Most recent submission data
- Confidence level
- Administered/historical indicator value

- This business rule may be implemented in multiple ways—for example, storing or inferring the required information.
- The information required by this business rule is sufficient to consolidate records but not to unmerge records. Additional information may be required to unmerge records. Unmerging may also require manual intervention. BR6001 provides unmerging considerations.
- <u>Appendix A: Terms and Definitions Defined via Domain Model</u> defines data source and discusses use of IIS-AO to identify a specific data source.
- Confidence level: Local considerations influence determination of the confidence level in reported data.
- <u>BR5202</u> lists data elements that form data groups.
- Best practice: The IIS should keep an audit trail of all changes made to a data element, especially a subset that includes the original data source and the data source for the last modification. The IIS will be able to access the audit trail to know if the record originally came from a record that was changed later by the IIS (e.g., data validation or address cleansing) or by a provider through a UI.
- Data retention laws and policies differ. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.

References:

P03: Make original information accessible.

BR5202: Data elements considered to be data groups.

BR5701: Use information with highest confidence level.

BR6001: Prevent remerging of previously unmerged records.

Appendix A: Terms and Definitions Defined via Domain Model

BR5102. Administered/historical indicator.

The IIS should determine the value of the administered/historical indictor for each vaccination event record.

- IIS implementations differ in the case of an empty administered/historical indicator.
- Best practice: The submitter of a vaccination event record should indicate the value for the administered/historical indicator.
- Good practice: The IIS should consistently determine the value for the administered/historical indicator based on local considerations. For legacy records, the IIS may need to assign the value of the administered/historical indicator.
- <u>Chapter 7: Implementation Considerations</u> discusses factors to consider in determining the value for the administered/historical indicator.

References:

Chapter 7: Implementation Considerations

Business Rules	Remarks
BR5103. Retain all past IIS vaccination event IDs. All past IIS vaccination event IDs associated with a consolidated vaccination event record should be retained by the IIS.	 An IIS vaccination event ID has a unique single value per record. When existing records are consolidated, their IIS vaccination IDs need to be retained. For example, if a vaccination event has two records with different IIS vaccination event IDs (i.e., the ID assigned by the IIS for each vaccination event) and the records are consolidated, both IIS vaccination event IDs should be retained. Data retention laws and policies differ. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records.
	References: Chapter 7: Implementation Considerations P11: Specific local laws control. BR5901. Local laws, regulations, and policy control.
BR5104. Use current (i.e., active) IIS vaccination event ID. The current IIS vaccination event ID should be included in all IIS-originated communications about a vaccination event.	 A patient has only one current (active) IIS vaccination event ID at any point in time for a given vaccination event. BR5103 states that all IIS vaccination event IDs should be retained by the IIS. References: Chapter 7: Implementation Considerations BR5103: Retain all past IIS vaccination event IDs.
BR5105. Retain past values. IIS should make accessible past values for the following data group: Alternate vaccination event ID	 Making past values accessible facilitates IIS functions such as matching and unmerging. In bidirectional data exchanges, challenges caused by changing vaccination event IDs can be mitigated if vaccination event IDs (i.e., alternate vaccination event IDs) are preserved. All values in a data group should be made accessible as a unit. Data retention laws and policies differ among IIS jurisdictions. The amount of time data are retained will impact the ability of an IIS to consolidate and unmerge records. References:
	Chapter 7: Implementation Considerations BR5103. Retain all past IIS vaccination event IDs. BR5202: Data elements considered to be a data group. BR5204: Treat elements of data group as one.

Business Rules	Remarks
Data element of same type/data groups	
BR5201. Compare data elements of same type. Only data elements of the same type should be compared for consolidation purposes.	 In some cases, a concept of "type" can be applied to some sets of data elements that do not constitute a data group. Categorization of data elements/groups into types is determined by local implementation. References:
	Appendix A: Terms and Definitions Defined via Domain Model
BR5202. Data elements considered to be data groups. All of the following collections of data elements should be considered as data groups: Alternate vaccination event ID (vaccination event ID and vaccination event ID: assigning authority ID) Vaccine dose volume and unit (vaccine dose volume and vaccine unit) Contraindication(s)/precautions(s) (contradiction(s)/precautions(s), contraindication(s)/precautions(s) observation date(s)) Exemptions(s) (exemption(s)/parent refusal(s) of vaccine, date of exemption/parent refusal of vaccine) History of vaccine-preventable disease (history of vaccine-preventable disease and date of history of vaccine-preventable disease) Vaccine adverse reaction(s) (adverse reaction(s) and date of adverse reaction observation) Original submission data (original submission date and data source ID for original submission) Most recent submission data (most recent submission date)	 Certain data elements are grouped together and treated as one data group in which the value for each data element must come from the same data source. It is important to select all values for data elements in data groups from the same data source because mixing values from different data sources would incorrectly change the interpretation of the values. The Grouping of demographic data elements section of Appendix A: Terms and Definitions Defined via Domain Model provides more detail about data groups. References: BR5203: Data group values are from same data source. BR5204: Treat elements of data group as one. BR5205: Values within a data group must be consistent. Table A-5 and Grouping of demographic and vaccination event data elements in Appendix A: Terms and Definitions Defined via Domain Model

Business Rules	Remarks
BR5203. Data group values are from same data source.	■ Example: Adverse event (vaccine reaction) and adverse event observation/vaccine encounter date
The value for each data element in a data group must come	must come from the same data source.
from the same data source.	References:
	BR5202: Data elements considered to be data groups.
	BR5204: Treat elements of data group as one.
	BR5205: Values within a data group must be consistent.
BR5204. Treat elements of data group as one.	■ Data elements within a group are treated together as one.
All data elements within a data group should be treated as a single data element.	For example: Alternate vaccination event ID data group with the data elements, vaccination event ID and vaccination event ID: Assigning authority ID (i.e., owning data source).
	References:
	BR5202: Data elements considered to be data groups.
	BR5203: Data group values are from same data source.
	BR5205: Values within a data group must be consistent.
BR5205. Values within a data group must be consistent.	If all elements in a data group are not internally consistent, the IIS should reject all values in the data
Values of all data elements within a data group should be	group.
consistent with each other.	References:
	BR5202: Data elements considered to be data groups.
	BR5203: Data group values are from same data source.
	BR5204: Treat elements of data group as one.

Business Rules	Remarks
Single/multiple values (<u>Step VER1.1</u>)	
BR5301. Data elements with a single value.	References:
The following data elements must have a single value: Vaccination administration date Vaccine product type administered (CVX-NDC-CPT) Vaccine manufacturer name Vaccine lot number Vaccine expiration date Vaccine dose volume and unit Vaccine site of administration Vaccine route of administration Vaccine ordering provider name Vaccine administering provider name Vaccination event information source (i.e., administered or historical) VFC/grantee program vaccine eligibility at dose level Vaccine funding source IIS vaccination event ID Original submission date Most recent submission date	Step VER1.1 Table A-4 in Appendix A: Terms and Definitions Defined via Domain Model

Business Rules	Remarks
BR5302. Retain all values from data elements with multiple values. All unique values should be retained for data elements that can have multiple current values.	 See Table A-5 and Table A-6 for data elements and data groups. The following data groups can have multiple current values: Alternate vaccination event ID (one per data source) Contraindication(s)/precaution(s) History of vaccine-preventable disease Exemption(s) Vaccine adverse reaction(s) Each of four data groups (contraindication(s)/precautions(s), history of vaccine-preventable disease, exemption(s), and vaccine adverse reaction(s)) may be associated by the data source with a vaccination event or with a patient or encounter date. For example, a vaccine adverse reaction may be submitted to the IIS through a UI and associated with a specific vaccination. Future modifications to HL7 may also allow association of an adverse event with a specific vaccination. Alternatively, a data source may not know the date of vaccination or the specific vaccinations given and may submit a vaccine adverse reaction with an observation date or date of vaccination encounter (but not a specific vaccine). The IIS should associate contraindication(s)/precautions(s), history of vaccine-preventable disease, exemption(s), and vaccine adverse reaction(s) with a demographic record, vaccination event record, patient, or encounter as reported by the data source.
	References: Chapter 7: Implementation Considerations
	Step VER1.1
	S1103. Multiple values permitted.
	Table A-4 and Table A-6 in Appendix A: Terms and Definitions Defined via Domain Model

Business Rules	Remarks
Administered/historical (Step VER2.1)	
BR5401. Use administered vaccination event information over historical. The value of the data element from the administered record should be selected over the value of the same data element from a historical record, except for data elements that can have multiple values.	 For example, vaccine adverse reaction(s) can have multiple values. Sometimes historical and administered are mislabeled. See the remarks for vaccination event record data element in the domain model and Table A-5 for information included in a vaccination event record. If multiple values are allowed, all unique values should be selected. References: Step VER2.1 P07. Accuracy over completeness. BR5302. Retain all unique values from data elements with multiple values. S1101: Base record: existing administered and historical vaccination event records. S1104: Administered vaccination event records compared to historical vaccination event records. Table A-6 in Appendix A: Terms and Definitions Defined via Domain Model
BR5402. Two administered vaccination event records (different data sources). The IIS should investigate if two administered vaccination event records are submitted by different data sources.	 All administered vaccination event records for a single vaccination event should be from the same data source. If two administered vaccination event records are submitted by different data sources (incoming versus existing and existing versus existing) for the same vaccination event: Best practice: The IIS should investigate. Good practice: If an IIS does not have resources to investigate, the IIS should establish local rules (e.g., considering recency, completeness, etc.) for an automated process to choose the best value. References: Stan VERS 14
BR5403. Use information that has most recent submission date. The value from the vaccination event record with the most recent submission date should be used when comparing two administered vaccination event records from the same source.	Step VER2.1A ■ See BR5802 for an exception to the general rule stated. If the IIS has validated values in a record, a subsequent submission of the same "bad" value by the same data source should not be used in place of the validated value. References: Step VER2.1B S1105: Data validation by IIS.

Business Rules	Remarks
Valid/invalid value (Step VER3.1)	
BR5501. Use valid values. A valid value for a data element or data group should be used over an invalid value.	 An invalid value in a data element or data group may not be sufficient to reject the entire incoming record; however, the data may be flagged as invalid. For example, a vaccine lot number may have extraneous characters (e.g., "ABE123-VFC," indicating that an administered vaccine dose is for a VFC-eligible child). In special cases, an empty value should be used instead of other submitted values. References: Step VER3.1 Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 1 P05: Use best value for each data element. BR5507: Use invalid value in certain cases. BR5508. Use empty value over invalid value for non-required data element. S1106: Two historical vaccination event records: Valid value versus blank/invalid value.
BR5502. Use either of two identical valid values. A data element value from either one of two records under consideration should be selected as the best value for a consolidated record when all of the following are true: Values are valid. Values are the same.	References: Step VER3.1A Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 2
BR5503. Use populated values over empty values. A valid value for a data element or data group should be chosen over an empty value.	 ■ In special cases, an empty value should be used instead of other submitted values. ■ A known valid value should be chosen over an unknown (empty, blank) value. References: Step VER3.1C Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 4 P05: Use best value for each data element. BR5507: Use invalid value in certain cases. S1106: Two historical vaccination event records: valid value versus blank/invalid value. S1107: Record-level completeness.
BR5504. Use either invalid value for required data elements.	■ A data element value is required because it is a software minimum field required to save the data element.
A data element value from either one of two records under consideration should be selected as the best value for a consolidated record when all of the following are true: Values are invalid. Values are the same. Data element is required to have a value.	References: Step VER3.1D Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 5

Business Rules	Remarks
BR5505. Use empty value instead of invalid value for non- required data element.	■ A data element value is required because it is a software minimum field required to save the data element References:
The value of a data element in a consolidated vaccination event record should be empty if all of the following are true: The data element is not required by the IIS The data values in both matched records are invalid	Step VER3.1E Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 6
BR5506. Use local implementation rules for invalid values for required data element.	A data element value is required because it is a software minimum field required to save the data element References :
Local policies should be implemented for choosing between two different invalid values for a required data element in a consolidated record.	Step VER3.1F Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 7
BR5507. Use invalid value in certain cases.	■ A data element value is required because it is a software minimum field required to save the data element
An invalid value should be selected over an empty value for a data element that is required to have a value.	 For example, a vaccine lot number with extraneous characters (e.g., "ABC123-VFC," where "ABC123" is a correct vaccine lot number and "VFC" was added by a provider to indicate the vaccine was from the VFC program). Best practices for validating vaccine lot numbers are described in MIROW Lot Number Validation Best Practices [1.11].
	References: Step VER3.1G Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 8
BR5508. Use empty value over invalid value for non-required data element.	■ A data element value is required because it is a software minimum field required to save the data element References:
An empty value for a data element should be used over an invalid value when the data element is not required.	Step VER3.1H Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 9
BR5509. Use either value when both values are empty.	■ An IIS may have data quality procedures to assign values.
The value of a data element in a consolidated record should be empty when the values in both matched records are empty.	References: Step VER3.1 Table 4-2 in Chapter 4: Consolidating Records Process, Process Scenario 10

Business Rules	Remarks
Completeness/specificity (Step VER3.3)	
BR5601. Use more complete information. More complete information should be used over less complete information.	 Examples: Data element vaccine ordering provider name: "J. Smith" versus "John Smith"—a name that includes a full first name is more complete than a name with an initial. References: Step VER3.3 S1107: Record level completeness.
BR5602. Use more specific information. More specific information should be used over less specific information.	 For example, a more specific vaccine product type administered (Hib-PRP-T) should be selected over the more generic vaccine product type administered (Hib-unspecified). References: Step VER3.3
Record-level considerations (<u>Step VER4.2</u>)	
BR5701. Use information with highest confidence level.	Confidence level is discussed in detail in Appendix D: Confidence Level Indicator.
The value of the higher confidence level should be used for a data element in a consolidated record when comparing two historical vaccination event records.	References: Chapter 7: Implementation Considerations Step VER4.1 P07. Accuracy over completeness. P08: Confidence ranking for data sources. Appendix D: Confidence Level Indicator
BR5702. Use information that has most recent submission date. The value with the most recent submission date should be used in a consolidated record when comparing two historical vaccination event records.	 For two administered vaccination event records from the same source, use the value from the vaccination event record with the most recent submission date. See <u>BR5403</u>. For two historical vaccination event records from the same or different sources, use the values from the vaccination event record with the most recent submission date. <u>Chapter 7: Implementation Considerations</u> discusses action codes. <u>References:</u> <u>Step VER4.2.</u> <u>P09: Recency.</u> <u>BR5403: Use information that has most recent submission date.</u> <u>BR5802: Prevent overwriting validated data.</u>
BR5703. Implement local policies to select value.	■ If no value is selected for the consolidated record after application of other business rules, the IIS
An IIS should consistently implement local policies to select a value for the consolidating records process if other business rules do not result in selection of a value.	should develop a policy to consistently choose one of the two values. References: Step VER4.2A

Business Rules	Remarks
Data validation	
BR5801. Data validation. Data validation should occur within each vaccination event record and between each vaccination event record and associated demographic record.	 Consolidated records should be subject to the same data validation rules as other records in the IIS. Best practice: Validate incoming data using the same rules as for existing data to prevent a cycle of overwriting validated data. Good practice: Perform regular data validation for existing data. If the IIS has limited resources, incoming data may be subject to less stringent validation rules than existing data.
	References: Chapter 7: Implementation Considerations BR5802. Prevent overwriting validated data. BR5803: No conflict with existing data. S1105: Data validation by IIS.
BR5802. Prevent overwriting validated data. The consolidating records process should not result in overwriting validated data.	 See <u>BR5403</u>. If an IIS changes a value through data validation, the value can be locked/flagged for the same value from the same data source. Example: IIS strips extraneous characters from a vaccine lot number through data validation and the data source submits the same "bad" information. The IIS should make accessible the value that was replaced.
	References: Chapter 7: Implementation Considerations P12: Business routines should not be counterproductive. BR5801. Data validation. BR5803: No conflict with existing data. S1105: Data validation by IIS.
BR5803. No conflict with existing data. The value of any data element should be consistent (i.e., in agreement) with other values in the patient record.	 This BR applies to existing data. Incoming data that are inconsistent with existing data should be used in a consolidated record in accordance with these guidelines and after consolidation subjected to regular data validation. Cross-field validation should be performed across vaccination event record and demographic record. Example: Existing record is marked as "deceased patient," but incoming record has "administered vaccination." Example: Vaccine type administered is inconsistent with age recommendations. Inconsistent data should be investigated.
	References: Chapter 7: Implementation Considerations P12: Business routines should not be counterproductive. BR5801. Data validation. BR5802. Prevent overwriting validated data.

Business Rules	Remarks
Local laws	
BR5901. Local laws, regulations, and policy control.	■ The IIS should consult with local authorities about consent, foster care, protective custody, and adoption.
Information should not be included in a consolidated record if local laws, regulations, or policies prohibit utilizing that information.	Local laws, regulations, or policies may differ in implementation—for example, some IIS may limit access to certain information for some or all entities but allow the information to be stored in the IIS. Other IIS may prohibit inclusion of information in the IIS.
	References:
	P11: Specific local laws control.
Unmerging	
BR6001. Prevent remerging of previously unmerged records.	■ The IIS should have a way (e.g., a special indicator) to flag pairs of records that should not be merged
Consolidation of previously unmerged records should	with each other, preventing remerging.
be prevented.	References:
	<u>Chapter 7: Implementation Considerations</u>
	P03: Make original information accessible.
	P10: Unmerge.

Chapter 6: Operational Scenarios

This chapter presents typical and challenging consolidation scenarios. Using real situations to evaluate principles and business rules (<u>Chapter 5: Principles and Business Rules</u>) will help the user of this guide to test and explore best practice recommendations.

The operational scenarios presented in this section do not include all data elements from two records that are under consideration for consolidation or all data elements in a consolidated record. Selected data elements are presented to illustrate the application of one or more principles and business rules in each operational scenario. These operational scenarios also do not constitute an exhaustive set of all possible scenarios related to consolidating records. Rather, they are a limited set of typical and challenging situations and recommended resolutions based on principles and business rules described in Chapter 5: Principles and Business Rules. Individual IIS can expand this set of scenarios for training and operational purposes.

Demographic record consolidation: selected operational scenarios

- <u>\$101</u>. Base record: incoming and existing demographic records.
- <u>\$102</u>. Base record: two existing demographic records.
- S103. Patient first name: two invalid values.
- \$104. Patient first name: one valid, one invalid value.
- <u>\$105</u>. Address: same type.
- <u>\$106</u>. Patient first name: demographic record recency.
- <u>\$107</u>. Phone number: same type.
- <u>\$108</u>. Patient last name: vital statistics compared with later provider submission.
- <u>\$109</u>. Patient last name: provider submission compared with later vital statistics submission.
- <u>S110</u>. Address: vital statistics compared with later provider submission.
- <u>S111</u>. Patient date of birth: vital statistics compared with later provider submission.

See <u>Vaccination event record consolidation section</u> in this chapter for operational scenarios that focus on consolidating vaccination event records.

Scenario S101. Base record: incoming and existing demographic records.

Description: An incoming demographic record matches an existing IIS demographic record.			
Conditions	Provider A (existing demographic record)	Provider B (incoming demographic record)	Consolidated Record
Original submission data	1/12/17	_	1/12/17 (Provider A)
Most recent submission data	_	1/13/17	1/13/17 (Provider B)
IIS-ID	2407	_	2407
Patient name	John Doe	John Doe	John Doe
Patient date of birth	1/1/17	1/1/17	1/1/17

Resolution:

■ Use the record from Provider A as the base record. Use IIS-ID from Provider A.

References: Chapter 3: Fundamentals, Figure 3-3, Option 1; BR101

Remarks:

■ Existing record (from provider A) is used as a base record. No updates have been made in this particular case to the base record.

Scenario S102. Base record: two existing demographic records.

Description: Two existing IIS records are matched.					
Conditions	nditions Provider A Provider B Consolidated Record				
Original submission data	1/10/17	_	1/10/17 (Provider A)		
Most recent submission data	_	1/13/17	1/13/17 (Provider B)		
IIS-ID	2407	4826	2407 or 4826 or new IIS-ID		
Patient name	John Doe	John Doe	John Doe		
Patient date of birth	1/1/17	1/1/17	1/1/17		

Resolution:

Use either of two options consistently:

- Create a new IIS record and IIS-ID. Update the new record with the best value for each data element from both existing records.
- Choose either of the two existing records. Update the record with the best value for each data element from both existing records.

References: Chapter 3: Fundamentals, Figure 3-4, Option 2A and Option 2B; BR102

Remarks: None

Scenario S103. Patient first name: two invalid values.

Description: Vital statistics submits patient name X (Baby Boy Smith) and IIS creates a record. Later, Provider B submits patient name Y (Unknown Smith).

Conditions	Vital statistics	Provider B (hospital)	Consolidated Record
Original submission data	2/1/16	_	2/1/16 (Vital statistics)
Most recent submission data	_	2/3/16	2/3/16 (Provider B)
Patient first name	Baby Boy	Unknown	Baby Boy
Patient last name	Smith	Smith	Smith

Resolution:

- Vital statistics is not a definitive data source for patient name.
- The value in patient first name in both records is invalid. Because patient name is required, a value must be selected.
- Local implementation rules should determine which value to select, based on confidence in the data source or other considerations.

References: Step DR1.1F, BR301, BR302, BR506, BR601

Scenario S104. Patient first name: one valid, one invalid value.

Description: Provider A submits patient name X (John Smith) and IIS creates a record. Later, Provider B submits patient name (Unknown Smith) Y.

Conditions	Provider A	Provider B	Consolidated Record
Original submission data	2/1/16	_	2/1/16 (Provider A)
Most recent submission data	_	4/1/16	4/1/16 (Provider B)
Patient first name	John	Unknown	John
Demographic data	Patient name (John Smith) X	Patient name (Unknown Smith) Y	

Resolution:

■ Patient X and Patient Y are considered the same patient, based on other information. Select patient name X from Provider A record. It is a valid value. Patient name Unknown from Provider B record is not a valid value.

References: BR501, Appendix A: Terms and Definitions, Table A-5

Remarks: None

Scenario S105. Address: same type.

Description: Provider A submits address X. Later, Provider B submits address Y.				
Conditions	Provider A Provider B Consolidated Record			
Original submission data	2/1/16	_	2/1/16 (Provider A)	
Most recent submission data	_	4/1/16	4/1/16 (Provider B)	
Address	2680 Clinton St. (address X) (valid)	9991 E Progress Circle (address Y) (valid)	9991 E Progress Circle	

Resolution:

- If address X and address Y are the same type of address (e.g., both street addresses), then select address Y because it is the most recent.
- Select both addresses if address X and address Y are different types of addresses (e.g., street/physical address vs. mailing/PO Box address)
- If address Y is selected, then address X should be made accessible (i.e., stored or derived) from history.

References: <u>P06</u>, <u>BR201</u>, <u>BR204</u>, <u>BR401</u>, <u>BR702</u>, <u>BR902</u>

Remarks:

- Phase 1 and <u>Step DR2.1</u> of the consolidation process for demographic records did not result in selection of a best value.
- An IIS should compare only the same type of address, and type is determined locally. See <u>BR401</u> and <u>Appendix A: Terms</u> and <u>Definitions Defined via Domain Model</u>, <u>Grouping of demographic and vaccination event data elements</u>.
- IIS need to be able to identify mailing address and geographic address.

Scenario S106. Patient first name: demographic record recency.

Description: Provider A submits patient first name X. Later, Provider B submits patient first name Y.					
Conditions Provider A Provider B Consolidated Record					
Original submission data	3/1/16 — 3/1/16 (Provider A)				
Most recent submission data – 6/1/16 (Provider B)					
Patient first name Y (valid) First name Y (valid) See Resolution					

Resolution:

- Earlier steps of the process did not result in selection of a best value.
- Local rules could consider factors that could result in placing more confidence in one provider over the other as a data source. The IIS should establish local rules for confidence in data sources.
- If both data sources have the same level of confidence, then select first name Y because it comes from the most recent demographic record.

References: <u>P06</u>, <u>BR201</u>, <u>BR901</u>, <u>BR902</u>

Remarks:

First name X should be accessible in history.

Scenario S107. Phone number: same type.

Description: Provider A submits phone numbers X and Y. Later, Provider B submits phone number Z.			
Conditions	Provider A Provider B Consolidated Record		
Original submission data	2/1/16	_	2/1/16 (Provider A)
Most recent submission data	_	4/1/16	4/1/16 (Provider B)
Phone number	(xxx) xxx-xxxx (phone number X) (xxx) xxx-xxxx (phone number Y)	(xxx) xxx-xxxx (phone number Z)	See Resolution

Resolution:

- Select phone number Z (and replace phone numbers X and Y) because it comes from the most recent demographic record.
 - Only compare data elements of the same type. Phone numbers X, Y, and Z are of the same type.
- Phone numbers X and Y should be accessible (stored or can be derived) in history.

References: <u>P06</u>, <u>BR201</u>, <u>BR204</u>, <u>BR401</u>, <u>BR702</u>, <u>BR902</u>

Remarks:

- Phase 1 and <u>Step DR2.1</u> of the consolidation process for demographic records did not result in selection of a best value.
- If the phone numbers are not of the same type, multiples are allowed, and X, Y, and Z should all be retained. See <u>BR702</u>.

Scenario S108. Patient last name: vital statistics compared with later provider submission.

Description: Patient last name: two demographic records, one from vital statistics and a later submission from Provider B.			
Conditions Vital statistics Provider A Consolidated Record			
Original submission data	2/1/16	_	2/1/16 (Vital statistics)
Most recent submission data — 4/1/16 (Provider A)			
Patient last name	Last name X (valid)	Last name Y (valid)	Last name Y

Resolution:

■ Select last name Y from Provider A because it comes from the most recent demographic record.

References: <u>P06</u>, <u>BR201</u>, <u>BR601</u>, <u>BR902</u>

Remarks:

- Patient was matched through the birth certificate number.
- Vital statistics is a definitive source of information for some data elements but not for patient name.
- Some IIS may store the "legal" or "birth" name in addition to a consolidated patient name, if required by local law, regulations, or policy.

Scenario S109. Patient last name: provider submission compared with later vital statistics submission.

Description: Patient last name: two demographic records, one from Provider A (initial IIS record) and a later submission from vital statistics.

The state of the s						
Conditions	Provider A	Vital statistics	Consolidated Record			
Original submission data	2/1/17	_	2/1/17 (Provider A)			
Most recent submission data	_	2/15/17	2/15/17 (Vital statistics)			
Date of birth	Same	Same	Same			
Patient last name	Last name X (valid)	Last name Y (valid)	Last name Y			

Resolution:

- Patient was matched through the birth certificate number.
- Select the last name from vital statistics. It is the value from the most recent record.

References: P06, BR901, BR902

Remarks:

■ Vital statistics is a definitive source of information for some data elements but not for patient name.

Scenario S110. Address: vital statistics compared with later provider submission.

Description: Patient address: two demographic records, one from vital statistics (initial IIS record) and a later submission from Provider A.

Conditions	Vital statistics	Provider A	Consolidated Record
Original submission data	2/1/15	_	2/1/15 (Vital statistics)
Most recent submission data	_	2/1/17	2/1/17 (Provider A)
Patient address	Address X	Address Y	Address Y

Resolution:

■ Select address Y because it is the most recent

References: <u>P06</u>, <u>BR201</u>, <u>BR601</u>, <u>BR902</u>

Remarks:

■ Vital statistics is a definitive data source for some data elements but not for address.

Scenario S111. Patient date of birth: vital statistics compared with later provider submission.

Description: Patient date of birth: two demographic records, one from vital statistics (initial IIS record) and a later submission from Provider A.

Conditions	Vital statistics	Provider A (hospital)	Consolidated Record
Original submission data	1/12/17	_	1/12/17 (Vital statistics)
Most recent submission data	_	1/13/17	1/13/17 (Provider A)
Demographic data	Date of birth (1/11/17)	Date of birth (1/10/17)	1/11/17

Resolution:

- Select the patient date of birth from vital statistics. Vital statistics is the definitive source of data for patient date of birth.
- IIS should communicate with provider A to correct the date of birth to prevent the problem from recurring.

References: P06, BR201, BR601

Vaccination event record consolidation: selected operational scenarios

- S1101. Base record: existing administered and historical vaccination event records.
- <u>\$1102</u>. Base record: existing versus incoming historical vaccination event records.
- S1103. Multiple values permitted.
- <u>\$1104.</u> Administered vaccination event records compared with historical vaccination event records.
- <u>S1105</u>. Data validation by IIS.
- <u>S1106</u>. Two historical vaccination event records: valid value versus blank/invalid value.
- <u>S1107</u>. Record-level completeness.
- S1108. Delete code: consolidated historical vaccination event records.
- \$1109. Delete code: consolidated administered and historical vaccination event records.

See <u>Demographic record consolidation</u> section in this chapter for operational scenarios that focus on consolidation of demographic record.

Scenario S1101. Base record: existing administered and historical vaccination event records.

Description: One of the two data values under consideration was submitted in an administered vaccination event record.					
Conditions	Provider A	Provider B	Consolidated Record		
Original submission data	1/12/17	_	1/12/17 (Provider A)		
Most recent submission data	_	1/13/17	1/13/17 (Provider B)		
IIS vaccination event ID	3220	8857	3220		
Alternate vaccination event ID	3220	8857	3220 (Provider A) 8857 (Provider B)		
Vaccination administration date	1/12/17	1/12/17	1/12/17		
Vaccine event information source (i.e., administered or historical)	Administered	Historical	Administered		
Same or different vaccination event?	Same	Same	_		

Resolution:

Use either of two options consistently (the second option is used for this example):

- Create a new vaccination event record and IIS vaccination event ID. Update the new record with the best value for each data element from both existing records.
- Choose either of the two existing records. Update the record with the best value for each data element from both existing records.
- Regarding updates: The value of the data element from the administered record should be selected over the value of the same data element from a historical record, except for data elements that can have multiple values (e.g., adverse reactions).

References: BR5002, BR5401

Scenario S1102. Base record: existing versus incoming historical vaccination event records.

Description: Both data values under consideration were submitted in historical vaccination event records.						
Conditions Provider A (existing) Provider B (incoming) Consolidated Rec						
Original submission data	3/13/17	_	3/13/17 (Provider A)			
Most recent submission data	_	5/14/17	5/14/17 (Provider B)			
Vaccination administration date	1/12/17	1/12/17	1/12/17			
Vaccine product type administered (CVX-NDC-CPT)	1234	1234	1234			
Vaccine event information source (i.e., administered or historical)	Historical	Historical	Historical			
Same or different vaccination event?	Same	Same	_			

Resolution:

- Use the vaccination event record from Provider A as the base record because it is the existing vaccination event record.
- For two existing historical vaccination event records, the IIS would apply local considerations to choose a base record.
- Data elements from Record A and B are selected based on the data-element-level business rules.

References: BR5001, Figure 4-5

Remarks:

■ See <u>Chapter 7: Implementation Considerations</u>.

Scenario S1103. Multiple values permitted.

Description: Provider A submits administered vaccination event record to IIS. Provider B submits a historical record for the same vaccination event, including adverse events.

Conditions	Provider A	Provider B	Consolidated Record (Provider A)
Original submission data	1/1/17	_	1/1/17 (Provider A)
Most recent submission data	_	1/13/17	1/13/17 (Provider B)
Vaccination administration date	1/1/17	1/1/17	1/1/17
Adverse reaction(s)	Fever	Rash	Fever, Rash
Vaccine event information source (i.e., administered or historical)	Administered	Historical	Administered
Same or different vaccination event?	Same	Same	

Resolution

■ Use adverse event values from Provider B to update the vaccination event record or demographic record from Provider A.

References: BR5302

Scenario S1104. Administered vaccination event records compared with historical vaccination event records.

Description: Provider A submits historical vaccination event record to IIS. Provider B submits an administered vaccination event record to the IIS for the same vaccination event after establishing connection to the IIS (i.e., five months after vaccination event).

Conditions	Provider A	Provider B	Consolidated Record
Original submission data	3/2/17	_	3/2/17 (Provider A)
Most recent submission data	_	5/1/17	5/1/17 (Provider B)
Vaccination administration date	1/1/17	1/1/17	1/1/17
Vaccine lot number	abcd	Blank	Blank
Vaccine product type administered (CVX-NDC-CPT)	1234	1234	1234
Vaccine expiration date	1/1/19	Blank	Blank
Vaccine event information source (i.e., administered or historical)	Historical	Administered	Administered
Same or different vaccination event?	Same	Same	

Resolution:

■ Use the values for vaccine lot number and vaccine lot number expiration date from the administered vaccination event record even though the values are blank in the administered vaccination event record. Accuracy is more important than completeness in a vaccination event record, and the administered record from Provider B is presumed to be more accurate because the patient presented to Provider B for the vaccination.

References: P07, BR5401

Scenario S1105. Data validation by IIS.

Description: Provider A submits administered vaccination event record to IIS. Vaccine lot number contains extra characters. IIS accepts vaccine lot number. IIS performs regularly scheduled data validation and strips the extra characters from the vaccine lot number. Provider A submits the same vaccination event record to the IIS again containing vaccine lot number with extra characters.

Conditions	Provider A	Data Validation	Provider A	Consolidated Record
Original submission data	1/1/17	_	1/20/17	1/1/17 (Provider A)
Submission date	_	1/13/17	_	
Most recent submission data			1/20/17	1/13/17 (IIS)
Vaccination administration date	1/1/17		1/1/17	1/1/17
Vaccine lot number	1234VFC	1234	1234VFC	1234
Vaccine product type administered (CVX-NDC-CPT)	abcd		abcd	abcd
Vaccine lot number expiration date	1/1/19		1/1/19	1/1/19
Vaccine event information source (i.e., administered or historical)	Administered		Administered	Administered
Same or different vaccination event?	Same		Same	

Resolution:

■ The general rule is that if there are two administered vaccination event records from the same data source, the value from the most recently submitted record is used in a consolidated record. In this scenario, the vaccination event record submitted on 1/20/17 is the most recently submitted vaccination event record. However, an exception to the general rule provides that IIS processes should not be counterproductive and the same "bad" data from the same data source should not overwrite data validated by the IIS.

References: Step VER2.1A, BR5403, P12, Step VER2.1B, BR5801, BR5802

Remarks:

- IIS will need to keep track of validated data to prevent it from being overwritten.
- If the facts in S1105 were changed and the second submission from Provider A contained a totally different vaccine lot number, the vaccine lot number from the second submission would be chosen for the consolidated record.

Scenario S1106. Two historical vaccination event records: valid value versus blank/invalid value.

Description: Provider A submits historical vaccination event record to IIS. Provider B submits a historical vaccination event record to the IIS for the same vaccination event.

Conditions	Provider A (existing record)	Provider B (incoming record)	Consolidated Record (Provider A vaccination event record is the base)
Original submission data	1/2/17	_	1/2/17 (Provider A)
Most recent submission data	_	1/13/17	1/13/17 (Provider B)
Vaccination administration date	1/1/17	1/1/17	1/1/17
Vaccine lot number	1234 (valid)	1234VFC (invalid)	1234
Vaccine product type administered (CVX-NDC-CPT)	678	Blank	678
Vaccine lot number expiration date	Blank	1/1/19	1/1/19
Vaccine event information source (i.e., administered or historical)	Historical	Historical	Historical
Same or different vaccination event?	Same	Same	

Resolution:

■ Use the vaccination event record from Provider A as the base record because it is the vaccination event record already existing in the IIS. For each data element, choose a valid value over an invalid/empty value.

References: BR5001, BR5501, BR5503

Remarks: None

Scenario S1107. Record-level completeness.

Description: A submits historical vaccination event record to IIS. Provider B submits a historical vaccination event record to the IIS for the same vaccination event.

the hardrine vaccination event.					
Conditions	Provider A	Provider B	Consolidated Record		
Original submission data	1/2/17	_	1/2/17 (Provider A)		
Most recent submission data	_	1/13/17	1/13/17 (Provider B)		
Vaccination administration date	1/1/17	1/1/17	1/1/17		
Vaccine lot number	abcd	abcd	abcd		
Vaccine product type administered (CVX-NDC-CPT)	1234	Blank	1234		
Vaccine lot number expiration date	1/1/19 (valid)	1/10/19 (valid)	1/1/19		
Vaccine event information source (i.e., administered or historical)	Historical	Historical	Historical		
Same or different vaccination event?	Same	Same			

Resolution:

■ For the vaccine product type administered, choose the valid value over the blank value. For the vaccine lot number expiration date, choose the value from Provider A because the vaccination event record from Provider A is more complete than the vaccination event record from Provider B.

References: BR5503, BR5601

Scenario S1108. Delete code: consolidated historical vaccination event records.

Description: Provider A submits a historical vaccination event record to IIS. Provider B submits historical vaccination event record to the IIS for the same vaccination event. Provider C submits historical vaccination event record to the IIS for the same vaccination. Records from A, B, and C are consolidated. Provider A submits a vaccination event record with a delete code for the same vaccination event.

Conditions	Provider A	Provider B	Provider C	Consolidated Record	Provider A (delete code; information deleted)	Final Consolidated Record (consolidation of records from Providers B and C)
Original submission data	1/2/17	_	_	1/2/17 (Provider A)	1/15/17	1/13/17 (Provider B)
Most recent submission data	_	1/13/17	1/14/17	1/14/17 (Provider C)	_	1/14/17 (Provider C)
Vaccination administration date	1/1/17	1/1/17	1/1/17	1/1/17	1/1/17	1/1/17
Vaccine lot number	abcd			abcd	abcd	
Adverse reaction(s)	Fever		Seizure	Fever, Seizure	Fever	Seizure
Vaccine lot number expiration date	1/1/19			1/1/19	1/1/19	
Vaccine event information source (i.e., administered or historical)	Historical	Historical	Historical	Historical	Historical	Historical
Same or different vaccination event?	Same	Same	Same		Same (with delete code)	Same

Resolution:

■ The vaccination event record from Provider A on 1/2/17 is the base record. The adverse reactions reported by Providers B and C update the vaccination event record from Provider A in a consolidated record. The delete code from Provider A deletes the information submitted by Provider A but not the information submitted by Providers B and C. Information from Providers B and C is reviewed in the same manner as other records in the IIS and consolidated as appropriate.

References: None

Remarks:

■ The resolution would be the same if the record submitted by Provider A was an administered vaccination event record. Information can be deleted only by the data source that submits the information.

Scenario S1109. Delete code: consolidated administered and historical vaccination event records.

Description: Provider A submits an administered vaccination event record to IIS. Provider B submits historical vaccination event record to the IIS for the same vaccination event. Provider C submits historical vaccination event record to the IIS for the same vaccination. Records from A, B, and C are consolidated. Provider A submits a vaccination event record with a delete code for the same vaccination event.

Conditions	Provider A	Provider B	Provider C	Consolidated Record	Provider A (delete code; information deleted)
Original submission data	1/1/17	_	_	1/1/17 (Provider A)	1/15/17
Most recent submission data		1/13/17	1/14/17	1/14/17 (Provider C)	
Vaccination administration date	1/1/17	1/1/17	1/117	1/1/17	1/1/17
Vaccine lot number	abcd			abcd	abcd
Adverse reaction(s)	_	Fever	Seizure	Fever, Seizure	
Vaccine lot number expiration date	1/1/19			1/1/19	1/1/19
Vaccine event information source (i.e., administered or historical)	Administered	Historical	Historical	Administered	Administered
Same or different vaccination event?	Same	Same	Same	_	Same (with delete code)

Resolution:

■ The vaccination event record from Provider A on 1/1/17 is the base record. The adverse reactions reported by Providers B and C update the vaccination event record from Provider A in a consolidated record. The IIS should investigate whether an immunization event took place upon receipt of the delete code from Provider A.

References: None

Remarks:

■ The resolution would be the same if the record submitted by Provider A was a historical vaccination event record. Information can be deleted only by the data source that submits the information.

Chapter 7: Implementation Considerations

When considering any enhancement to an IIS, there are many implementation considerations. Based on the different IIS platforms nationally, some enhancements may be more daunting than others and might have different levels of impact on an IIS. Most likely, every IIS has already been doing some form of consolidation. Before modifying that process, the following section outlining key implementation considerations should be reviewed. These items occur both internally and externally to an IIS.

Key implementation considerations described in this section include the following:

- Overarching concepts of consolidation
 - Education about consolidation process
 - Methods of updating records
 - System IDs
 - <u>IIS resources and staff time</u>
- Data quality
 - Provider profiles
 - Data validation process
- HL7 immunization messaging
 - Vaccination action code concepts
 - Administered/historical indicator
 - Formatting of patient address

Overarching concepts for consolidation

The concepts in this section are overarching for the consolidating records process and it is important to understand them before implementing this process.

Education about consolidation process

Provider education is essential for the IIS process of creating and leveraging consolidated records. IIS should communicate with providers about the value of consolidating records for clinical and public health purposes. Likewise, the IIS will need to be well prepared to educate providers about how the consolidating records process impacts data in the IIS and what providers can do to support this process.

While addressing the technical aspects of consolidating records, it is recommended that the IIS staff collaborate with communication, education, and training staff to create a communication and training plan to implement these guidelines. Messages (e.g., in an IIS newsletter or

announcement) for providers and EHR staff should describe the following high-level key points and offer guidance on where to find and access more detailed information:

- The difference between the role of the IIS and the role of an EHR: Provider organizations are responsible for maintaining the patient's clinical record. An EHR should ensure that data are accurately recorded and can be accurately messaged to the IIS. An IIS should take advantage of its role as the repository of records from many data sources to create the most robust and comprehensive record possible via consolidation.
- A summary of the IIS functions that will be based on data from consolidated records: This summary should offer context to the provider about how the IIS is functioning and increase trust in the tools and data. The consolidated record should be used in all IIS functions, including clinical decision support, query response, reminder/recall, VFC activities, and coverage assessment reports, and for viewing via direct UI (PO2).

During the rollout of the consolidating records process, providers may also be interested in the business rules that guide consolidating records. This could be described in more depth in an appendix of the user guide or supporting documents. Alternatively, providers could be directed to contact IIS staff by phone or e-mail for specific questions about the logic behind the consolidating records process.

IIS staff should be prepared to answer questions about whether an IIS can change or share data submitted by a provider. The AIRA Confidentiality and Privacy Considerations for IIS document [2.6] offers a useful summary of different IIS confidentiality/privacy issues and may be helpful in addressing questions about federal, state, and local requirements. Likewise, IIS staff should be aware of any local laws, regulations, or policies that relate to the process of consolidating records.

IIS staff should also work with communication, education, and training staff to create specific user guidance, FAQs, training, or other tools that can support providers in working with consolidated records. These can include best practices for submitting data to ensure that high-quality data are included in the consolidated record. They may also address more specific topics such as how providers should import old data or how to contact the IIS to report incorrect data in a consolidated record. This guidance may also be an opportunity to encourage providers to incorporate data that were cleaned or corrected in the IIS into their EHR (either through consumption of the response message or a manual change via the UI of the EHR).

Methods of updating records

An IIS can receive incoming records from a provider organization via two submission methods (direct UI and EDE). This section discusses the implications of these two submission methods.

First, data may be entered via the direct UI, meaning that an approved user of the IIS logs directly into the IIS. When users make an update, they should review all information on either the demographic screen or the vaccination event screen, respectively, before saving the information. During that process, the IIS may perform system data validation for each field, requiring the user to then ensure that all of the data at that time conforms to the requirements set by that IIS. It is important to recognize that not all IIS have the option for users to enter data via the UI if they already submit data through EDE; some may offer "view-only" access while requiring electronic submissions.

Electronic HL7 data submissions, the second method of receiving records from a provider organization, can be received in either of two ways. The first is through a common VXU submission message. VXU messages should conform to the *HL7 Implementation Guide for Immunization Messaging* [2.4; 2.5], referred to as the "National HL7 IG" in the remainder of this document. The VXU message may contain demographic and vaccination event information and is the most common format accepted by IIS. The second method is the ADT message,

which provides only demographic information. Not all IIS allow this type of message to be sent, and some accept an ADT message only for a patient that already exists in the IIS. Although it is not in scope for this guide to recommend what type of messages an IIS should accept, it should be noted that ADT messages may contain demographic information for a patient (e.g., address) that was updated in the provider EHR system without a vaccination event attached. The updated demographic information may be more current than the information contained in the IIS. IIS that do not accept ADT messages may be missing this information.

When comparing how data in the IIS are updated through direct UI versus electronic HL7 submissions, it is assumed that the individual submitting information through a direct UI has reviewed all of the information in the demographic or vaccination event record before saving the information. In contrast, an electronic HL7 submission is rarely reviewed by an individual prior to submission to the IIS. The process for triggering HL7 messages to the IIS is not always known by the provider organization (or the IIS). Some EHR systems have a process that automatically submits information to the IIS after a user has left a screen. In this case, the EHR user might not have even reviewed the information in the record, let alone confirmed its accuracy. Other EHR systems have an actual button that is used to send data to the IIS. Therefore, it is recommended that EHR and IIS systems submit (or save) demographic and vaccination event information only after the user has had the opportunity to review, confirm, and update the information.

Updates to records are accomplished differently depending on the method used. For example, a UI user might be able to change the date of a vaccination event without having to delete the complete vaccination event and reenter it. In an EDE, the provider organization may be required to submit two different HL7 messages to accomplish the same outcome.

While the method of submission does impact aspects of how records are created and updated, it is important to emphasize that the principles and business rules in this quide apply to all methods of data submission (P13).

System IDs

Four types of IDs referenced in this guide benefit from further clarification about how they are assigned and used. These IDs are:

- IIS assigned IDs
 - IIS patient ID—for a demographic record
 - IIS vaccination event ID—for a vaccination event record
- Submitting data source assigned IDs
 - Alternate patient ID—for a demographic record
 - Alternate vaccination event ID—for a vaccination event record

The more commonly known of the IDs are the IIS patient ID and alternate patient ID. The IIS patient ID is assigned by the IIS and is unique for each demographic record in the IIS. It is used in many different functional areas of the IIS beyond consolidating records. Each patient's demographic record within the IIS is associated with a unique single IIS patient ID. It is recommended (BR204) that IIS should retain all past (i.e., previously assigned) IIS patient IDs when existing demographic records are consolidated.

Each demographic record within the IIS can subsequently have multiple associated alternate patient IDs—one alternate patient ID per immunization provider. Alternate patient IDs are assigned by submitting data sources, such as provider organizations, vital statistics, and health insurance companies. In addition to being associated with an assigning authority, an alternate patient ID will also generally have an ID type (e.g., Social Security ID, medical record, birth certificate number, Medicaid, or insurance number, etc.). Typically, an IIS will first become aware of a given alternate patient ID as part of vaccine event submitted to the IIS via direct UI or through EDE. Once stored within the IIS, the alternate patient IDs can then be used by immunization providers for matching incoming IIS records to their EHR records. In addition, an alternate patient ID should be included as part of an electronic query for information (an HL7 QBP message) and may be critical in identifying a single high-threshold-matching patient.

Less commonly discussed are the IIS vaccination event ID and the alternate vaccination event ID. Although every IIS has some mechanism for assigning an ID to each vaccination event, in many implementations it has not

been displayed or exported outside of the IIS database, and, therefore, it might be less familiar. However, the same approach should be applied as for the IIS patient IDs described above. An IIS vaccination event ID is assigned by the IIS and is unique to each vaccination event in the IIS.

The alternate vaccination event ID is assigned by a data source system such as an EHR, and it uniquely identifies the vaccination event within the EHR system. Like the alternate patient ID, the alternate vaccination event ID is transmitted to the IIS via EDE in the ORC-3 field of the HL7 message. It is not certain how many IIS currently retain these alternate vaccination event IDs, but a business case can be made that utilization of these alternate IDs in the EDE between IIS and EHRs would lead to improvements in data quality and matching of the vaccination event records. If IIS were to retain these IDs, then they could be incorporated into a matching algorithm at the vaccination event record level when updates are made to a vaccination event record or when the submitting system indicates that the vaccination event record should be deleted. Likewise, the alternate vaccination event IDs can play a critical role in vaccination event reconciliation in the EHR when they are returned to external partners via EDE as part of a query response message.

The example in this section demonstrates how an IIS could implement the return of alternate vaccination event IDs to assist entities who exchange data with the IIS [2.7]. The basic premise of this example is that the system that is querying the IIS would benefit from having its own alternate vaccination event ID returned as part of the vaccination event data. Having its own vaccination event ID returned will allow the querying system to efficiently match the incoming data to a record in its own system. This is particularly important when the IIS has consolidated records and the data being returned may be more complete than the data in the guerying system for the same vaccination event. This example assumes that, when an alternate vaccination event ID is not available for the guerying system, the IIS vaccination event ID is the best ID to return in the query response. When reviewing the example, keep in mind that alternate vaccination event IDs are typically received only when the vaccination event was submitted electronically, so not all events will have such an ID.

Vaccination Event Record Data in the IIS:

Immunization	Date	IIS vaccination event ID	Alternate vaccination event ID from Provider A	Alternate vaccination event ID from Provider B
НерВ	01/01/2010	123	456	789
DTaP	03/01/2010	124	457	No ID on File
Polio	03/01/2010	125	No ID on File	No ID on File

When Provider A queries for this patient, the IIS should return the alternate vaccination event ID from Provider A when it is available, as it is for HepB and DTaP. Because no alternate vaccination event ID exists for Polio, the IIS vaccination event ID is returned.

Immunization	Date	ORC-3 (vaccination event ID)
НерВ	01/01/2010	456^PROVIDER_A vaccination event ID
DTaP	03/01/2010	457^PROVIDER_A vaccination event ID
Polio	03/01/2010	125^IIS vaccination event ID

When Provider B queries for this patient, the IIS should return the alternate vaccination event ID from Provider B when it available, as it is for HepB. Because an alternate provider ID does not exist for Provider B for DTaP and Polio, the IIS vaccination event ID is returned, even though an alternate vaccination event ID is available from Provider A for DTaP.

Immunization	Date	ORC-3 (vaccination event ID)
НерВ	01/01/2010	789^PROVIDER_B vaccination event ID
DTaP	03/01/2010	124^IIS vaccination event ID
Polio	03/01/2010	125^IIS vaccination event ID

The IIS community could benefit from better understanding and using these four types of IDs. There is a need for IIS and EHRs to retain and share all IDs for the purpose of more efficient patient and vaccination event matching and consolidation practices.

IIS resources and staff time

To implement consolidating records successfully, an IIS will need access to funding and staff to support IIS functionality and data structure enhancements. Depending on the awardee, funding may come from federal grants (e.g., 317) or from the state/local area. The IIS will want to ensure there is funding to develop and enhance consolidating records functionality and to support the maintenance of long-term infrastructure. The IIS may have to enhance functionality to fully implement the consolidating records process. This will require the appropriate resources (i.e., funding and staff) to design, develop, and test the new functionality, as well as to implement a communication plan and training curriculum for internal staff and provider organizations. During the process of adding functionality or modifying

previous functionality for consolidating records, the IIS may need system enhancements to ensure that the new functionality works as designed. The IIS will need to ensure that adequate staff are available to put the consolidating records process in place, including time to design, develop, and test the consolidating records process. Staff also will be needed for communication with and education and training of providers, as well as for ongoing support and maintenance of the functionality. It is important that resources and staff time are budgeted not only for the initial development of consolidating records functionality but also for the ongoing maintenance to support and improve the consolidating records process as new business rules are identified.

Data Quality

Provider profile

This guide recommends that data source type (e.g., vital statistics, immunization provider organization) be used to determine confidence level for a record and that that should then be used to determine the best value for each data element to include in a consolidated record (PO8, Appendix D: Confidence Level Indicator). Since most IIS categorize providers by type, IIS should be able to implement this recommendation. However, an IIS may need to better standardize the definition and use of the "provider type" field.

This guide also encourages IIS to explore ways to implement a more specific version of this recommendation by ranking data quality at the provider organization level. Doing so would require creating a process for scoring a provider organization's data quality and storing that score within the provider profile. This would allow for a more specific input in determining confidence level for a record. Given the large number of provider organizations using an IIS, this would likely need to be an automated process so that it could be implemented, sustained, and regularly updated. The ability to regularly reevaluate and update the ranking is important because a provider organization's data quality is not constant and may change based on new staffing, system upgrades, and other changes. Currently, an IIS may use knowledge of a provider organization's data quality to support manual interventions but not in any automated process. Some IIS have created reports to score provider organizations on their data quality; however, this scoring does not seem to be recorded in the provider profile. Recognizing that implementing this process would be a significant undertaking, it would likely lead to more a precise determination of the confidence level for a record. More information about IIS data quality can be found in Data Quality Assurance in Immunization Information Systems: Incoming Data [1.7].

Data validation process

The IIS should validate incoming information, including HL7 format conformance testing and data validation checks, before the consolidating records process begins. Likewise, IIS are encouraged to perform regular data validation on existing data to support high data quality. The relationship between data quality/validation processes and the consolidating records process can be mutually symbiotic or counterproductive, depending on the rules that are set by the IIS.

Since the records in the consolidating records process have already undergone data quality/validation processes, there should be no truly invalid data in either record. As mentioned in the process model, the term "invalid value" for a data element in the consolidating records process means an irregular value that did not result in a rejection during the IIS validation process. Usually, invalid values that occur in the consolidating records process result from the requirement that a data element must have a value. Examples for invalid demographic data elements include a patient name of "Baby Boy" and a patient date of birth that is "01/01/1900."

The consolidating records process supports the selection and consolidation of the best possible values for a consolidated record, thus increasing data quality within the IIS. The new consolidated record should be subject to the same data validation rules as other records in the IIS. Data validation should be within each record and between each vaccination event record and associated demographic record (BR1001 and BR5801). As a best practice, an IIS should validate incoming data using the same rules as for existing data to prevent a cycle of overwriting validated data. An alternate good practice is to perform regular data validation on existing data. If the IIS has limited resources, incoming data may be subject to less stringent validation rules. When structured properly, data quality/validation processes and the consolidating records process work together to greatly improve the quality of data in the IIS.

It is equally important to ensure that data quality/ validation processes and the consolidating records process do not become counterproductive (P12). An IIS should ensure that its consolidating records process does not result in overwriting validated data. This can be accomplished by flagging/locking data that has been updated in a data quality/validation process (BR1002 and BR5802). For example, the IIS strips extraneous characters from a vaccine lot number through data validation and the data source submits the same "bad" information. As stated as a best practice in BR5101, the IIS should also keep an audit trail of all changes made to a data element. The IIS can then use the audit trail to know whether the record originally came from a record that was changed later by the IIS (for example, through data validation or address cleansing) or by a provider

through a UI. By properly identifying and tracking changes, the IIS can implement rules to prevent a counterproductive cycle of changes between the data quality/validation processes and the consolidating records process.

IIS need to consider how best to implement a flagging/locking data feature. Some IIS may choose to allow only IIS administrators to trigger the flag or lock. However, some IIS allow provider organization users to have access to the direct UI to clean their data. Often, this is the case if a provider organization's EHR cannot send "update" action codes in its HL7 messages or if the IIS does not accept them. In this case, it may be helpful to assign these specific users the ability to flag or lock cleansed data elements so that changes from their EHR do not counteract the data cleansing.

HL7 Immunization Messaging

This section discusses specific HL7 messaging issues that impact the consolidating records process.

Vaccination action code concepts

Per the National HL7 Implementation Guide [2.4; 2.5], there is a specific field in an HL7 VXU message (the field is not present in an ADT message) that allows the electronic submitter to indicate the desired action to be taken on individual vaccination events. This field is called the "action code" in HL7 (RXA-21), and the values that can be sent are add ("A"), update ("U"), or delete ("D"). If the action code "add" is sent, it notifies the receiving system that the vaccine should be added (i.e., it is the first time the vaccination is being submitted). The "update" action code indicates an update is needed to a previously submitted vaccination. Lastly, the "delete" action code indicates that the sending system would like the receiving system to delete the vaccination.

All IIS should have the capability to accept add and update action codes. However, standards for use of action codes are limited, and some EHRs cannot currently submit correct action codes. An IIS should apply additional validation rules before automatically assuming these codes are correct [2.4; 2.5]. An IIS should process every vaccination event through its deduplication process, which evaluates whether a vaccine with the same CVX code and same vaccination date already exists in the IIS. If a vaccination event is determined to be a match, then the two records should proceed through the consolidating

records process. For the purpose of this guide, the add code results in the creation of a new record and is, therefore, out of scope. The update code is in scope and is treated the same as a matched record without any code. The delete code is not a trigger for consolidation but may be used to trigger an unmerging of records; therefore, it is in scope. Figure 2-2 in Chapter 2: Scope Overview illustrates the scope visually.

In addition, all IIS should have the capability to accept delete codes. A provider may submit a delete code in several situations (for example, the vaccination event was not administered or was not completed and a vaccination event was incorrectly submitted to the IIS). When a provider submits a delete action code for a vaccination event that has not been consolidated, the action is simple—delete the vaccination event. The result should be the same for both the direct UI and incoming HL7 data submission. Alternatively, if a provider sends in a delete action code for an administered vaccination event that has been consolidated, then the IIS should investigate whether a vaccination event occurred. If a provider submits a delete action code for a historical vaccination, the IIS should unmerge the consolidated record and delete the provider's record but retain any records that were submitted by different providers. If more than one vaccination event record remains after records are unmerged, they should be reconsolidated. See scenario \$1108 for an example. In either case, no information is retained from the provider when it sends in a delete code.

Administered/historical indicator

As described in Chapter 4: Consolidating Records Process, sections of the vaccination event record consolidation process rely heavily on the use of the administered/historical indicator (see Phase 2 of the vaccination event record consolidation process). The indicator is automatically assigned in the direct UI based on how the user adds vaccination event information to the IIS. In an incoming HL7 message, the data are assigned by the sending system and submitted in the HL7 RXA-9 field [2.4; 2.5]. However, this field is required in HL7 only if the vaccination event is considered a complete or partial administered dose. It's important to note that a historical vaccination event is considered complete: therefore, all administered or historical vaccination events should have a value in the administered/historical indicator. However, the field is often empty, or the IIS may know that the value is incorrect. An IIS may have local rules that consider the value to be historical if the value is empty. As stated in BR5102, it is best practice for the submitter of a vaccination event record to indicate the value of the administered/historical indicator. However, as a good practice, an IIS should consistently determine the value of the administered/historical indicator based on local considerations. For legacy records, the IIS may need to assign the value of the administered/historical indicator.

The administered/historical indicator becomes problematic when the sending EHR system uses different definitions within the system for classifying administered versus historical vaccination events. For the purpose of an IIS, an administered value means that the authorized provider organization submits its own vaccination event [1.3]. This can include legacy immunizations that were given prior to onboarding with the IIS but still administered by the sending provider organization. A historical value means that the sending provider organization is submitting vaccination event information that was administered by another provider organization [1.3].

In addition, an IIS may have imported one-time data loads (e.g., flat file or batch loads as part of a standard practice for onboarding) for provider organizations, or the IIS may have even conducted a data migration of its own from one IIS to a new platform. Depending on how data were loaded/migrated (e.g., all historical), this may cause problems during the consolidating records process. When examining the consolidating records process steps that involve the administered/historical indicator field, it is important to recognize if this occurred.

Formatting of patient address

This document references the concept of patient address several times because it is key demographic information and benefits from consolidation. However, address information is complex because it can have six or more data elements (e.g., street, other designation such as PO Box, city, state, zip code, country, and county of residence) to make up just one address. In addition, different types of addresses can be submitted via an HL7 message for one patient (BR702). Some of the HL7 address types include the following:

- "C" for current or temporary
- "P" for permanent
- "M" for mailing
- "H" for home
- "N" for birth
- "F" for country of origin
- "L" for legal address
- "BDL" for birth delivery location
- "RH" for registry home

IIS should apply locally determined rules consistently to map these values into their IIS address database structure. Some IIS may limit the number of active addresses for any patient and may label them differently from HL7. For example, an IIS may have two addresses called "primary" and "secondary" or "physical" and "mailing." Each of the two addresses would contain the six data elements listed above (i.e., street, city, etc.).

Patient address can be received from various data sources and is, therefore, not a data group under this guide. However, when comparing data elements from different records, it is important that the IIS compare the same data elements of the same address type (BR401). Due to the differences in IIS address database structure, this guide cannot go beyond that recommendation, and IIS staff should keep this in mind when considering the principles, business rules, and scenarios that deal with address.

Conclusions

Consolidating information about the patient or vaccination event from different sources, as well as information from multiple reports by the same source, leads to a more accurate and complete reflection of reality in the IIS. Likewise, consolidation of records helps maintain data quality within the IIS and allows for accurate evaluation of population- and vaccination-based assessments of a specified area. Provider organizations rely heavily on these consolidated records for clinical decision support when providing services to their patients. Consolidation of records is a valuable process to ensure comprehensive and high-quality records in an IIS. This guide offers best practice recommendations to support IIS staff in implementing and sustaining the consolidating records process.

Selected References

MIROW recommendations documents for previous topics, abridged mini-guides, and other materials are available at the AIRA and CDC websites [3.1, 3.2, and 3.3]:

- 1.1) AIRA Modeling of Immunization Registry Operations Workgroup (eds). *Decrementing Inventory via Electronic Data Exchange*. Atlanta, GA: American Immunization Registry Association. May 2016. http://www.immregistries.org/resources/aira-mirow/AIRA_MIROW_Decrementing_Inventory_via_Electronic_Data_Exchange_Guide.pdf
- 1.2) AIRA Modeling of Immunization Registry Operations Workgroup (eds). *Management of Patient Active/Inactive Status in Immunization Information Systems: Replacement of 2005 Guidelines.* Atlanta, GA: American Immunization Registry Association. April 2015. https://www.immregistries.org/resources/FINAL_AIRA_PAIS_Guide_FullFormat.pdf
- 1.3) AIRA Modeling of Immunization Registry Operations Workgroup (eds). *Data Quality Assurance in Immunization Information Systems: Selected Aspects.* Atlanta, GA: American Immunization Registry Association. May 2013. http://www.immregistries.org/resources/AIRA-MIROW_DQA_Selected_Aspects_best_practice_guide_05-17-2013.pdf
- 1.4) AIRA Modeling of Immunization Registry Operations Workgroup (eds). *Immunization Information System Inventory Management Operations*. Atlanta, GA: American Immunization Registry Association. June 2012. http://www.immregistries.org/AIRA-MIROW-Inventory-Management-best-practice-guide-06-14-2012.pdf
- 1.5) AIRA Modeling of Immunization Registry Operations Workgroup (eds). *Immunization Information System Collaboration with Vaccines for Children Program and Grantee Immunization Programs.* Atlanta, GA: American Immunization Registry Association. April 2011.

 http://www.immregistries.org/AIRA-MIROW_IIS-VFC_Best_Practice_Guide_04-14-2011.pdf
- 1.6) AIRA Modeling of Immunization Registry Operations Workgroup (eds). *Reminder/Recall in Immunization Information Systems.* Atlanta, GA: American Immunization Registry Association. April 2009. http://www.immregistries.org/resources/AIRA-MIROW_RR_041009.pdf
- 1.7) AIRA Modeling of Immunization Registry Operations Workgroup (eds). *Data Quality Assurance in Immunization Information Systems: Incoming Data.* Atlanta, GA: American Immunization Registry Association. February 2008. http://www.immregistries.org/AIRA_MIROW_Chap3_DQA_02112008.pdf
- 1.8) AIRA Modeling of Immunization Registry Operations Workgroup (eds). *Vaccination Level Deduplication in Immunization Information Systems.* Atlanta, GA: American Immunization Registry Association. December 2006. http://www.immregistries.org/resources/AIRA-BP_guide_Vaccine_DeDup_120706.pdf
- 1.9) AIRA Vaccine Safety and Registry Community Workgroup (eds). *IIS-VAERS Collaboration for Vaccine Adverse Events Reporting. Functional and Process Recommendations.* Atlanta, GA: American Immunization Registry Association. April 2005. http://www.immregistries.org/resources/IIS-VAERS_Collaboration_-_VASREC_Workgroup_04-20-2005.pdf
- 1.10) AIRA Micro Guide. Lot Number Patterns by Manufacturer and Vaccine Table. Atlanta, GA: American Immunization Registry Association. Last updated May 2016. http://www.immregistries.org/resources/aira-mirow/AIRA_MIROW_Microguide-_2015_Lot_Number_Patterns.pdf
- 1.11) AIRA Micro Guide. Lot Number Validation Best Practices. Atlanta, GA: American Immunization Registry Association. Last updated June 2015. http://www.immregistries.org/resources/AIRA-MIROW_Lot_Numbers_Validation_Best_Practices_Micro-Guide_-Final-.pdf

General references

- 2.1) 2018–2022 Immunization Information System (IIS) Functional Standards. Available at the Centers for Disease Control and Prevention website: http://www.cdc.gov/vaccines/programs/iis/func-stds.html
- 2.2) MIROW Best Practices. Available at the American Immunization Registry Association website: http://www.immregistries.org/resources/aira-mirow
- 2.3) MIROW: Modeling of Immunization Registry Operations Workgroup. Available at the Centers for Disease Control and Prevention website: http://www.cdc.gov/vaccines/programs/iis/activities/mirow.html
- 2.4) HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 Addendum. Published July 2015. https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf
- 2.5) HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5. Published November 2014. https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf
- 2.6) AIRA Confidentiality and Privacy Considerations for IIS. Published October 2016. http://www.immregistries.org/AIRA_Confidentiality_and_Privacy.pdf
- 2.7) AIRA Frequently Asked Question Series Reviewed and Approved by AIRA and CDC Staff. Published December 2016. http://repository.immregistries.org/files/resources/59381df5b583e/hl7_faq_december_2016.pdf
- 2.8) AIRA Immunization Information Systems (IIS) Implementation Guidance for a Shared Address Cleansing and Geocoding Service. Published May 2017. http://repository.immregistries.org/files/resources/5942a1f3c8d86/address_cleansing_implementation_guidance.pdf
- 2.9) Immunization Information Systems NVAC Progress Report. Published February 2007. https://www.hhs.gov/sites/default/files/nvpo/nvac/reports/nvaciisreport20070911.pdf
- 2.10) PHII: Connections Unique Records Portfolio. Published in 2006. http://phii.org/sites/www.phii.org/files/resource/pdfs/UniqueRecordsPortfolio.pdf
- 2.11) Immunization Information Systems Patient-Level De-Duplication Best Practices. Published June 2013. https://www.cdc.gov/vaccines/programs/iis/interop-proj/downloads/de-duplication.pdf

Selected literature and presentation references

- 3.1) Williams W. Development of Best Practices for Immunization Information Systems. Presented at AIRA IIS Meeting; September 2012; Saint Paul, MN. http://www.immregistries.org/resources/iis-meetings/Final_-_MIROW_Plenary_ presentation_at_the_2012_AIRA_Meeting_09-18-2012.pdf
- 3.2) Williams W. Evaluating IIS Best Practice Operational Guidelines: Emerging Trends and Challenges. Presented at 44th National Immunization Conference; April 2010; Atlanta, GA. http://cdc.confex.com/cdc/nic2010/webprogram/Paper22530.html
- 3.3) Williams W, Lowery E, Lyalin D, Lambrecht N, Riddick S, Sutliff C, Papadouka V. Development and Utilization of Best Practice Operational Guidelines for Immunization Information Systems. *Journal of Public Health Management and Practice*. 2011; 17(5): 449-456.
- 3.4) Grant F. National Practice Assessment: Immunization Information System Patient De-duplication. Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Immunization Information Systems Support Branch; September 2012; Atlanta, GA.

 http://www.immregistries.org/resources/iis-meetings/Fred_Grant_AIRA_De-Duplication_Presentation.pdf
- 3.5) Hinman AR, Ross DA. Immunization Registries Can Be Building Blocks for National Health Information Systems. Health Affairs. 2010;29(4):676–682.
- 3.6) Lowery, E. MIROW Decrementing Inventory via Electronic Data Exchange. Presented on an AIRA Discovery Session; May 2016. http://repository.immregistries.org/files/resources/584f1c1f0281c/aira_discovery_session__may_2016_.pdf
- 3.7) Williams, W, Lowery, E, Lyalin, D, Harris, M, Altstadter, B, and Sathya, B. The "101" of MIROW: Workshop on New Guidance "Decrementing Inventory via Electronic Data Exchange." Presented at the 2015 AIRA National Meeting; April 2015; New Orleans, LA. http://repository.immregistries.org/files/resources/5835ade1a314b/track_a_the_'101'_of_mirow_.pdf

Abbreviations

Abbreviation	Full version	
AIRA	American Immunization Registry Association	
BR	business rule	
CDC	Centers for Disease Control and Prevention	
DOB	date of birth	
DR	demographic record	
DXC	DXC Technology Company	
EDE	electronic data exchange	
EHR	electronic health record	
HL7	HEALTH Health Level Seven International (global authority on standards for interoperability of health information technology)	
IIS	immunization information system	
IIS-AO	immunization information system authorized organization	
MIROW	Modeling of Immunization Registry Operations Workgroup	
PAIS	patient active inactive status	
PCP	primary care provider	
PO	post office	
SME	subject matter expert	
STC	Scientific Technologies Corporation	
UI	user interface	
VER	vaccination event record	

Appendix A: Terms and Definitions Defined via Domain Model

Purpose of a domain model

A domain model captures a business vocabulary (i.e., agreed upon terms and definitions). It ensures that all terminology and concepts that will appear in the process description, principles, and business rules are known and understood by the domain practitioners.

The purpose of employing a domain model is to:

- Document agreed upon terms and definitions for the project.
- Facilitate discussions of the terms and definitions among project participants and provide tools to capture outcomes of these discussions.
- Establish a foundation and a reference source (common vocabulary) for other project materials.

Domain model for the records consolidation functional area

The domain model for the IIS records consolidation functional area includes:

- Domain diagram that shows major business entities, concepts, and terms and their relationships and responsibilities (Figure A-1).
 - <u>Figure A-1</u> includes the following interconnected parts that describe areas of IIS operations relevant to this topic:
 - Vaccination event (blue color)
 - Demographic (green color)
 - Patient (yellow color)
 - Organizations/systems (brown color)
- Tables of terms and definitions (<u>Table A-1</u> and <u>Table A-2</u>) that provide the descriptive details of the business concepts and terms represented in the domain diagram
 - The numbering of the concepts and terms in the diagram (Figure A-1) corresponds to numbers in the tables of terms and definitions.
 - <u>Table A-1</u> presents terms and definitions in numerical order (as numbered in the diagram in <u>Figure A-1</u>).
 - <u>Table A-2</u> presents terms and definitions in alphabetical order.

- <u>Table A-3</u>, which contains definitions for additional terms for the consolidated records topic.
- <u>Table A-4</u>, <u>Table A-5</u>, and <u>Table A-6</u>, which list specific demographic and vaccination event data elements.
- Description of facts shown in the domain diagram (relating the IIS record consolidation story).

A domain diagram is a high-level static representation of the main entities/concepts involved in the immunization process, including a description of how these entities/concepts are related. A domain diagram differs from a data model diagram that depicts storage of information or a workflow/process diagram that depicts the sequence of steps in a process. A domain diagram is not a technical specification. Instead, a domain diagram provides the foundation (in the form of a common vocabulary) for other modeling diagrams and materials.

How to read and interpret the domain diagram

- Relationships between entities are visualized by connecting lines.
- Names associated with these lines describe the types of relationships between entities.
 - For example, the relationship between *Vaccination Event Record* and *Vaccination Event* is shown as a connecting line with the word "describes." The relationship should be read as "Vaccination Event Record describes Vaccination Event."
 - The arrowhead "←" placed before the word "describes," which points to the Vaccination Event, indicates the direction in which to read the diagram (i.e., from Vaccination Event Record to Vaccination Event).
 - To read the description in the opposite direction (i.e., from *Vaccination Event* to *Vaccination Event Record*), a different phrase (i.e., "described by") could be placed at the bottom of the line. The description would be "Vaccination Event is described by Vaccination Event Record."

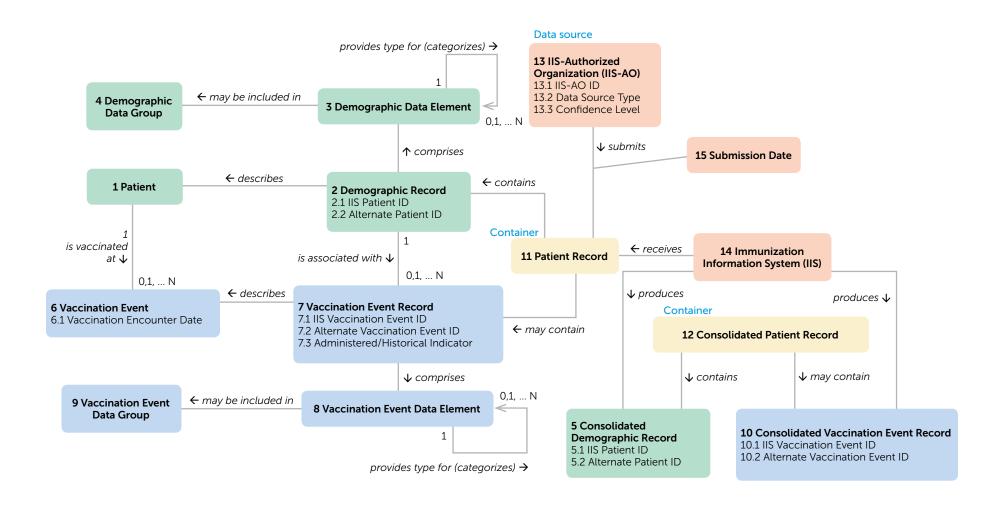


Figure A-1. Domain diagram for the consolidated record topic

Facts shown on the domain diagram

The following narrative describes facts shown on the diagram in <u>Figure A-1</u>, relating the IIS record consolidation story:

- A Patient is vaccinated at a Vaccination Event.
- One Patient may have zero, one, or more Vaccination Events.
- A Demographic Record describes a Patient.
- A Vaccination Event Record describes a Vaccination Event.
- One Demographic Record may be associated with zero, one, or more Vaccination Event Records.
- A Demographic Record consists of Demographic Data Elements.
- A Demographic Data Element may be included in a Demographic Data Group.
- A Demographic Data Element can provide a type for (categorize) other Demographic Data Elements.
 - For example, Demographic Data Element, patient telephone number type categorizes another Demographic Data Element, patient telephone number, within the data group patient telephone, in categories such as home telephone number, work telephone number, and mobile telephone number. See section Grouping of demographic and vaccination event data elements and Table A-4 in the appendix for a discussion.
- A Vaccination Event Record consists of Vaccination Event Data Elements.

- A Vaccination Event Data Element may be included in a Vaccination Event Data Group.
- A Patient Record (submitted from IIS-AO [e.g., provider organization] to IIS) contains a Demographic Record and may contain Vaccination Event Record(s).
- An IIS-AO is the Data Source for Patient Records.
- An IIS-AO submits Patient Record to the IIS.
- An IIS receives a Patient Record.
 - Note: An IIS receives a Patient Record from an IIS-AO (e.g., provider organization). The IIS deduplication process operates to determine whether the Patient Record received from the IIS-AO is classified by the IIS as a New Record, an Identical Record (which is not added to the IIS), or a Duplicate Record evaluated to determine if it is a match with a Record in the IIS. Matched Demographic/Vaccination Event Records are consolidated. See Figure 2-2 in Chapter 2: Scope Overview.
- An IIS produces a Consolidated Demographic Record.
- An IIS produces a Consolidated Vaccination Event Record.
- A Consolidated Patient Record contains a Consolidated Demographic Record.
- A Consolidated Patient Record may contain Consolidated Vaccination Event Record(s).

Tables of terms and definitions

Table A-1. Terms and definitions for consolidated records

The following table presents terms and definitions in numerical order (as numbered in the diagram in Figure A-1).

ID	Term	Definition	Remarks
1	Patient	An individual who is the actual or potential recipient of a vaccine dose administered.	■ Information about a Patient is reflected in a Demographic Record. All data elements listed in <u>Table A-4</u> are part of the Demographic Record. Data elements listed in <u>Table A-6</u> may be part of the Demographic Record.
2	Demographic Record	A group of related Demographic Data Elements that represent information about a Patient.	 Record is a group of related data elements treated as a unit. All data elements listed in <u>Table A-4</u> are part of the Demographic Record. Data elements listed in <u>Table A-6</u> may be part of the Demographic Record. When referencing Demographic Record in this document, it is implied it is coming to the IIS or resides in the IIS.
2.1	IIS Patient ID	Unique identifier assigned by IIS to each Patient.	■ See also item 5.1.
2.2	Alternate Patient ID	Unique identifier assigned by IIS-AO (Data Source) to each Patient.	 See also item 5.2. See <u>Table A-4</u>. Alternate Patient ID (data group) Patient ID Patient ID: Assigning Authority ID (i.e., owning Data Source) Patient ID: Type (e.g., medical record number, birth certificate number)
3	Demographic Data Element	A part of Demographic Record.	 Demographic Data Elements are listed in <u>Table A-4</u> and <u>Table A-6</u>. Examples of patient Demographic Data Elements include: IIS Patient ID (Unique identifier assigned by IIS to each Patient) Patient First Name Patient Last Name Patient Date of Birth Patient Gender See <u>Table A-4</u> for partitioning of Demographic Data Elements into Demographic Data Groups.
4	Demographic Data Group	A category of Demographic Data Elements that can be logically grouped together.	 Demographic Data Group combines several Demographic Data Elements. For example, Demographic Data Elements "Patient Telephone Number" and "Patient Telephone Number Type" are combined in the Demographic Data Group "Patient Telephone." Demographic Data Groups are listed in <u>Table A-4</u> and <u>Table A-6</u>.

ID	Term	Definition	Remarks
5	Consolidated Demographic Record	A Consolidated Demographic Record contains consolidated demographic information for a Patient.	 A Consolidated Demographic Record contains best available information (for every Demographic Data Element) from all demographic records. All data elements listed in <u>Table A-4</u> are part of the Consolidated Demographic Record. Data elements listed in <u>Table A-6</u> may be part of the Consolidated Demographic Record.
5.1	IIS Patient ID	Unique identifier assigned by IIS to each Patient.	■ See also item 2.1.
5.2	Alternate Patient ID	Unique identifier assigned by IIS-AO (Data Source) to each Patient.	 See also item 2.2. See <u>Table A-4</u>. Alternate Patient ID (data group): Patient ID Patient ID: Assigning Authority ID (i.e., owning Data Source) Patient ID: Type (e.g., medical record number, birth certificate number)
6	Vaccination Event	A medical occurrence of administering one vaccine to a Patient.	■ Information about Vaccination Event is reflected in a Vaccination Event Record. All data elements listed in <u>Table A-5</u> are part of the Vaccination Event Record. Data elements listed in <u>Table A-6</u> may be part of the Vaccination Event Record.
6.1	Vaccination Encounter Date	Date when Vaccination Event (vaccination encounter/office visit) occurred.	 Alias name: Vaccination Administration Date (see <u>Table A-5</u>) Vaccination encounter represents one Patient office visit during which Vaccination Events occurred. During the vaccination encounter (office visit), several Vaccination Events can be performed. In some cases, no Vaccination Events take place at a Vaccination Encounter (e.g., a Patient refuses vaccinations).
7	Vaccination Event Record	A group of related Vaccination Event Data Elements that represent information about a Vaccination Event.	 Record is a group of related Data Elements treated as a unit. All Data Elements listed in <u>Table A-5</u> are part of the Vaccination Event Record. Data elements listed in <u>Table A-6</u> may be part of the Vaccination Event Record. When referencing Vaccination Event Record in this document, it is implied it is coming to the IIS or resides in the IIS.
7.1	IIS Vaccination Event ID	Unique identifier assigned by IIS to each Vaccination Event.	See also item 10.1.
7.2	Alternate Vaccination Event ID	Unique identifier assigned by IIS-AO (Data Source) to each Vaccination Event.	 See also item 10.2. See <u>Table A-5</u>. Alternate Vaccination Event ID (data group) Vaccination Event ID Vaccination Event ID: Assigning Authority ID (i.e., owning Data Source)

ID	Term	Definition	Remarks
7.3	Administered/ Historical Indicator	Administered/Historical Indicator describes an association between a Vaccination Event and the provider organization that originally initiates a submission for this Vaccination Event. Values for the indicator are Administered or Historical. Administered value means that the provider organization recorded and/or submitted its own Vaccination Event (i.e., attests that it conducted the Vaccination Event). Historical value means that the provider organization submitted a Vaccination Event conducted by a different provider organization (i.e., states that it did not conduct the Vaccination Event).	 Alias name: Vaccination Event Information Source (i.e., administered or historical) (see <u>Table A-5</u>) See a detailed discussion of the Administered/Historical Indicator in the "Discussion and notes" section in <i>MIROW 2013 Data Quality Assurance Guidelines</i> [1.3], and in <u>Chapter 3: Fundamentals</u>. Administered/Historical Indicator provides key information for the consolidation of Vaccination Event Records (<u>BR5001</u>, <u>BR5102</u>).
8	Vaccination Event Data Element	A part of Vaccination Event Record.	 Vaccination Event Data Elements are listed in Table A-5 and Table A-6. Examples of Vaccination Event Data Elements include: Vaccine Product Type Administered Vaccine Manufacturer Name Vaccine Lot Number (alias name Lot Number, as per previous MIROW guides) Vaccine Expiration Date (alias name Expiration Date, as per previous MIROW guides) Vaccine Dose Volume Vaccine Unit Vaccine Site of Administration Vaccine Route of Administration Vaccination Administration Date, also known as Vaccination Encounter Date [MIROW 2013 Data Quality Assurance Guidelines [1.3], Vaccination Encounter Date, page 44] Vaccination Event Information Source, also known as Administered or historical [MIROW 2013 Data Quality Assurance Guidelines [1.3], Administered/Historical Indicator, pages 26–27]
9	Vaccination Event Data Group	A category of Vaccination Event Data Elements that can be logically grouped together.	 Vaccination Event Data Group combines several Vaccination Event Data Elements. Vaccination Event Data Groups are listed in <u>Table A-5</u> and <u>Table A-6</u>.

ID	Term	Definition	Remarks
10	Consolidated Vaccination Event Record	An IIS Consolidated Vaccination Event Record contains consolidated immunization information about a single Vaccination Event.	 A Consolidated Vaccination Event Record contains best available information (for every Vaccination Event Data Element) from all Vaccination Event Records. All Data Elements listed in <u>Table A-5</u> part of the Consolidated Vaccination Event Record. Data elements listed in <u>Table A-6</u> may be part of the Vaccination Event Record.
10.1	IIS Vaccination Event ID	Unique identifier assigned by IIS to each Vaccination Event.	See also item 7.1.
10.2	Alternate Vaccination Event ID	Unique identifier assigned by IIS-AO (Data Source) to each Vaccination Event.	 See also item 7.2. See <u>Table A-5</u>. Alternate Vaccination Event ID (data group) Vaccination Event ID Vaccination Event ID: Assigning Authority ID (i.e., owning Data Source)
11	Patient Record	A combination of a Demographic Record for an individual Patient and Vaccination Event Records for that Patient.	■ Each Patient Record contains one Demographic Record and zero, one, or more Vaccination Event Records.
12	Consolidated Patient Record	A combination of a Consolidated Demographic Record for an individual Patient and zero or more consolidated Vaccination Event Records for that Patient.	 A Consolidated Patient Record is a container for a Consolidated Demographic Record and zero or more Consolidated Vaccination Event Records. A Consolidated Patient Record (for an individual Patient): Contains a Consolidated Demographic Record for a Patient. May contain a Consolidated Vaccination Event Record(s) for that Patient.
13	IIS-Authorized Organization (IIS-AO)	IIS-Authorized Organization (IIS-AO) is any organization that has an agreement with the IIS that allows submittal and/or retrieval of the IIS data.	 This term was introduced in the MIROW 2013 Data Quality Assurance Guidelines [1.3]. The role of IIS-AO in consolidating records is to indicate the Data Source. Data Sources may include vital statistics, birthing hospitals, immunization provider, billing, claims (Medicaid), schools, and health plans.
13.1	IIS-AO ID	Identifier assigned by IIS to the IIS-Authorized Organization.	 Alias names: Data Source ID Assigning Authority ID (i.e., owning Data Source)
13.2	Data Source Type	Category of Data Source as determined by the IIS.	■ Vital statistics, immunization provider organization, etc.
13.3	Confidence Level	Level of confidence in data quality with respect to an IIS-AO (Data Source).	■ See Appendix D: Confidence level indicator.

ID	Term	Definition	Remarks
14	Immunization Information Systems (IIS)	Immunization information systems (IIS) are confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area.	 An IIS performs functions such as: Consolidating Demographic and Vaccination Event Records for persons with multiple health care providers. Supporting clinical decision making. Generating reminder/recall notices. Producing official vaccination records. Providing practice- and population-based vaccination coverage assessments.
15	Submission Date	Date when the Demographic or Vaccination Event Record was received by the IIS.	 Submission to the IIS contains relevant information that is known to an IIS-AO regarding a Patient and his/her Vaccination Events per MIROW 2013 Data Quality Assurance Guidelines [1.3], item 11.1, page 44. Used to capture the Original Submission Date and Most Recent Submission Date (see Table A-4 and Table A-5).

Table A-2. Terms and definitions for consolidated records (sorted alphabetically)

The following table presents terms and definitions in alphabetical order (see the diagram in Figure A-1).

ID	Term
<u>7.3</u>	Administered/ Historical Indicator
<u>2.2</u> , <u>5.2</u>	Alternate Patient ID
<u>7.2</u> , <u>10.2</u>	Alternate Vaccination Event ID
<u>13.3</u>	Confidence Level
<u>5</u>	Consolidated Demographic Record
<u>12</u>	Consolidated Patient Record
<u>10</u>	Consolidated Vaccination Event Record
<u>13.2</u>	Data Source Type
<u>3</u>	Demographic Data Element
<u>4</u>	Demographic Data Group
2	Demographic Record
<u>2.1</u> , <u>5.1</u>	IIS Patient ID
<u>7.1</u> , <u>10.1</u>	IIS Vaccination Event ID
<u>13.1</u>	IIS-AO ID
<u>13</u>	IIS-Authorized Organization (IIS-AO)
<u>14</u>	Immunization Information Systems (IIS)
<u>1</u>	Patient
<u>11</u>	Patient Record
<u>15</u>	Submission Date
<u>6.1</u>	Vaccination Encounter Date
<u>6</u>	Vaccination Event
<u>8</u>	Vaccination Event Data Element
9	Vaccination Event Data Group
7	Vaccination Event Record

Table A-3. Additional terms for the consolidated records topic

Term	Definition
Base Record	Base record is a record to be updated with information from another record during the consolidating records process.
Best (originally submitted) Record	The (one) originally submitted record (in a set of duplicate records) that is deemed to be the best representation of the Patient or Vaccination Event (e.g., accuracy, completeness).
Consolidated Record	See items <u>5</u> , <u>10</u> , <u>12</u> in <u>Table A-1</u> .
Existing Record	Record that is stored within the IIS.
Identical Records	Duplicate records that have exactly the same data values for each corresponding data element (e.g., the exact same record was submitted twice). Must be from the same data source to be identical.
Incoming Record	Record that is received by the IIS from an IIS-AO via an electronic message or the direct user interface.
Matched Records	Records that are identified to be duplicate records (same patient or same vaccination event).
New Record	An incoming record that has not been previously received by the IIS.

Grouping of demographic and vaccination event data elements

Some Demographic and Vaccination Event Data Elements can be logically grouped together. Data elements within a group are treated together as one Demographic Data Group where the value for each Data Element must come from the same Data Source. An example of such a data group is Patient Telephone, which includes Demographic Data Elements: Patient Telephone Number and Patient Telephone Number Type. For example, the values for Patient Telephone Number = "404-123-4567" and Patient Telephone Number Type = "Cell" must come to the IIS from the same Data Source. An example of a Vaccination Event Data Group is Vaccine Dose Volume and Unit, which includes Vaccination Event Data Elements: Vaccine Dose Volume and Vaccine Unit.

The terms "Demographic Data Element" and "Vaccination Event Data Element" in this guide (e.g., in principles and business rules, Chapter 5: Principles and Business Rules) point to both stand-alone Data Elements and data groups. Data groups and stand-alone Data Elements for a Demographic Record are listed in Table A-4 and for a Vaccination Event Record in Table A-5, and other Data Elements are listed in Table A-6.

The following example illustrates why Demographic Data Elements associated with Patient Name should not be treated as a data group.

- Data source A reports Patient Name as Patient First Name = "J.," Patient Middle Name = "Michael," Patient Last Name = "Smith."
- Data source B reports Patient Name as Patient First Name = "John," Patient Middle Name = "<none>," Patient Last Name = "Smith."
- Since Patient Name is not a data group, the IIS consolidated Patient Name can combine best values from all sources: Patient First Name = "John" (from data source B), Patient Middle Name = "Michael" (from data source A), Patient Last Name = "Smith" (from data source A), i.e., "John Michael Smith."
- If Patient Name were treated as a data group, consolidated Patient Name would be "J. Michael Smith" (from data source A) or "John Smith" (from data source B), depending on specific business rules for selecting the "best" data element for each of the data elements.

In addition to listing data groups and stand-alone Data Elements, <u>Table A-4</u> indicates which Demographic Data Groups and stand-alone Data Elements may have multiple values. Note that some of the data groups may have multiple values, and others can have only one single value. For example, a Demographic Record may have multiple Alternate Patient IDs but only one Patient Multiple Birth.

Certain Demographic Data Elements provide type for (categorize) other Demographic Data Elements. For example:

- Demographic Data Element, Patient Telephone Number Type, categorizes another Demographic Data Element, Patient Telephone Number, within the data group Patient Telephone. Examples of categories of telephone number are: home telephone number, work telephone number, and mobile telephone number.
- Demographic Data Element, Patient ID Type, categorizes other Demographic Data Elements, Patient ID and Patient Assigning Authority ID, within the data group Alternate Patient ID.
- Demographic Data Element, E-mail Type, categorizes another data element, Patient E-mail.

In some cases, a concept of "type" can be applied to some sets of Demographic Data Elements that do not constitute a data group (e.g., Patient Address contains six data elements: street, city, state, country, zip code, and county of residence). For example, for consolidation purposes, compare a street address with a street address, but do not compare a street address with a PO Box. Categorization of data elements/groups into types is determined by local implementation. Examples of types of Patient Address are: physical (e.g., street), mailing (e.g., PO Box or street), primary (home), and secondary. See BR401 and 2.8.

Note that the list of data elements presented in <u>Table A-4</u>, <u>Table A-5</u>, and <u>Table A-6</u> is not exhaustive but, rather, represents a subset of the most common data elements identified by the expert panel. These data elements represent specific examples of Demographic Data Elements and Vaccination Event Data Elements and are based on core data elements developed as a part of the IIS Functional Standards (2013–2017). Names of some of these data elements are alias names for the terms used in the domain model in Table A-1.

Table A-4. Grouping of demographic data elements

Data Grouping	Data Group Level	Repeating? (i.e., can have multiple values)
Original Submission Data ■ Original Submission Date ■ Data Source ID for Original Submission	Yes	No
Most Recent Submission Data ■ Most Recent Submission Date ■ Data Source ID for Most Recent Submission	Yes	No
 Alternate Patient ID Patient ID Patient ID: Assigning Authority ID (i.e., owning Data Source) Patient ID: Type (e.g., medical record number, birth certificate number) 	Yes	Yes
Patient Name ■ Patient Name: First ■ Patient Name: Middle ■ Patient Name: Last	No	No
Patient Alias Name ■ Patient Alias Name: First ■ Patient Alias Name: Middle ■ Patient Alias Name: Last	No	Yes
Patient Multiple Birth ■ Patient Multiple Birth Indicator ■ Patient Birth Order	Yes	No
Responsible Person Name Responsible Person Name: First Responsible Person Name: Middle Responsible Person Name: Last Responsible Person Name: Relationship to Patient	Yes	Yes
Mother's Name Mother's Name: First Mother's Name: Middle Mother's Name: Last Mother's Name: Maiden last	No	Yes
Patient Address Patient Address: Street Patient Address: City Patient Address: State Patient Address: Country Patient Address: ZIP Code Patient Address: County of Residence	No	Yes
Patient Telephone ■ Patient Telephone Number ■ Patient Telephone Number Type (e.g., home, cell)	Yes	Yes
Patient Status ■ Patient status indicator—Provider Facility Level ■ Provider Facility (IIS-AO)	Yes	Yes

Data Grouping	Data Group Level	Repeating? (i.e., can have multiple values)	
Data elements not associated with a data group			
IIS Patient ID	No	No	
Patient Date of Birth	No	No	
Patient Gender	No	No	
Patient E-mail Address	No	Yes	
Race	No	Yes	
Ethnicity	No	No	
Birthing Facility Name	No	No	
Patient Birth State	No	No	
Patient Primary Language	No	No	
Patient Status Indicator—IIS level	No	No	

Table A-5. Grouping of vaccination event data elements

Data Grouping	Data Group Level	Repeating? (i.e., can have multiple values)
Original Submission Data ■ Original Submission Date ■ Data Source ID for Original Submission	Yes	No
Most Recent Submission Data ■ Most Recent Submission Date ■ Data Source ID for Most Recent Submission	Yes	No
Alternate Vaccination Event ID Vaccination Event ID Vaccination Event ID: Assigning Authority ID (i.e., owning Data Source)	Yes	Yes
Vaccine Dose Volume and Unit ■ Vaccine Dose Volume ■ Vaccine Unit	Yes	No
Data elements not associated with a data group		
IIS Vaccination Event ID	No	No
Vaccination Event Information Source (i.e., administered or historical)	No	No
Vaccine Product Type Administered (CVX-NDC-CPT)	No	No
Vaccination Administration Date	No	No
Vaccine Manufacturer Name (MVX)	No	No
Vaccine Lot Number	No	No
Vaccine Expiration Date	No	No
Vaccine Site of Administration	No	No
Vaccine Route of Administration	No	No
Vaccine Ordering Provider Name	No	No
Vaccine Administering Provider Name	No	No
VFC/Grantee Program Vaccine Eligibility at Dose Level	No	No
Vaccine Funding Source	No	No

111

The following table includes items that can either be included with Demographic Record Data Elements or Vaccination Event Record Data Elements. A consensus was not reached within the workgroup on how these data elements should be associated (Demographic Record versus Vaccination Event Record). Instead of listing them in <u>Table A-4</u> and <u>Table A-5</u>, it was decided it was best to leave them separate so that each IIS can determine how it will associate the data elements with records. The important piece is that the group felt that these data elements still needed to follow the recommendation set forth in this guide as it pertains to consolidating records.

Table A-6. Grouping of additional data elements

Data Grouping	Data Group Level	Repeating? (i.e., can have multiple values)
Contraindication(s)/Precaution(s) ■ Contraindication(s)/Precaution(s) ■ Contraindication(s)/Precaution(s) Observation Date(s)	Yes	Yes
Exemption(s) ■ Exemption(s)/Parent Refusal(s) of Vaccine ■ Date of Exemption/Parent Refusal of Vaccine	Yes	Yes
History of Vaccine-Preventable Disease ■ History of Vaccine-Preventable Disease (e.g., Varicella) ■ Date of History of Vaccine-Preventable Disease	Yes	Yes
Vaccine Adverse Reaction(s) ■ Adverse Reaction(s) ■ Date of Adverse Reaction Observation	Yes	Yes

Appendix B: About MIROW

AIRA, in partnership with NCIRD at CDC, formed MIROW in 2005 to develop best practice guidance for various aspects of IIS. Since 2005, MIROW has developed the following operational guidelines for IIS functional areas (see <u>Table B-1</u>):

- Decrementing Inventory via Electronic Data Exchange (DI-v-EDE)
- Management of Patient Active/Inactive Status in IIS
- Data Quality Assurance—Selected Aspects
- Inventory Management
- Patient Eligibility for the VFC Program and Grantee Immunization Programs
- Reminder/Recall
- Incoming Data Quality Assurance—Incoming Data
- Vaccination Level Deduplication
 - Note: The consolidating records guide acts as a replacement for Chapter 5: Resolution Phase and Appendix B of this guide.
- IIS-Vaccine Adverse Event Reporting System Collaboration (pilot project)

MIROW recommendation documents, abridged miniguides, and other materials are available at the AIRA and CDC websites [2.2, 2.3]. Specific presentations that describe MIROW's efforts are also available [3.1, 3.2, and 3.3].

The approach used and results presented are relevant to and can be used beyond IIS (e.g., for developing and documenting best practices and operational requirements for domain-specific applications in public health, health care, and other areas).

Table B-1. MIROW: Topics/workshops overview

Ref	Title	Guideline document released	Face-to-face meeting	Subject Matter Expert panel size	Guideline document highlights
	Consolidating Demographic Records and Vaccination Event Records	In Progress	August 2016 2.5 days Decatur, GA	12*	13 principles69 business rules3 activity diagrams20 operational scenarios
1.1	Decrementing Inventory via Electronic Data Exchange (current topic)	May 2016	July 2015 2.5 days Decatur, GA	12*	9 principles26 business rules3 decision tables27 operational scenarios
1.2	Management of Patient Active/ Inactive Status in IIS (replaced the 2005 MOGE guide)	April 2015	June 2014 3.5 days Decatur, GA	13	14 principles13 business rules4 decision tables22 operational scenarios
1.3	Data Quality Assurance in IIS: Selected Aspects	May 2013	August 2012 3.5 days Decatur, GA	13	2 principles27 business rules7 general recommendations27 updated business rules
1.4	IIS Inventory Management Operations	June 2012	September 2011 3.5 days Atlanta, GA	14	8 principles25 business rules23 general recommendations20 key reports
1.5	IIS-VFC/Grantee Programs Collaboration	April 2011	June 2010 2.5 days Atlanta, GA	14	26 eligibility screening scenarios17 business rules9 general recommendations
1.6	Reminder/Recall in IIS	April 2009	October 2008 2.5 days Tampa, FL	13	29 principles23 business rules30 general recommendations
1.7	Data Quality Assurance in IIS: Incoming Data	February 2008	August 2007 2.5 days Atlanta, GA	11	13 principles32 business rules
1.8	Vaccination Level Deduplication in IIS	December 2006	May 2006 2.5 days Washington, DC	20	9 principles20 business rules23 illustrative scenarios (examples)
1.2	Management of Patient Active/ Inactive Status in IIS guide— Replacement of 2005 Guidelines	December 2005	August 2005 2.5 days Atlanta, GA	16	6 statuses defined on the Provider level5 statuses on the Geographic Jurisdiction level
1.9	IIS-VAERS Guide (pilot project)	April 2005	June 2004 1.5 days Atlanta, GA	21	10 functional standards8 business rules11 alternative scenarios (process)

^{*} Panel included three paid public health consultants. Refer to the <u>Development approach</u> section in <u>Chapter 1:</u> <u>Introduction</u> for more information.

Appendix C: 2016 MIROW Consolidating Records Workshop Participant List

MIROW hosted a 90-minute workshop at the 2016 AIRA National Meeting to gather input from a larger spectrum of subject matter experts across the IIS community regarding the topic of consolidating records. The main objective was to gather inputs for the expert panel's preparatory work in the form of "Pains" (challenges, issues, and barriers) and "Solutions" to those pains surrounding consolidating records. The workshop participants are listed in the following table. They include IIS staff members, software vendor staff members, and public health consultants.

Table C-1. Workshop participant list

Name	Organization	Email
Annette Aguon	Guam Immunization Program	annette.aguon@dphss.guam.gov
Bridget Ahrens	Vermont Department of Health	bridget.ahrens@vermont.gov
Teneale Chapton	CDC/Nevada WeblZ	tchapton@health.nv.gov
Meghan Collett	Strategic Solutions Group	mcollett@ssg-llc.com
Josh Davis	Strategic Solutions Group	jdavis@ssg-llc.com
Sasha DeLeon	Washington State Department of Health	sasha.deleon@doh.wa.gov
Melissa Fankhauser	Tennessee Department of Health	melissa.fankhauser@tn.gov
Chris Freedman	Battelle	freedmanc@battelle.org
Nicole Freeto	Washington State Department of Health	nicole.freeto@doh.wa.gov
Christy Gray	Virginia Department of Health	christy.gray@vdh.virginia.gov
Holly Groom	Kaiser Permanente NW	holly.c.groom@kpchr.org
Christine Hamilton	Pennsylvania Department of Health	chrhamilto@pa.gov
John Harwood	MCIR	jrharw@kalcounty.com
Andrew Luker	Arkansas Department of Health	andrew.luker@arkansas.gov
Jeanne McCoy	MCIR	jmccoy@phdm.org
Beth Meadows	North Carolina Department of Health and Human Services – Immunization Branch	beth.meadows@dhhs.nc.gov
Sara Morgan	Nebraska Department of Health and Human Services	sara.morgan@nebraska.gov
Steve Murchie	Envision Technology	smurchie@envisiontechnology.com
Miriam Muscoplat	Minnesota Department of Health	miriam.muscoplat@state.mn.us
Vikki Papadouka	New York City IIS	vpapadou@health.nyc.gov
Tiffany Pothapragada	Student at Kansas University Medical Center	tpothapragada@kumc.edu
Loren Rodgers	CDC/IISSB	lrodgers@cdc.gov
Veronica Rodriguez	Puerto Rico Health Department	vrodriguez@salud.gov.pr
Hari Siva	Alabama Department of Public Health	hari.siva@adph.state.al.us
Kim Spencer	CDC/IISSB	xlp8@cdc.gov
Jason Suchon	MetaStar	jsuchon@metastar.com
Patricia Swartz	Maryland Department of Health	patricia.swartz@maryland.gov
Amanda Timmons	Oregon Immunization Program	amanda.j.timmons@state.or.us
Deb Warren	AMCI	debjwarren52@gmail.com

Appendix D: Confidence Level Indicator

Confidence level indicator for information in a demographic record

The confidence level indicator aggregates factors that impact selection of the best value for a demographic data element from multiple data sources; it reflects the level of confidence or trust regarding quality of data. These factors include:

- How a record containing the data element/data group is submitted to an IIS (submission method).
- What type of information the record containing the data element/data group represents (submission type).
- Who submitted the record containing the data element/data group (data source type).
- When the record containing the data element/data group is submitted (recency).
- Any specific knowledge of the data source submitting the record containing the data element/data group.

Materials presented in this section do not constitute a precise and exhaustive best practice prescription but, rather, illustrate a general approach that an IIS can reference when considering application of confidence level considerations in its consolidating records process.

The cause-and-effect diagram in Figure D-1 illustrates key factors that impact confidence level in data submitted to IIS. A cause-and-effect diagram (also known as a "fishbone diagram" or an "Ishikawa diagram") illustrates various factors causing an overall effect. A cause-and-effect diagram does not quantify or rank the impact of various factors; therefore, the order and positioning of factors on the diagram should not be interpreted to imply ranking.

The following factors shown in <u>Figure D-1</u> can impact the confidence level:

- Data source type (who sends the record)
- Submission method (how the record is sent)
- Submission type (what type of record)
- Recency
- Specific knowledge of data source

<u>Table D-1</u> provides cross-references for the first three factors (i.e., who can send the record, how the record is sent, and what type of record). Information in <u>Figure D-1</u> and in <u>Table D-1</u> supports calculation of a confidence level indicator for various combinations of factors:

Decision <u>Table D-2</u> provides a simplified example to determine the confidence level indicator for demographic records.

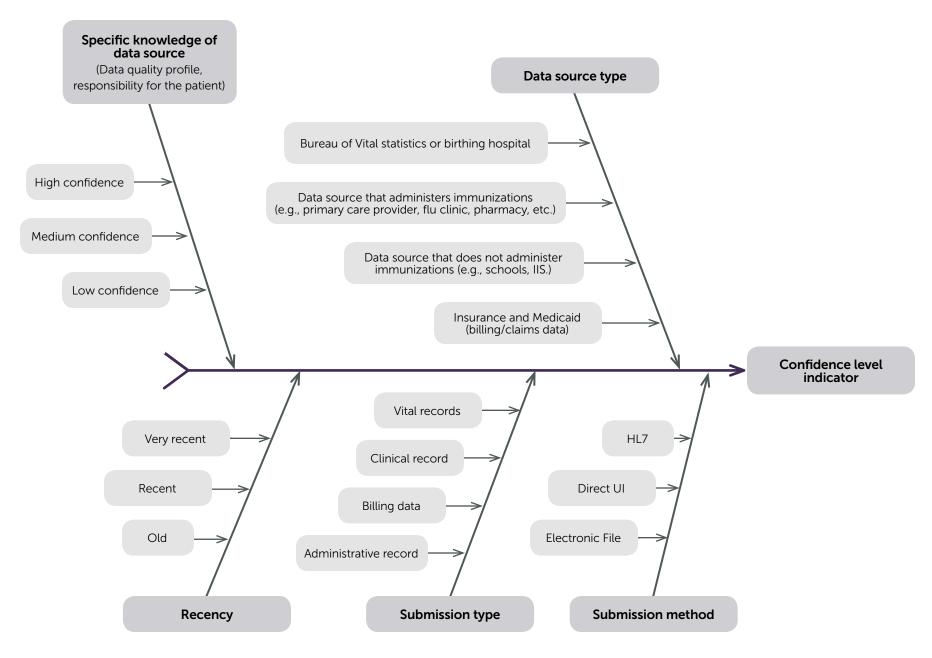


Figure D-1. Cause-and-effect diagram—confidence level indicator

Table D-1. Data source type (who) can send what information (submission type) and how (submission method)

Data Source Type (Who)	Submission Type (What)	Submission Method (How)
■ Vital statistics or birthing hospital (as a source of vital statistics information in some states)*	■ Vital statistics	■ Electronic file
■ Data source that administers immunizations (e.g., primary care provider, flu clinic, pharmacy, etc.)	 Clinical record Billing data[†] 	HL7 messageDirect UIElectronic file
■ Data source that does not administer immunizations (e.g., school, IIS)	■ Administrative Record [†]	Direct UIElectronic fileHL7 message
■ Insurance, Medicaid (submitting billing/claims data)	■ Billing data	■ Electronic file

^{*} In some states, IIS receive vital statistics information from birthing hospitals.

Assumptions:

- Submission Type (What): In general, for demographic records:
 - Vital statistics are more trustworthy than clinical records for a set of data elements (BR601).
 - Vital statistics are a definitive source of data for a set of data elements (e.g., patient date of birth and patient date of death). <u>BR601</u>
 - Vital statistics are not a definitive source of data for all data elements (e.g., address-related data elements).
 - Clinical records are more trustworthy than billing data.
 - Billing data are more trustworthy than administrative records.
- Submission Method (How): In general, for demographic records:
 - HL7 message is more trustworthy than direct UI.
 - Direct UI is more trustworthy than electronic file.
- Data Source Type (Who): In general, for demographic records:
 - Data source that administers immunizations (e.g., primary care provider, flu clinic, pharmacy) is more trustworthy than data source that does not administer immunizations (e.g., school, IIS).
 - Data source that does not administer immunizations (e.g., school, IIS) is more trustworthy than insurance/ Medicaid (submitting billing/claims data).

An IIS can use its specific knowledge to implement locally defined considerations as follows:

- Reflect a higher level of confidence in information from certain providers. For example, a provider with ongoing clinical responsibility for a patient versus a flu clinic (an example of specific knowledge of data source).
- Take advantage of a provider profile or other local knowledge. For example, issues at a particular provider EHR result in systematic miscoding of information.
- Use completeness and specificity at the record level based on locally defined key data elements:
 - A record with more populated key data elements should have a higher level of confidence compared with another record with fewer populated key data elements.
 - A record that contains more specific information for key data elements should have a higher confidence level compared with another record that contains less specific information for key data elements.
- Consider data uniqueness for a particular jurisdiction (e.g., Jo versus Nishani).

[†] Some immunization providers historically submitted billing data to an IIS instead of clinical records (for example, providers that did not have an EHR but had a billing system). Submission of billing data by provider that has an EHR is not a recommended best practice. However, billing data that are contained in existing records in the IIS should be accounted for in consolidating records.

[‡] Administrative record: submitted from a data source that does not administer immunizations (i.e., secondary information).

Table D-2. Decision table: simplified example of determining the confidence level indicator for demographic records

		CONDITIONS			OUTCOME		
		Submission Type	Submission Method	Data Source Type	Ranking:	Ranking:	Intermediate calculations
S Ce	1	С	EF	А	Med	3	3.6
den	2	В	EF	А	Low	4	1.8
Confidence Scenarios	3	С	UI	А	High	1	7.6
Ω _w	4	В	UI	А	Med	2	3.8

Notes:

- Submission Type (What): Clinical record (C), Billing data (B)
- Submission Method (How): Direct UI (UI), Electronic file (EF)
- Data Source Type (Who): Data source that administers immunizations (e.g., primary care provider, flu clinic, pharmacy, etc.) (A)
- Ranking: High Med Low (1 through 4, 1 is highest ranking)
- Intermediate calculations assigned hypothetical weights: C = 2, B = 1, UI = 1.9, EF = 0.9, A = 2.
 - Calculations example for Confidence Scenario 1: C
 x EF x A = 2 x 0.9 x 2 = 3.6

- Limitations (simplifications):
 - Submission Type (What) Clinical records and billing data only
 - Submission Method (How) Electronic files and direct UI only
 - Data Source Type (Who) Data source that administers immunizations (e.g., primary care provider, flu clinic, pharmacy, etc.) (A) only
 - Local considerations (specific knowledge of data source) are not accounted for in this decision table
 - Recency considerations are not accounted for in this decision table

Confidence level indicator for information in a vaccination event record

Most of the considerations for demographic records discussed in the previous section are applicable for vaccination event records as well. However, these confidence level considerations are applicable only to comparison of historical records (see process diagram, Figure 4-5).



http://www.immregistries.org