
Defining Functional Requirements for Immunization Information Systems

September 2012

Acknowledgments

The following Immunization Information System (IIS) experts participated in this project:

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** Participated in both the IIS Requirements and Onboarding workgroups

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The Institute welcomes comments on this document and related issues. Please send all correspondence via email or phone using the contact information listed at the Public Health Informatics Institute web site (www.phii.org).

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Table of Contents

Introduction.....	1
What Is In This Document.....	1
How to Use This Document	2
Business Process Tools and Terms.....	2
Business Processes for Immunization Information Systems	4
Immunization Information Systems Framework.....	5
Create Newborn Record.....	6
Vital Record Amendments	10
Facility/Organization Registration.....	13
Administer Vaccine/Determine Vaccine Funding Source (Sub-process of Administer Vaccine).....	17
Query, Add, and/or Update Patient Record.....	24
Patient De-Duplication	29
Vaccine De-Duplication	33
Manage Inventory	37
Public Purchase Vaccine Ordering.....	42
Manage Forecasting Rules	46
“Read Only” Data Exchange	49
Data Exchange Response/Output.....	53
User Report Generation	57
Patient Reminder/Recall	60
EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange.....	65
Provider Approval/Reapproval for Bidirectional IIS Data Exchange.....	72
Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	84
Appendix A - The Collaborative Requirements Development Methodology	90
Appendix B - Functional Standard – Business Process Crosswalk for IIS	91
Appendix C - Provider Registration Data Elements	99
Appendix D - EHR-HIE-IIS Data Exchange Business Process.....	100
Appendix E - Example Business Process Matrix, Task Flow Diagram, and Requirements Document	109

Appendix F - Request for Proposal 113

Appendix G - General System Assessment 115

Appendix H - Vendor Assessment 117

Appendix I - Glossary 120

Appendix J - Explanation of Terminology 124

Introduction

This document contains the products of three workgroup sessions to collaboratively and rigorously define a full range of important IIS functions, referred to here as business processes. This detailed documentation for seventeen such business processes is intended to establish best practice for how an IIS should function in an increasingly e-health world. The IIS experts who participated in this effort represent local, state and federal level health agencies (see the preceding Acknowledgments page).

This documentation can be used by your IIS program to:

- Examine and challenge your current workflows and “ways of doing business.”
- Identify enhancements for your IIS application to make it more functionally robust.
- Decide if it is time to migrate to a new system.
- Develop a Request for Proposal to procure a new system.

What Is In This Document

For each business process addressed by the expert workgroup, three interrelated work products were created, each a useful tool for your program:

- **Business Process Matrix:** A table that outlines the components that describe a business process. Like a Logic Model, it captures elements like the goal, desired outcomes, inputs, outputs, and other factors that comprise a process.
- **Task Flow:** A graphical model that illustrates the activities of a business process and the entity that performs the activities. The task flow provides a “story” for the diagrammed process.
- **System Requirements:** Statements that describe the functionality needed for an information system to support the business process. Requirements answer the question: “How would you see information systems supporting activity X?”

In addition, this document includes a number of helpful appendices:

- Appendix A: A summary of the Collaborative Requirements Development Methodology used by the Institute for this and other requirements gathering projects.
- Appendix B: A listing of the IIS functional standards mapped to the relevant business processes detailed in this project.
- Appendix C: Recommended data elements to collect when enrolling a new provider site or organization.
- Appendix D: EHR-HIE-IIS Data Exchange business process matrix and task flow. This business process demonstrates what immunization data exchange might look like using a Health Information Exchange (HIE)/Health Information Organization (HIO) as an intermediary; a model in which the HIE/HIO does not transform the message but simply passes it through.
- Appendix E: Example Business Process Matrix, Task Flow Diagram, and Requirements Document.
- Appendix F: Recommendations for preparing a Request for Proposal (RFP) and a RFP table of contents template.
- Appendix G: General System Assessment (attachment to the RFP).
- Appendix H: Vendor Assessment (attachment to the RFP).
- Appendix I: A glossary of key IIS terms used in this document.
- Appendix J: Explanation of terminology used in this document.

How to Use This Document

You and your team may use the work products described above in several ways:

- Review the Business Process Matrices to identify areas where your current activities and system functions may not be as comprehensive as best practices require.
- Utilize a blank Business Process Matrix template to create a new business process or programmatic function, supporting comprehensive and thoughtful initial planning.
- Review the task flow diagrams for guidance to make your own workflows more efficient or effective, and use them to create Standard Operating Procedures to ensure consistency across your program.
- Compare the functionality of your current IIS against the list of system requirements to identify possible enhancements for new or improved functionality.
- Evaluate whether it is more cost-effective to migrate to a new system or to enhance an existing system by using the system requirements.
- Compare the features of available systems using the system requirements as a benchmark.
- Utilize the system requirements to help craft a Request for Proposal for an information system.

You are invited to adopt and modify the information in this document as needed to address specific or unique requirements. For example, you may want to remove business processes and/or requirements that do not address a specific need or refine and customize the templates presented in this document to better serve your particular needs.

Please note these requirements describe what is needed from an information system to support a business process; we do not attempt to identify existing software or systems that might meet those needs in this document. Whether you develop a custom software solution or purchase a commercial, off-the-shelf (COTS) product is a determination only you can make based on your own programmatic and organizational needs.

Business Process Tools and Terms

Appendix E contains an example of each business process tool with explanatory text.

Business Process Matrix

The **business process matrix** is a table that outlines the components that describe the process (objective, business rules, trigger, inputs, outputs, and outcome). The business process matrix is designed to be used as a quick reference for groups who are analyzing business processes. It is useful as a reference when developing graphical models, such as the task flow diagrams, to focus everyone on the same objectives.

Components of a business process matrix

Process Name: The title given to a business process

Objective: A concrete statement describing what the business process is trying to achieve

Business Rule: A set of criteria that defines or constrains some aspect of the business process

Trigger: An event, action or state that initiates the first course of action in a business process

Task Set: The key activities that are carried out in a business process

Input: Information or tangible items needed for the business process

Output: Information or tangible items produced by the business process

Outcome: The resulting output that indicates the objective has been met

Task Flow Diagram

The **task flow diagram** is a graphical model that illustrates the activities of a business process, as well as who performs those activities. The task flows provide a “story” for the process being diagrammed.

Components of a task flow diagram

Pool: A group, department, organization or unit that contains multiple functional swim lanes

Swim Lanes: A functional individual or group; these are entities that perform or are accountable for designated activities in the process.

Start Event: A process-mapping shape used to define the “start” of the process

Activity: An action performed by the functional individual or group

Decision: A decision needed to move the process forward; these are typically approvals or resolutions

Sub-Process: A process-mapping shape used as a call out to another process

End Event: A process-mapping shape used to define the “end” of the process

Activity Details / Narrative: The supporting information for each process

Requirements

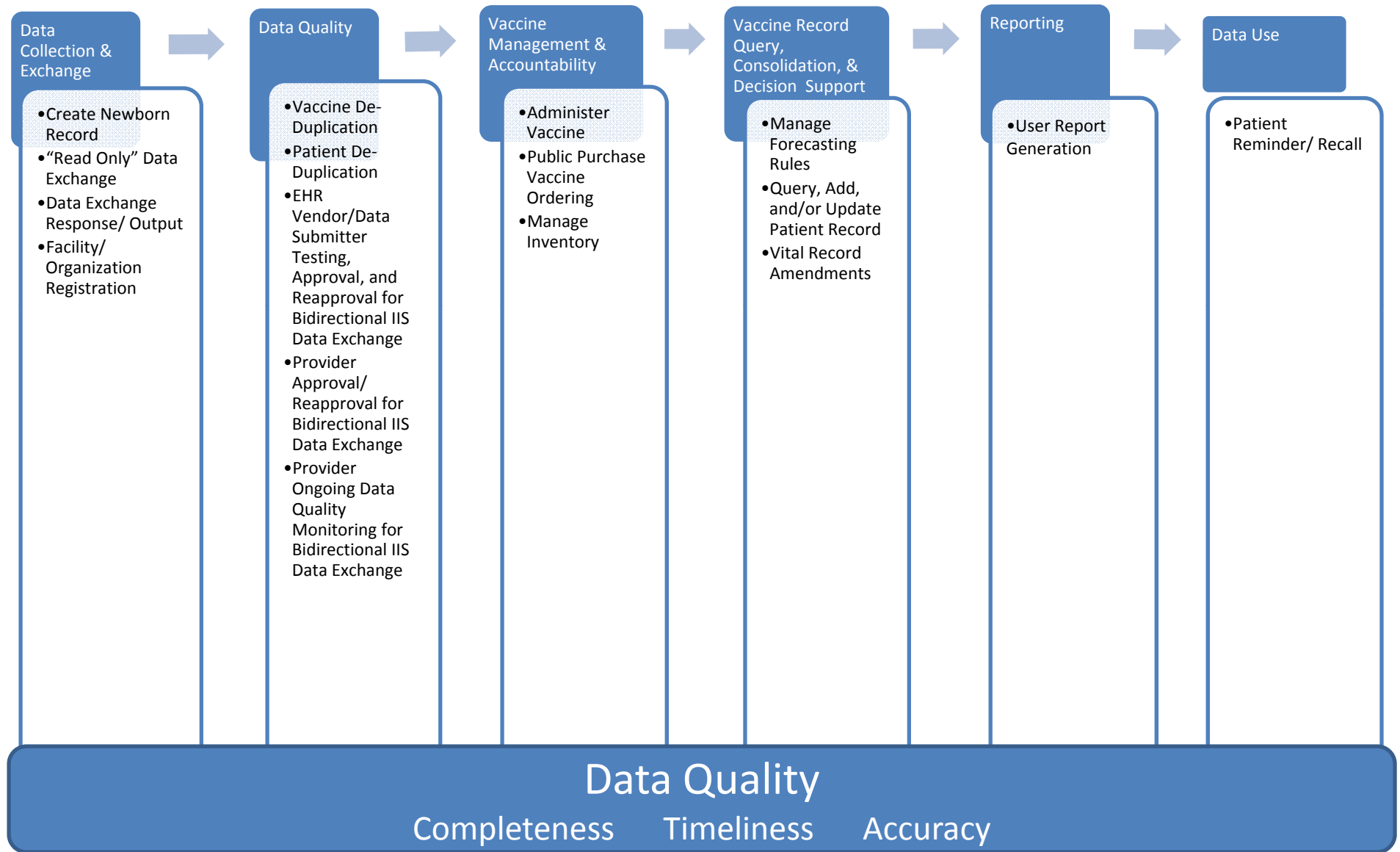
Requirements are the statements that describe the functionality needed for an information system to support the business process. Requirements answer the question: “How would you see information systems supporting activity X?” The requirements associated with each business process are not intended to suggest any physical implementation strategy for an information system.

Business Processes for Immunization Information Systems

This section contains the work products developed by the workgroup. First, an overall framework for the IIS business processes is provided. Then, each individual business process is defined with a business process matrix, a task flow diagram, and a requirements document. The business processes included in this document are as follows:

- Create Newborn Record
- Vital Record Amendments
- Facility/Organization Registration
- Administer Vaccine
- Determine Vaccine Funding Source (Sub-process of Administer Vaccine)
- Query, Add, and/or Update Patient Record
- Patient De-Duplication
- Vaccine De-Duplication
- Manage Inventory
- Public Purchase Vaccine Ordering
- Manage Forecasting Rules
- “Read Only” Data Exchange
- Data Exchange Response/Output
- User Report Generation
- Patient Reminder/Recall
- EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange
- Provider Approval/Reapproval for Bidirectional IIS Data Exchange
- Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange

Immunization Information System Framework



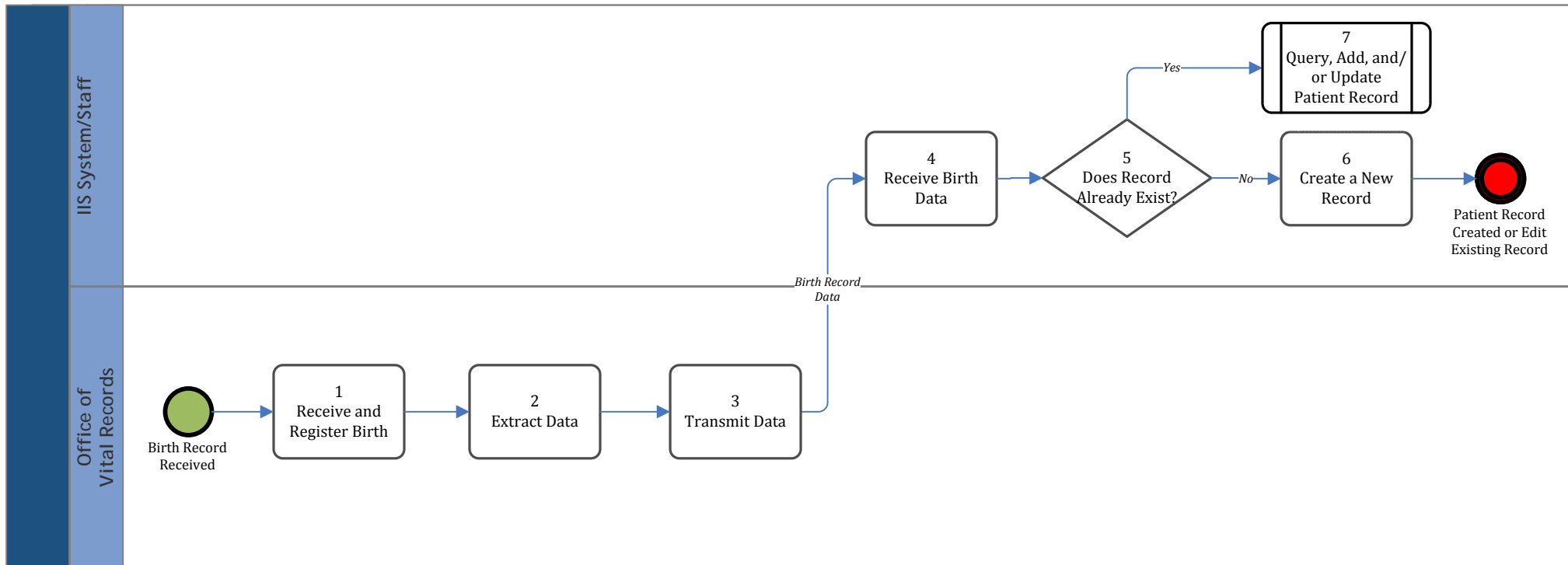
IIS Collaborative Requirements Development Project

Business Process Matrix

Create Newborn Record

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> To create an initial record in the IIS system following the birth of a newborn 	<ul style="list-style-type: none"> Office of Vital Records protocol State/jurisdictional rules and regulations Birth facility protocol IIS protocol 	<ul style="list-style-type: none"> A baby is born 	<ol style="list-style-type: none"> Receive and Register Birth Extract Data Transmit Data Receive Birth Data Does Record Already Exist? Create a New Record Query, Add, and/or Update Patient Record 	<ul style="list-style-type: none"> Newborn birth record 1st dose of vaccines (i.e. hepatitis B) HBV/HBIG Core data elements Newborn screening results Newborn hearing results (EHDI) 	<ul style="list-style-type: none"> Newborn birth is registered in the Office of Vital Records Newborn electronic birth record is added to the IIS system 1st doses of vaccinations recorded 	<ul style="list-style-type: none"> Percentage of newborn electronic birth records are created/updated in the IIS system within two weeks of birth Percentage of newborn records in IIS with Hep B or HBIG Percentage of newborn records created in the IIS from vital records, birthing hospital, or other source Percentage of newborn records created in the IIS by source within specified timeframe Percentage of newborn records created in the IIS

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
						<p>that were recorded in vital records, i.e.: # newborn records created in IIS divided by # newborn records recorded in vital records</p>



Activity Details / Narrative

General Process Notes

Objective:

- To create an initial record in the IIS system following the birth of a newborn

Measurable Outcomes:

- Percentage of newborn electronic birth records are created/updated in the IIS system within two weeks of birth
- Percentage of newborn records in IIS with Hep B or HBIG
- Percentage of newborn records created in the IIS from vital records, birthing hospital, or other source
- Percentage of newborn records created in the IIS by source within specified timeframe
- Percentage of newborn records created in the IIS that were recorded in vital records, i.e.: # newborn records created in IIS divided by # newborn records recorded in vital records

General Notes:

- Births can be registered directly with the Vital Record Office or via an Electronic Birth Registry System (EBRS) and transmitted to the Office of Vital Records
- The State and Territorial Exchange of Vital Events (STEVE) system is a messaging system used by some vital records offices to facilitate electronic exchange of vital event data between jurisdictions and systems
- Immunization providers may include Physicians, Nurses, Pharmacists, Nurse Practitioners, Physician's Assistants, DoD Paraprofessionals, Medical Students, etc.

Activity Description:

1. Receive and Register Birth

- The Vital Records Office receives the new birth record and registers the birth within 5 days of receipt

2. Extract Data; 3. Transmit Data

- Vital records information including child name, gender, date of birth, mother's full name (including maiden), mother's race/ethnicity, birth certificate number, and address are extracted from the vital record data repository on a scheduled basis and transmitted to the IIS

4. Receive Birth Data

- The Office of Vital Records extracts the newborn data and sends it to the IIS

5. Does Record Already Exist?

- The IIS compares the birth data against the records in their system to determine if it is a new record or a match/update to an existing record or a duplicate
- If an existing record is located, then a new record is not created

6. Create a New Record

- The IIS staff initializes a new record for the baby with a unique identification number, the baby's name, date of birth, mother's maiden name, address, parents' names and addresses, birth state, birthing facility, and birth registration number

7. Query, Add, and/or Update Patient Record

- Predefined process

Functional Requirements for IIS Collaborative Requirements Development Project

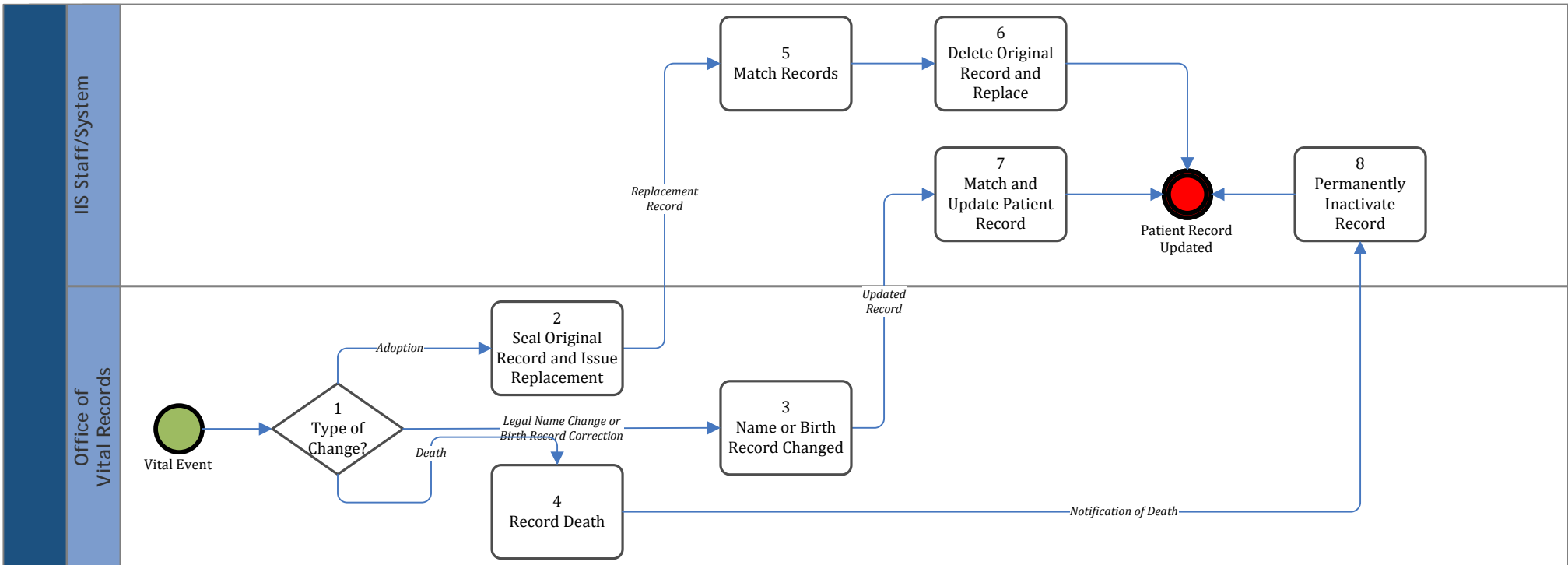
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Create Newborn Record	Receive Birth Data	Ability to receive "real-time" records from vital records birth certificates	Flat file, HL7, etc.
2	Create Newborn Record	Receive Birth Data	Have ability to accept files from vital records in multiple formats	Flat file, HL7, etc.
3	Create Newborn Record	Does Record Already Exist?	Have ability to detect if a newborn record is a new record, a match/update to an existing record, or a duplicate	
4	Create Newborn Record	Does Record Already Exist?	Have ability to display possible duplicate records	As allowed by local policy
5	Create Newborn Record	Create a New Record	Allow system administrator to create a new patient record	See appendix for recommended data elements
6	Create Newborn Record	Create a New Record	Have ability to prevent a record from being saved unless required data elements are completed	Ex. First name, last name, DOB, gender
7	Create Newborn Record	Create a New Record	Have ability to prompt user to confirm creation of a new patient record after possible matches are found	The End User is presented possible matches and determines if they are not the person they are searching for
8	Create Newborn Record	Create a New Record	Have ability to flag new patient records where possible matches are found	
9	Create Newborn Record	Create a New Record	Have ability to generate a unique patient ID	
10	Create Newborn Record	Create a New Record	Have the ability to create error file reports	
11	Create Newborn Record	Create a New Record	Have ability to automatically identify new patient records as possible duplicates	
12	Create Newborn Record	Create a New Record	Have the ability to create a possible duplicate report	
13	Create Newborn Record	Query, Add, and/or Update Patient Record	SEE QUERY, ADD, AND/OR UPDATE PATIENT RECORD REQUIREMENTS	

IIS Collaborative Requirements Development Project

Business Process Matrix

Vital Record Amendments

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To determine the type of record change required • To update or replace record • To delete or seal record 	<ul style="list-style-type: none"> • Security protocol • IIS protocol • Other state and local rules and regulations • Vital registration laws 	<ul style="list-style-type: none"> • Patient death • Adoption • Name change • Record correction 	<ol style="list-style-type: none"> 1. Type of Change? 2. Seal Original Record and Issue Replacement 3. Name or Birth Record Changed 4. Record Death 5. Match Records 6. Delete Original Record and Replace 7. Match and Update Patient Record 8. Permanently Inactivate Record 	<ul style="list-style-type: none"> • Death record • Birth record • Adoption record • Name/ demographic change record 	<ul style="list-style-type: none"> • Updated patient record • Delete/seal patient record 	<ul style="list-style-type: none"> • Number of patient records updated or replaced within a certain timeframe • Number of patient records deleted/sealed within a certain timeframe



General Process Notes

Objective:

- To determine the type of record change required
- To update or replace record
- To delete or seal record

Measurable Outcomes:

- Number of patient records updated or replaced within a certain timeframe
- Number of patient records deleted/sealed within a certain timeframe

General Notes:

- The IIS must maintain an accurate registry of patient information. This means that changes in vital records transmitted to the IIS must be recorded timely and accurately
- Other events may require changes in IIS records but only updates to the original birth record are addressed in this process
- Typically, the changes described here require system administrator privileges to minimize the number of authorized users

Activity Description:

1. Type of Change?

- Changes in the original birth record or notification of a death require modification of the data stored in the vital records system & transmission of the updates to affected parties

2. Seal Original Record and Issue Replacement

- Upon legal adoption, the baby's original birth record is sealed in the vital record system and a replacement record is issued showing the adoptive name and adoptive parents' information as indicated in the court order
- Key data from the replacement record is transmitted to the IIS

3. Name or Birth Record Changed

- Addition of a birth name is typically permitted at a fee. Other changes (e.g. name change due to marriage) are treated as amendments requiring a court order

3. Name or Birth Record Changed, cont.

- The updated birth record is transmitted to the IIS

4. Record Death

- Upon receipt of notification of death, the vital records office registers the death, matches the birth certificate and death certificate, and marks the birth certificate "deceased"
- Once the IIS receives the updated birth certificate information indicating the death of the patient, the record is then updated

5. Match Records

- The IIS matches the replacement record with the original record using the state file number, a unique identifier that remains unchanged
- If an original record is not found, the replacement record from vital record information is forwarded to Query, Add, and/or Update Patient Record

6. Delete Original Record and Replace

- The original record is deleted, or in some states, changed to "permanently inactive" & is replaced with data from the adoptive record and deidentified historical vaccine information

7. Match and Update Patient Record

- The corrected record from the vital records system is matched to the existing record in the IIS using patient identifiers (ID, date of birth, etc.)
- Once the record is matched, the data is corrected to match the vital record data
- Inability to match the record may result in a duplicate record being created in the IIS

8. Permanently Inactivate Record

- The IIS receives notification of death from the vital records office and updates the patient's immunization record status to "permanently inactive"
- While the record will still be viewable depending on the jurisdiction, no further notifications or forecasts will be generated for this patient

Activity Details / Narrative

Functional Requirements for IIS Collaborative Requirements Development Project

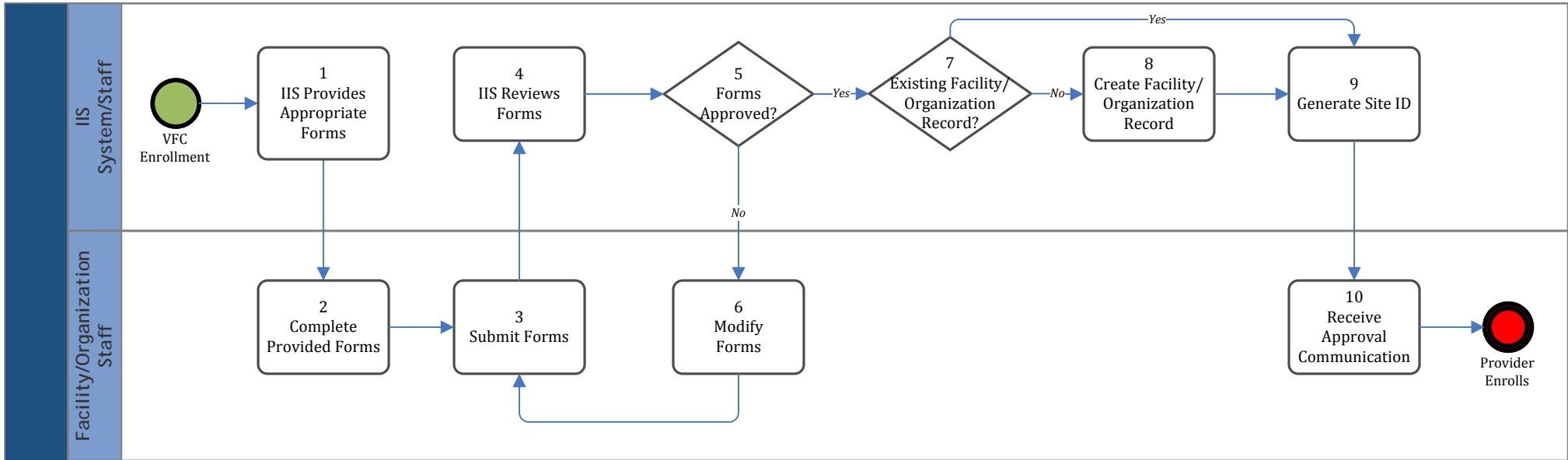
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Vital Record Amendments	Match Records	Have ability to prevent duplicate records from being created	Match IIS record with incoming vital record data using birth record number or other demographic information
2	Vital Record Amendments	Delete Original Record and Replace	Have ability to delete a record	Necessary to protect privacy in adoption cases
3	Vital Record Amendments	Delete Original Record and Replace	Have ability to create a new record	Necessary to protect privacy in adoption cases
4	Vital Record Amendments	Delete Original Record and Replace	Have ability to copy selected data elements from the record to be deleted into a newly created record	Wanted data: Gender, DOB, shot date, and type of vaccine -- Unwanted Data: last name at birth, birth mother's name. Necessary to protect privacy in adoption cases
5	Vital Record Amendments	Match and Update Patient Record	Have ability to match an existing record with incoming vital record data	Using birth record number or other demographic information
6	Vital Record Amendments	Match and Update Patient Record	Have ability to use new vital record data to update patient demographic data	Name, DOB, gender, and other core data elements
7	Vital Record Amendments	Permanently Inactivate Record	Have ability for user to select patient record status indicator	Permanently inactivate refers to the death of the patient
8	Vital Record Amendments	Permanently Inactivate Record	Have the ability to display patient status indicator	
9	Vital Record Amendments	Permanently Inactivate Record	Have ability to capture date of death from vital records data	
10	Vital Record Amendments	Permanently Inactivate Record	Prevent access and updates to records that have been placed in an inactive status	
11	Vital Record Amendments	Permanently Inactivate Record	Exclude all records with an inactive status from coverage reports	

IIS Collaborative Requirements Development Project

Business Process Matrix

Facility/Organization Registration

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> To enroll facilities/ organizations and other authorized users into the IIS for vaccine reporting and/or other role based access to the system 	<ul style="list-style-type: none"> IIS protocol State and local laws, regulations, and policies 	<ul style="list-style-type: none"> Meaningful use testing Public health event (ex. H1N1) Change in state law New business (facility/organization) Merging of facilities/organizations Publicly purchased vaccines enrollment System enhancement upgrades Help desk calls 	<ol style="list-style-type: none"> IIS Provides Appropriate Forms Complete Provided Forms Submit Forms IIS Reviews Forms Forms Approved? Modify Forms Existing Facility/ Organization Record? Create Facility/Organiz -ation Record Generate Site ID Receive Approval Communication 	<ul style="list-style-type: none"> Facility/organization business purpose Organization demographics, Ex: <ul style="list-style-type: none"> Who is the sending organization Is it a public or private facility/organization Umbrella & individual sites health network Medical license number Authorizing medical provider/main point of contact IIS agreement Method of data receipt 	<ul style="list-style-type: none"> Facility/organization code Approval to access the system User ID/password Facility/organization record List of facilities linked with the facility/organization Facility/organization contact information list 	<ul style="list-style-type: none"> Percentage of publicly purchased vaccine facilities/organizations enrolled Percentage of Medicaid/Medicare facilities/organizations enrolled Percentage of schools enrolled



Activity Details / Narrative	<p>General Process Notes</p> <p>Objective:</p> <ul style="list-style-type: none"> To enroll facilities/organizations and other authorized users into the IIS for vaccine reporting and/or other role based access to the system <p>Measurable Outcomes:</p> <ul style="list-style-type: none"> Percentage of publicly purchased vaccine facilities/organizations enrolled Percentage of Medicaid/Medicare facilities/organizations enrolled Percentage of schools enrolled 	<p>Activity Description:</p> <p>1. IIS Provides Appropriate Forms</p> <ul style="list-style-type: none"> IIS provides interested facilities/organizations with the registration forms to complete <p>2. Complete Provided Forms</p> <ul style="list-style-type: none"> The facility/organization completes all required fields in the registration forms <p>3. Submit Forms</p> <ul style="list-style-type: none"> The facility/organization then submits the completed forms to the immunization program <p>4. IIS Reviews Forms</p> <ul style="list-style-type: none"> IIS staff reviews the completed forms to determine if the facility/organization qualifies to become an IIS participating facility/organization 	<p>5. Forms Approved?</p> <ul style="list-style-type: none"> IIS staff determine if the facility/organization is approved or rejected based on the registration forms review If an application is rejected, a reason code accompanies the rejection notice <p>6. Modify Forms</p> <ul style="list-style-type: none"> If immunization program staff does not approve the facility/organization for IIS registration, IIS staff can return the forms to the facility/organization to be modified <p>7. Existing Facility/Organization Record?</p> <ul style="list-style-type: none"> In some IIS systems, all VFC enrolled facilities/organizations can have vaccine orders placed on their behalf, regardless of whether they are enrolled to use the IIS or not. Then, when they sign up to use the IIS, they are matched to their existing facility/organization record in the IIS 	<p>8. Create Facility/Organization Record</p> <ul style="list-style-type: none"> If IIS approves registration, a new facility/organization record is created in the IIS system <p>9. Generate Site ID</p> <ul style="list-style-type: none"> IIS will generate a site identification number to assign to the facility/organization <p>10. Receive Approval Communication</p> <ul style="list-style-type: none"> IIS will send the facility/organization their approval for registration confirmation, along with their site ID

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Facility/Organization Registration	IIS Provides Appropriate Forms	Have ability to provide online access to enrollment form(s)	i.e., Hardcopy or electronic version
2	Facility/Organization Registration	Complete Provided Forms	Support the entry of all organization demographics and data when completing electronic forms	i.e., Authorized signature, address, organization name, relationships, etc.
3	Facility/Organization Registration	Complete Provided Forms	Allow user to save a form in progress and return to modify or submit it at a later time	
4	Facility/Organization Registration	Complete Provided Forms	Have ability to validate that all of the fields are complete before allowing the user to submit the forms online	
5	Facility/Organization Registration	Complete Provided Forms	Have ability to alert user of incomplete fields	
6	Facility/Organization Registration	Submit Forms	Have ability to submit forms electronically	Online form or return via email, fax, etc.
7	Facility/Organization Registration	Submit Forms	Allow user to modify forms until submitted	
8	Facility/Organization Registration	Submit Forms	Have ability to scan in paper forms	
9	Facility/Organization Registration	Submit Forms	Have ability to retrieve information from scanned forms and automatically fill required data fields with retrieved information	
10	Facility/Organization Registration	IIS Reviews Forms	Have ability to record person who is making the request	
11	Facility/Organization Registration	IIS Reviews Forms	Have ability to validate License Number against Professional Licensing Agency record database	
12	Facility/Organization Registration	IIS Reviews Forms	Have ability to display the submitted forms to user	
13	Facility/Organization Registration	IIS Reviews Forms	Have ability to search for and alert if there is a potential match of organizations	
14	Facility/Organization Registration	IIS Reviews Forms	Allow user to assign a rejection code to a rejected application	
15	Facility/Organization Registration	Forms Approved?	Support a rules-based algorithm to suggest approval or rejection based on review	
16	Facility/Organization Registration	Forms Approved?	Provide communication to applicant on registration status	i.e., Email, etc.

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
17	Facility/Organization Registration	Forms Approved?	Allow IIS staff to review and reject/approve forms	
18	Facility/Organization Registration	Modify Forms	Allow applicant to edit, save, and resubmit a rejected application	
19	Facility/Organization Registration	Existing Facility/Organization Record?	Have ability to compare application information to current records to find matches	
20	Facility/Organization Registration	Create Facility/Organization Record	Have ability to create and save new records for approved applicants	
21	Facility/Organization Registration	Generate Site ID	Have the ability to create unique provider site ID	i.e., System generated using an algorithm or manually assigned
22	Facility/Organization Registration	Receive Approval Communication	Have ability to send approval notification to applicant	i.e., Include site ID, instructions for enrollment, access and training

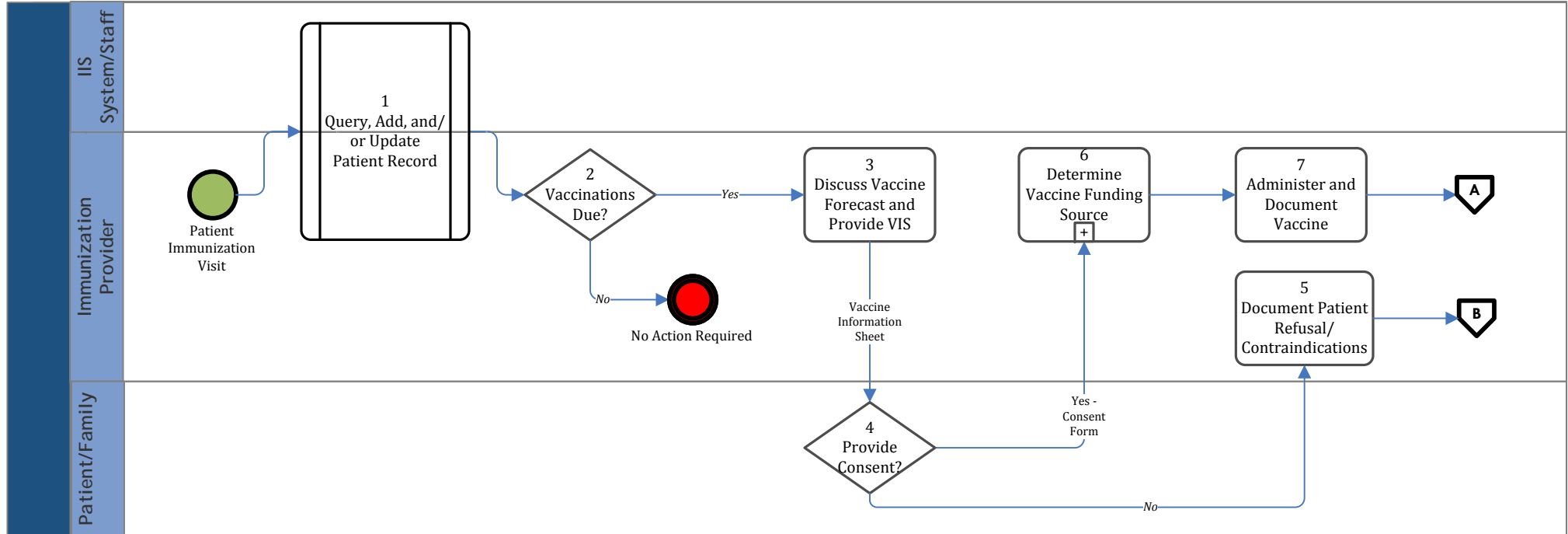
IIS Collaborative Requirements Development Project

Business Process Matrix

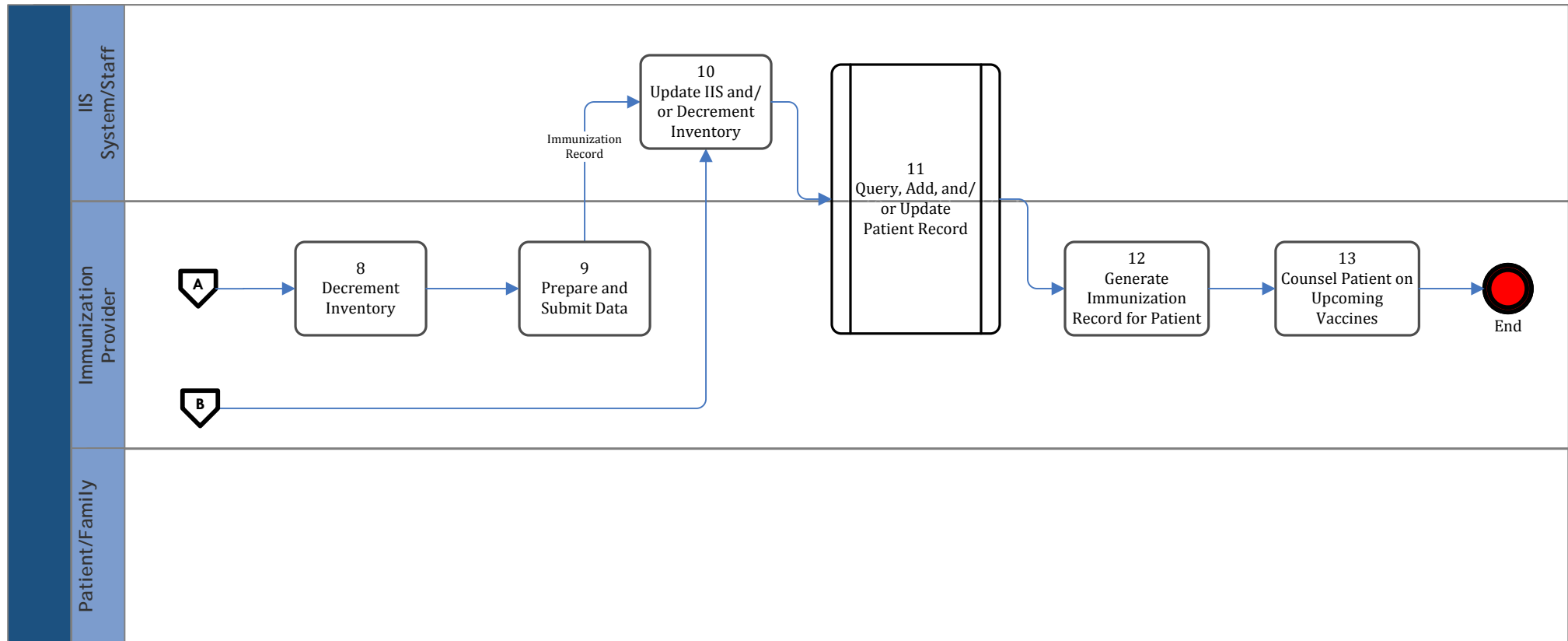
Administer Vaccine

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • Deliver age appropriate vaccinations • Submit vaccination data to IIS • Determine vaccine funding source 	<ul style="list-style-type: none"> • IIS regulation/ protocol • Provider standards of care • State/local rules and regulations • Vaccine funding rules • ACIP recommendations for precautions and contraindications • Record and vaccine de-duplication rules 	<ul style="list-style-type: none"> • Patient forecast recommends vaccination • Patient requests vaccination or shot record • Vaccine preventable disease outbreak • Reminder/ recall notification • University, school, day care, camp, etc. requirements • Employment requirements • International travel 	<ol style="list-style-type: none"> 1. Query, Add, and/or Update Patient Record 2. Vaccinations Due? 3. Discuss Vaccine Forecast and Provide VIS 4. Provide Consent? 5. Document Patient Refusal/ Contraindications 6. Determine Vaccine Funding Source 7. Administer and Document Vaccine 8. Decrement Inventory 9. Prepare and Submit Data 10. Update IIS and/or Decrement Inventory 11. Query, Add, and/or Update Patient Record 	<ul style="list-style-type: none"> • Patient vaccine record • Patient vaccine forecast • Precautions and contraindications 	<ul style="list-style-type: none"> • Record of patient consent • Patient receives age appropriate vaccination • Record of vaccination • Creation of vaccination data file/message • Vaccine inventory decremented as appropriate • Patient immunization history is updated and submitted to IIS • Appropriate dose-by-dose funding sources assigned • Provider EHR updated with immunization history 	<ul style="list-style-type: none"> • Number of patients that receive age appropriate vaccination • Number of shots due during clinic visit that are not given • Over-immunization is avoided • Count of vaccine inventory taken • Percentage of patients withheld/with-drawn give consent for vaccinations

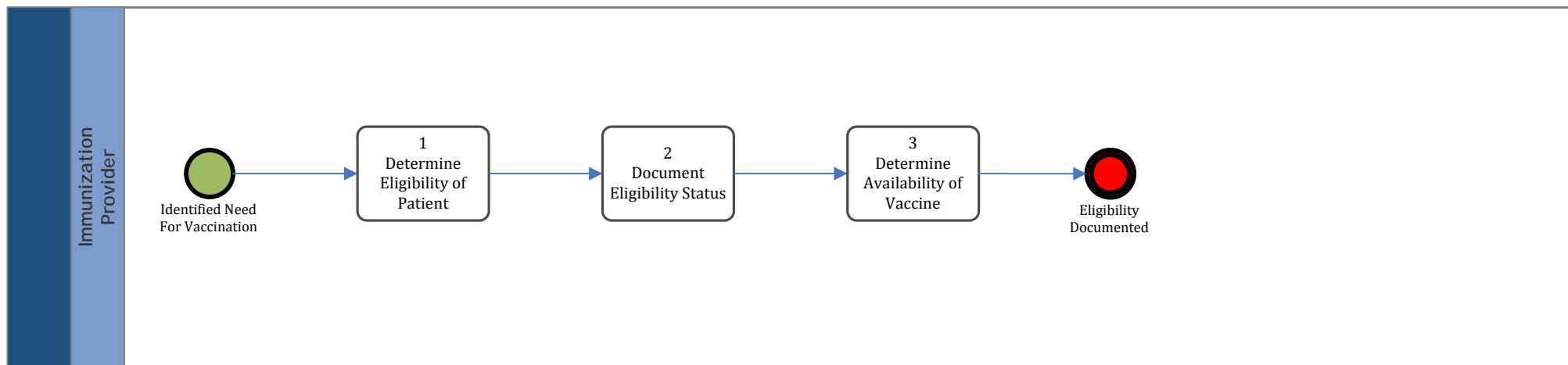
OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
			12. Generate Immunization Record for Patient 13. Counsel Patient on Upcoming Vaccines		<ul style="list-style-type: none"> • Patient is informed when their next vaccine is due • Patient immunization record for official purposes • Vaccine forecast for next visit • Record of patient refusal/contraindications • Completed medical examination form (school, summer camp, daycare, etc.) 	



Activity Details / Narrative	<p>General Process Notes</p> <p>Objective:</p> <ul style="list-style-type: none"> Deliver age appropriate vaccinations Submit vaccination data to IIS Determine vaccine funding source <p>Measurable Outcomes:</p> <ul style="list-style-type: none"> Number of patients that receive age appropriate vaccination Number of shots due during clinic visit that are not given Over-immunization is avoided Count of vaccine inventory taken Percentage of patients withheld/withdrawn give consent for vaccinations 	<p>General Notes:</p> <ul style="list-style-type: none"> Immunization providers may include Physicians, Nurses, Pharmacists, Nurse Practitioners, Physician’s Assistants, Medical Students, etc. Poor data quality or duplicated records may present an incomplete/inaccurate picture of patient immunizations as well as result in erroneous recommendations or skewed public policy decisions, so IIS data validation is critical While data source or reporting method may differ (batch file versus direct entry via UI), all data should be validated using the same criteria <p>Activity Description:</p> <p>1. Query, Add, and/or Update Patient Record</p> <ul style="list-style-type: none"> Predefined process 	<p>2. Vaccinations Due?</p> <ul style="list-style-type: none"> From the forecast received, the provider identifies any immunizations that are currently due If no vaccines are due, the provider may notify the patient of the next required vaccination, but no additional action is needed <p>3. Discuss Vaccine Forecast and Provide VIS</p> <ul style="list-style-type: none"> The provider reviews recommended vaccines with the patient Vaccine Information Sheets (VIS) are provided to outline benefits and possible side effects of each vaccine The patient is asked about precautions or contraindications that would prevent or delay immunization <p>4. Provide Consent? 5. Document Patient Refusal/Contraindications</p> <ul style="list-style-type: none"> If consent is granted, the signed consent form is documented Patient refusal is documented as non-administered vaccine 	<p>4. Provide Consent? 5. Document Patient Refusal/Contraindications</p> <ul style="list-style-type: none"> Documentation includes the date, type of vaccine, and exemption (medical, religious, philosophical or parent/patient refusal) <p>6. Determine Vaccine Funding Source</p> <ul style="list-style-type: none"> Sub-Process <p>7. Administer and Document Vaccine</p> <ul style="list-style-type: none"> The vaccine is prepared and given to the patient The vaccine event including vaccine type, manufacturer, lot number, vaccination date, route and site, expiration, and VIS document date are recorded If an adverse event occurs at the provider’s after vaccine administration; it is documented (see user report generation). Most adverse events occur after the patient has left the clinic
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Activity Details / Narrative	<p>8. Decrement Inventory</p> <ul style="list-style-type: none"> Publicly purchased or private inventory is decremented <p>9. Prepare and Submit Data</p> <ul style="list-style-type: none"> Data for one or more vaccination events is gathered and formatted into the required file format and submitted to the IIS <p>10. Update IIS and/or Decrement Inventory</p> <ul style="list-style-type: none"> The IIS is updated with the new patient vaccine information, and the vaccine is decremented from the IIS inventory <p>11. Query, Add, and/or Update Patient Record</p> <ul style="list-style-type: none"> Predefined process <p>12. Generate Immunization Record for Patient</p> <ul style="list-style-type: none"> The patient's immunizations are updated and the patient receives an updated immunization record Immunization record could possibly be generated from the IIS system following the Prepare and Submit Data task <p>13. Counsel Patient on Upcoming Vaccines</p> <ul style="list-style-type: none"> The immunization provider provides the patient/family with their updated immunization record and forecast and informs them of their upcoming vaccines
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Activity Details / Narrative	<p>General Process Notes</p> <p>General Notes:</p> <ul style="list-style-type: none"> States may use 317 or other funds to add vaccine eligibility categories, which vary from state to state Vaccines for Children (VFC) is a US federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated due to inability to pay CDC provides publicly purchased vaccines for eligible children at no charge to VFC enrolled public and private providers in all states, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands Any precautions or contraindications are identified and recorded <ul style="list-style-type: none"> Documentation of eligibility is required for each vaccine administered from VFC inventory Immunization providers may include Physicians, Nurses, Pharmacists, Nurse Practitioners, Physician’s Assistants, Medical Students, etc. <p>Activity Description:</p> <p>1. Determine Eligibility of Patient</p> <ul style="list-style-type: none"> Eligibility must be reassessed at each visit Children 18 years and younger are eligible for a VFC vaccine if they meet at least one criteria: Medicaid eligible, uninsured, American Indian or Alaskan Native, or underinsured Additional federal, state, and/or local criteria may be added (ex. 317) <p>2. Document Eligibility Status</p> <ul style="list-style-type: none"> The funding program’s eligibility is required for each immunization administered <p>2. Document Eligibility Status, cont.</p> <ul style="list-style-type: none"> The patient eligibility status should be updated and submitted with the VFC or other publicly funded vaccine immunization record If the patient’s status has not changed since the patient eligibility form was originally completed, the form does not need to be updated, but verification of status is still required to be submitted to the IIS Patient eligibility is then documented in IIS <p>3. Determine Availability of Vaccine</p> <ul style="list-style-type: none"> Office staff determine if the vaccine is available in office inventory If a publicly funded vaccine is out of stock, the office may borrow from private stock vaccine
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Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Administer Vaccine	Query, Add, and/or Update Patient Record	SEE QUERY, ADD, AND/OR UPDATE PATIENT RECORD REQUIREMENTS	
2	Administer Vaccine	Vaccinations Due?	Allow user to view patient vaccination history and forecast	The forecast is generated 'fresh' when record is accessed by user
3	Administer Vaccine	Vaccinations Due?	Have ability to send and receive patient query results in designated format	HL7 (recommended) or other format acceptable to both IIS and end user
4	Administer Vaccine	Discuss Vaccine Forecast and Provide VIS	Have ability to display and print patient history and forecast	Including contraindications and history of disease
5	Administer Vaccine	Discuss Vaccine Forecast and Provide VIS	Have ability to export patient history and forecasts in designated format	Including contraindications, ex. PDF, Personal Health Record
6	Administer Vaccine	Provide Consent?	Have ability to electronically document patient consent	Signature, check box, etc.
7	Administer Vaccine	Provide Consent?	Have ability to select patient opt-in status	For VFC program and for vaccination
8	Administer Vaccine	Document Patient Refusal/Contraindications	Have ability to indicate vaccine refusal by patient	By individual vaccine, since some patients only refuse a specific vaccine(s)
9	Administer Vaccine	Document Patient Refusal/Contraindications	Have ability to select patient vaccine refusal reason code	
10	Administer Vaccine	Document Patient Refusal/Contraindications	Have ability to display patient exemptions, contraindications and reactions	Based on ACIP and HL7 implementation guides
11	Administer Vaccine	Determine Vaccine Funding Source	SEE DETERMINE VACCINE FUNDING SOURCE REQUIREMENTS BELOW	
12	Administer Vaccine	Administer and Document Vaccine	Have ability to document all CDC-approved core data elements related to vaccine administration, which include but are not limited to, lot number, manufacturer, vaccine type, dose, date, route of administration, publication date of VIS, person who administered, etc.	The IIS should support all legal documentation requirements for vaccine administration
13	Administer Vaccine	Administer and Document Vaccine	Have ability to choose vaccine funding source	
14	Administer Vaccine	Administer and Document Vaccine	Have ability to document adverse reactions	
15	Administer Vaccine	Decrement Inventory	Support an interface with an EHR or other inventory management system/function	For end users who choose to not manage inventory directly in the IIS

Functional Requirements for IIS Collaborative Requirements Development Project

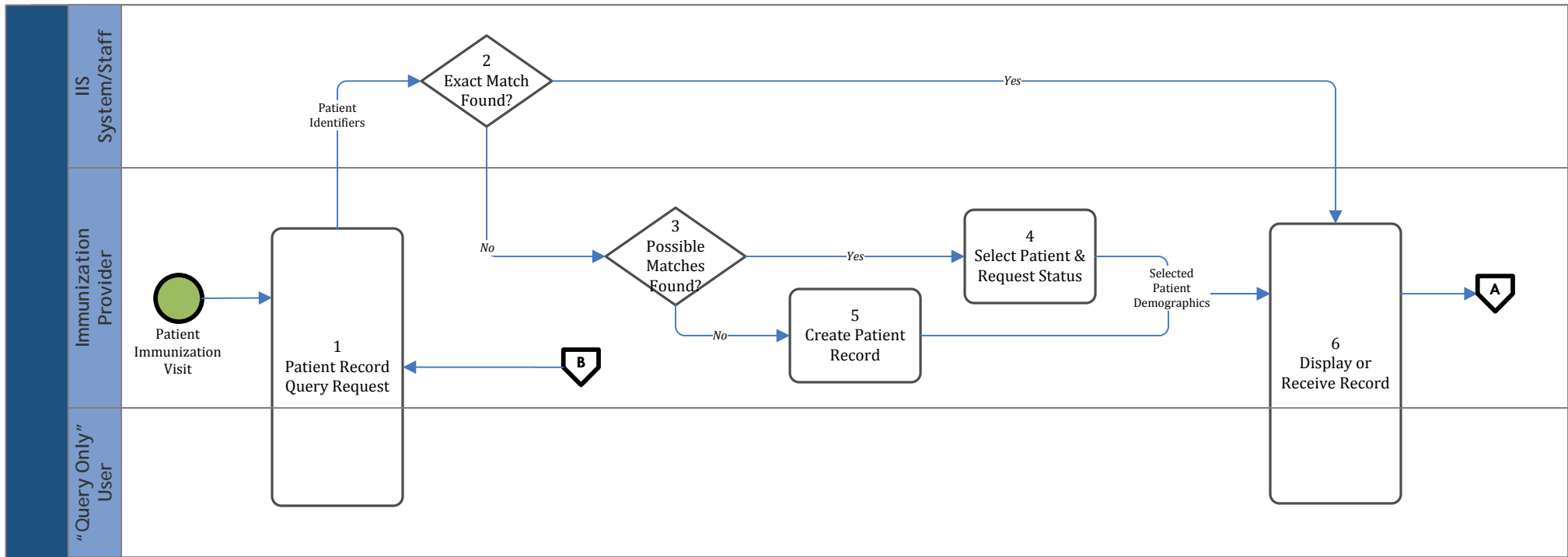
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
16	Administer Vaccine	Decrement Inventory	Have ability to receive inventory data from an EHR	
17	Administer Vaccine	Decrement Inventory	Have ability to reflect inventory decrementing as vaccines are administered and reported (real-time)	
18	Administer Vaccine	Prepare and Submit Data	Have ability to validate that all required data fields are complete	
19	Administer Vaccine	Update IIS and/or Decrement Inventory	Have ability to receive updated patient record in a designated format from the provider's EHR	
20	Administer Vaccine	Update IIS and/or Decrement Inventory	Have ability to decrement inventory including but not limited to the vaccine type, dose level, by funding source, by lot number, etc.	
21	Administer Vaccine	Query, Add, and/or Update Patient Record	SEE QUERY, ADD, AND/OR UPDATE PATIENT RECORD REQUIREMENTS	
22	Administer Vaccine	Generate Immunization Record for Patient	Have ability to display and print an updated immunization record and forecast	The printed report should not include patient address or SSN
23	Administer Vaccine	Generate Immunization Record for Patient	Have ability to export an updated immunization record and forecast	Via email, personal health record, etc.
24	Determine Vaccine Funding Source	Determine Eligibility of Patient	Have ability to document patient vaccine funding eligibility information	VFC eligibility status (5 statuses: uninsured, underinsured, Medicaid, Alaskan Native, and American Indian), insurance, etc.
25	Determine Vaccine Funding Source	Document Eligibility Status	Have ability to select vaccine funding eligibility for each vaccine dose	See above
26	Determine Vaccine Funding Source	Determine Availability of Vaccine	Have ability to query the inventory system/function by funding source and vaccine type	
27	Determine Vaccine Funding Source	Determine Availability of Vaccine	Have ability to display inventory by vaccine type and funding source	By vaccine type, funding source, etc.

IIS Collaborative Requirements Development Project

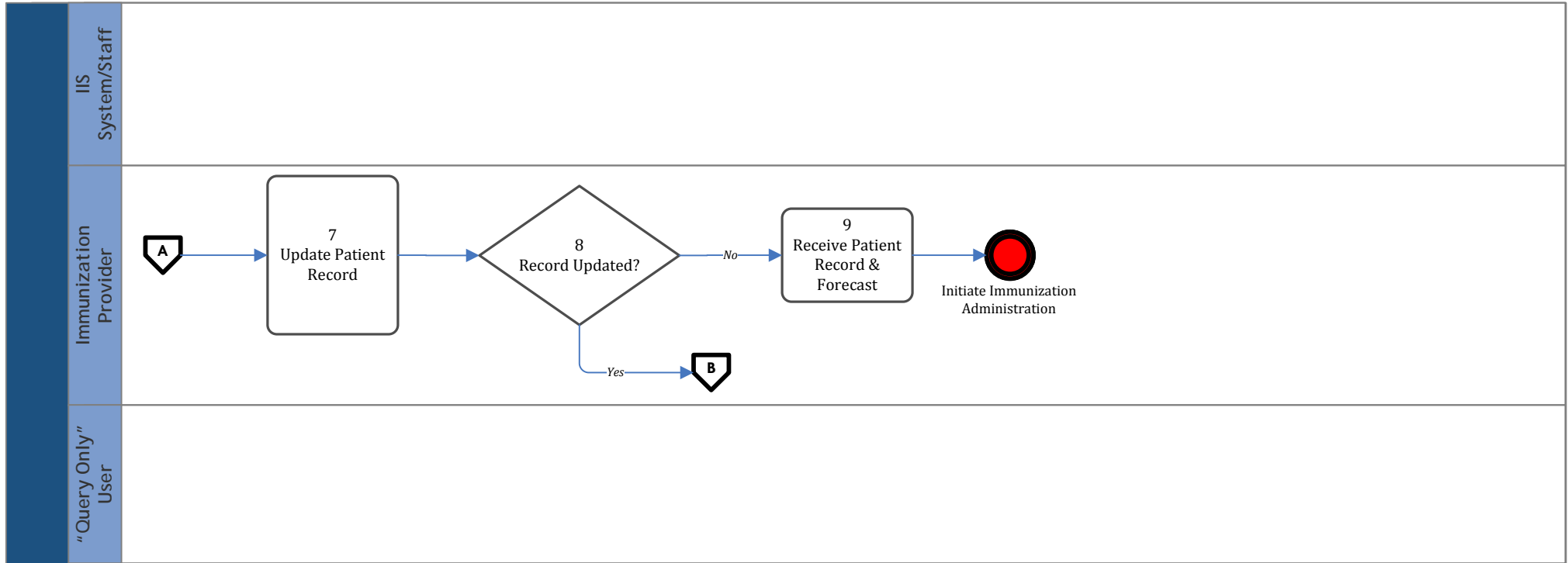
Business Process Matrix

Query, Add, and/or Update Patient Record

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To correctly locate or identify a patient's immunization record • To review and update a patient's record to provide a complete immunization history, which will be used to determine recommended vaccines and due dates, allowing providers to recommend and discuss immunizations with the patient 	<ul style="list-style-type: none"> • Federal, state, local and jurisdictional law • Provider protocol • Advisory Committee on Immunization Practices (ACIP) recommendation • School/child care protocols • FERPA 	<ul style="list-style-type: none"> • Patient clinical visit • Inquires about vaccines for school/child care attendance • Disease outbreak/surveillance • Reminder/ recall • Public inquiries • Immunization programs or other partners' needs • Patient death 	<ol style="list-style-type: none"> 1. Patient Record Query Request 2. Exact Match Found? 3. Possible Matches Found? 4. Select Patient & Request Status 5. Create Patient Record 6. Display or Receive Record 7. Update Patient Record, if necessary 8. Record Updated? 9. Receive Updated Patient Record & Forecast 	<ul style="list-style-type: none"> • Patient demographics (used to query, add, and/or update) including: <ul style="list-style-type: none"> ○ Name ○ Gender ○ Date of birth ○ Parents' names ○ Mother's maiden name ○ Medicaid number ○ Master patient index ○ Phone number ○ Email address • Patient immunization record (used to add or update) 	<ul style="list-style-type: none"> • Accurate patient vaccine record • Accurate patient forecast • User feedback on patient records (ex. duplicate patient/vaccine records, incorrect DOB, false merge, data quality) • Patient record inactivated/sealed due to death 	<ul style="list-style-type: none"> • Patient receives communication about recommended vaccines for the patient • Number of successful patient record searches • Percentage of up-to-date patient records in the IIS



<p>Activity Details / Narrative</p>	<p>General Process Notes</p> <p>Objective:</p> <ul style="list-style-type: none"> To correctly locate or identify a patient's immunization record To review and update a patient's record to provide a complete immunization history, which will be used to determine recommended vaccines and due dates, allowing providers to recommend and discuss immunizations with the patient <p>Measurable Outcomes:</p> <ul style="list-style-type: none"> Patient receives communication about recommended vaccines for the patient Number of successful patient record searches Percentage of up-to-date patient records in the IIS <p>General Notes:</p> <ul style="list-style-type: none"> Immunization providers may include Physicians, Nurses, Pharmacists, Nurse Practitioners, Physician's Assistants, Medical Students, etc. 	<ul style="list-style-type: none"> The Immunization Information System (IIS) is a registry of immunization records for patients active in that jurisdiction Utilizing accepted algorithms, forecasts are created based on patient date of birth and immunization history Forecasts are used by providers to recommend vaccinations, discuss options with patients, perform chart reviews, perform outside vaccine audits, and IE VFC AFIX evaluation Forecasts support decision making but cannot be substituted for professional judgment <p>Activity Description:</p> <p>1. Patient Record Query Request</p> <ul style="list-style-type: none"> The provider or "Query Only" user queries the IIS with patient identifiers (typically first and last name and date of birth) Some systems will only return an exact match 	<p>2. Exact Match Found?</p> <ul style="list-style-type: none"> The provider reviews matches returned by IIS to determine if the patient currently has a record in the system <p>3. Possible Matches Found?</p> <ul style="list-style-type: none"> The IIS returns a list of possible matches based on patient identifiers The provider reviews the list to determine if a patient record exists in the IIS that matches with their patient <p>4. Select Patient & Request Status</p> <ul style="list-style-type: none"> Some IIS systems will allow for the return of multiple matches If only exact matches are allowed, the user will either supply more information, continue to the search, or create a new record 	<p>5. Create Patient Record</p> <ul style="list-style-type: none"> If a patient record was not found in the IIS, the provider creates a new record using required patient demographic identifiers <p>6. Display or Receive Record</p> <ul style="list-style-type: none"> The IIS matches the patient record, validates vaccines, identifies missed vaccinations, and returns a response with the patient's immunization history and recommended doses with due dates This information can be made available through the sending of the data to the user
	<p>25</p>			



Activity Details / Narrative	<p>7. Update Patient Record, if necessary</p> <ul style="list-style-type: none"> The provider will update or consolidate existing patient records if new information is available Possible information may include additional patient demographics, addition of administered vaccines not reflected in the record, death, etc. <p>8. Record Updated?</p> <ul style="list-style-type: none"> If the record was updated then the system must re-query the patient record to recover the most accurate vaccine forecast <p>9. Receive Updated Patient Record & Forecast</p> <ul style="list-style-type: none"> The provider receives the patient record and forecast from the IIS and reviews vaccination needs with the patient Vaccines could be due at the time of the visit, overdue, or within the allowable window for administration
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Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Query, Add, and/or Update Patient Record	Patient Record Query Request	Have ability to perform a patient record query based on one or multiple user defined parameters	Possible parameters include name, DOB, etc.
2	Query, Add, and/or Update Patient Record	Patient Record Query Request	Support a rule-based patient record query algorithm	
3	Query, Add, and/or Update Patient Record	Patient Record Query Request	Support a maximum query response time of (X) seconds	
4	Query, Add, and/or Update Patient Record	Exact Match Found?	Have ability to produce an exact patient record match using user defined criteria	Example criteria: Full or partial first name, full or partial last name, DOB, etc.
5	Query, Add, and/or Update Patient Record	Exact Match Found?	Have ability to display or print patient record	
6	Query, Add, and/or Update Patient Record	Possible Matches Found?	Support a patient record query algorithm to return "best matches"	i.e., Tom, Tommy, etc. with DOB 01-01-1999
7	Query, Add, and/or Update Patient Record	Possible Matches Found?	Allow user to re-query for a patient record by modifying most current query parameters	Ex. Zip code, mother's maiden name, name only, etc.
8	Query, Add, and/or Update Patient Record	Possible Matches Found?	Have ability to query with a search string and/or filter	
9	Query, Add, and/or Update Patient Record	Possible Matches Found?	Have ability to limit the number of possible matches based on the immunization program policy	
10	Query, Add, and/or Update Patient Record	Select Patient & Request Status	Have ability to display patient record	
11	Query, Add, and/or Update Patient Record	Select Patient & Request Status	Have ability to display the list of returned possible matches as allowed by local policy	
12	Query, Add, and/or Update Patient Record	Select Patient & Request Status	Allow user to select a patient record from the list of possible matches	
13	Query, Add, and/or Update Patient Record	Create Patient Record	Allow user to create a new patient record	See appendix for recommended data elements
14	Query, Add, and/or Update Patient Record	Create Patient Record	Have ability to prevent a record from being saved unless specified data elements are completed	Ex. First name, last name, DOB, gender
15	Query, Add, and/or Update Patient Record	Create Patient Record	Have ability to identify the creation of a duplicate patient record	
16	Query, Add, and/or Update Patient Record	Create Patient Record	Have ability to prompt user to confirm creation of a new patient record after possible matches are found	The end user is presented possible matches and determines if none are the person they are searching for

Functional Requirements for IIS Collaborative Requirements Development Project

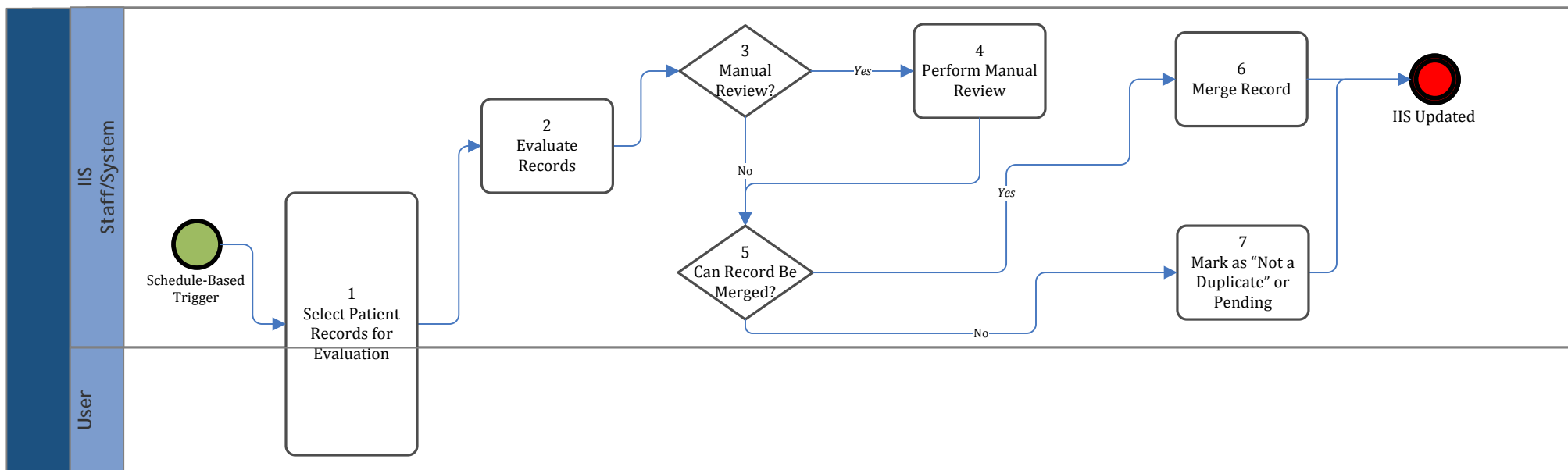
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
17	Query, Add, and/or Update Patient Record	Create Patient Record	Have ability to generate a unique patient ID	
18	Query, Add, and/or Update Patient Record	Display or Receive Record	Allow the user to view patient immunization record	i.e., Demographics, immunization history, forecast, contraindications, history of disease, adverse events, etc.
19	Query, Add, and/or Update Patient Record	Display or Receive Record	Have ability to print certificate or record	
20	Query, Add, and/or Update Patient Record	Update Patient Record, if necessary	Allow user to add/modify/delete vaccine and/or demographic information	Based on user roles
21	Query, Add, and/or Update Patient Record	Update Patient Record, if necessary	Have ability to flag patient record for death	
22	Query, Add, and/or Update Patient Record	Update Patient Record, if necessary	Have the ability to inactivate/lock patient record	i.e., When flagged as deceased, etc.
23	Query, Add, and/or Update Patient Record	Update Patient Record, if necessary	Have ability to reactivate patient record	
24	Query, Add, and/or Update Patient Record	Receive Updated Patient Record & Forecast	Have ability to display a patient record with vaccine forecast	
25	Query, Add, and/or Update Patient Record	Receive Updated Patient Record & Forecast	Allow the user to print a patient record with vaccine forecast	Patient address and SSN should never appear on a printed record

IIS Collaborative Requirements Development Project

Business Process Matrix

Patient De-Duplication

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To identify duplicate patient records and consolidate them into one best record 	<ul style="list-style-type: none"> • Evaluation criteria set by IIS program • National standards • State and local rules and regulations 	<ul style="list-style-type: none"> • Periodic evaluations • Duplicate patient records are reported/identified • Patient record accessed/updated 	<ol style="list-style-type: none"> 1. Select Patient Records for Evaluation 2. Evaluate Records 3. Manual Review? 4. Perform Manual Review 5. Can Record Be Merged? 6. Merge Record 7. Mark as "Not a Duplicate" or Pending 	<ul style="list-style-type: none"> • Patient demographics • Patient records • User flag to mark as duplicate 	<ul style="list-style-type: none"> • Single consolidated patient record • Records deemed as "Not a Duplicate" are marked accordingly • Duplicate record report • Records are marked as "requiring additional information" 	<ul style="list-style-type: none"> • Duplicate patient records have been consolidated into one record • Number of records deemed as "Not a Duplicate" are marked accordingly • Number of possible duplicates remaining in system queue/report • Number of records automatically de-duplicated by IIS versus number of manual de-duplications



Activity Details / Narrative

General Process Notes

Objective:

- To identify duplicate patient records and consolidate them into one best record

Measurable Outcomes:

- Duplicate patient records have been consolidated into one record
- Number of records deemed as "Not a Duplicate" are marked accordingly
- Number of possible duplicates remaining in system queue/report
- Number of records automatically de-duplicated by IIS versus number of manual de-duplications

General Notes:

- IISs receive data from several sources (e.g., providers, health plans, etc.) and while the IIS forces users to perform patient searches, any difference in the original record and the information used by the user search can result in the system returning no matches and ultimately, the subsequent creation of a duplicate patient record

- Duplication or incorrect de-duplication can result in an incomplete or inaccurate picture of patient immunizations and potentially erroneous vaccine recommendations

Activity Description:

1. Select Patient Records for Evaluation

- Patient records are reviewed on a periodic basis (daily or weekly) to determine if they are unique patients. Potentially duplicated records are identified and grouped
- Some systems automatically initiate this process to ensure data integrity; however, individual users can select, or flag, the patient records to be evaluated

2. Evaluate Records

- Potential patient record pairs are evaluated using demographic data including patient name, date of birth, social security number, insurance, parent/guardian information, mother's maiden name, address. As many fields as possible should be used for de-duplication purposes
- In addition to demographic data, immunization history can also be used to identify duplicate patient records

3. Manual Review?

- Potential patient records (duplicate/not a duplicate) are forwarded for resolution. If a merge cannot be automatically done by the system, the records will be directed for manual review

4. Perform Manual Review

- Patient records are reviewed manually to determine if they are duplicates
- Manual review often occurs with name or date of birth typos or where there is too little demographic information to determine whether the records are duplicated

5. Can Record Be Merged?

- User/system determines if the patient records can be merged into one record, if they are "not a duplicate", or if there is not enough information to make a decision
- Ex. If a name or date of birth is slightly different, but other components like social security number, insurance, and/or address match, a determination must be made whether the two records should be merged or marked as separate

6. Merge Record

- Patient records where the first and last name and date of birth match are merged. Extra precaution should be taken for pediatric patient records because the inappropriate merging of pediatric records is more consequential than for adult records due to complex vaccination schedules and the risk of undervaccination

7. Mark as "Not a Duplicate" or Pending

- If it is determined that the records are for different individuals, the patient records are marked as separate and immunization histories are maintained separately in the system
- If user is still unsure if the record is a duplicate, it is marked as pending and revisited

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Patient De-Duplication	Select Patient Records for Evaluation	Have ability to identify new patient records	
2	Patient De-Duplication	Select Patient Records for Evaluation	Have ability to automatically identify new patient records as possible duplicates	
3	Patient De-Duplication	Select Patient Records for Evaluation	Have ability to automatically identify existing patient records as duplicates	
4	Patient De-Duplication	Select Patient Records for Evaluation	Allow users to manually flag duplicate records	
5	Patient De-Duplication	Evaluate Records	Support a rules based algorithm to evaluate duplicate records	
6	Patient De-Duplication	Evaluate Records	Allow rules to be easily editable by IIS staff (add, remove, modify)	Many states rely on vendors for this role
7	Patient De-Duplication	Manual Review?	Flag duplicate records when possible that need manual review	
8	Patient De-Duplication	Manual Review?	Have ability to combine two or more duplicate records according to business rules	
9	Patient De-Duplication	Manual Review?	Allow user to manually flag records for manual review	
10	Patient De-Duplication	Perform Manual Review	Have ability to alert user of records pending for manual review	
11	Patient De-Duplication	Perform Manual Review	Allow user to view records simultaneously for decision to merge records	
12	Patient De-Duplication	Perform Manual Review	Allow user to open multiple screens at once within the application	i.e., Internet Explorer tabs
13	Patient De-Duplication	Perform Manual Review	Allow user to navigate the system while reviewing possible duplicates	
14	Patient De-Duplication	Merge Record	Allow user to select data elements to merge into a consolidated record	
15	Patient De-Duplication	Merge Record	Support an audit trail when records are merged	
16	Patient De-Duplication	Merge Record	Have ability to retain "pre-merged" records	
17	Patient De-Duplication	Mark as "Not Duplicate" or Pending	Allow user to flag record as "not a duplicate"	The system could believe records are duplicates, but they are not

Functional Requirements for IIS Collaborative Requirements Development Project

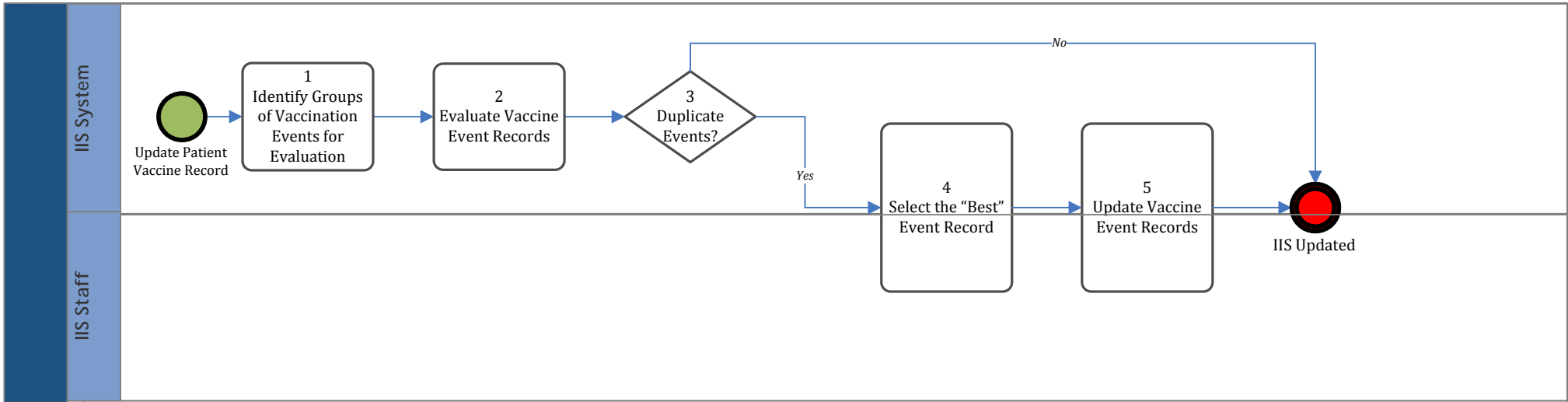
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
18	Patient De-Duplication	Mark as "Not Duplicate" or Pending	Have ability to prevent matching for the same pair of records that have been flagged as "not a duplicate"	
19	Patient De-Duplication	Mark as "Not Duplicate" or Pending	Allow user to manually flag a record as pending for manual review	i.e., Not enough information

IIS Collaborative Requirements Development Project

Business Process Matrix

Vaccine De-Duplication

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To identify duplicate immunization submission events within a patient record and update into one event 	<ul style="list-style-type: none"> • Vaccine de-duplication business rules • MIROW guidelines 	<ul style="list-style-type: none"> • Periodic evaluations • Data has been validated • Suspected duplicate records are identified/ reported • HL7 data is received • Patient record updates • Patient record queries 	<ol style="list-style-type: none"> 1. Identify Groups of Vaccination Events for Evaluation 2. Evaluate Vaccine Event Records 3. Duplicate Events? 4. Select the "Best" Event Record 5. Update Vaccine Event Records 	<ul style="list-style-type: none"> • Patient vaccine event record 	<ul style="list-style-type: none"> • Updated patient vaccine events 	<ul style="list-style-type: none"> • Duplicated events have been identified, updated into one event, and resolved



Activity Details / Narrative

General Process Notes

Objective:

- To identify duplicate immunization submission events within a patient record and update into one event

Measurable Outcomes:

- Duplicated events have been identified, updated into one event, and resolved

General Notes:

- Duplicated events may present an incomplete or inaccurate picture of patient immunizations as well as result in erroneous recommendations
- IISs receive data from several sources (e.g., providers, health plans, etc.) which may result in the same immunization event reported more than once
- IIS reviews records based on pre-defined criteria (ex. age, time of import, etc.)
- Duplication or inappropriate de-duplication can result in an incomplete or inaccurate picture of patient immunizations and potentially erroneous recommendations
- Refer to MIROW guidelines

Activity Description:

1. Identify Groups of Vaccination Events for Evaluation

- Vaccination events within a patient's record are investigated to determine if they are unique events
- Potential duplicated events are identified and grouped within a patient's record

2. Evaluate Vaccine Event Records; 3. Duplicate Events?

- Event groups are evaluated using encounter date, vaccine type and trade name, provider name, record source type, and vaccine lot number
- Categorized pairs (match/differ) are forwarded for resolution. If a classification cannot be made, they may be directed for manual review
- Invalid doses should be maintained and flagged in the registry

4. Select the "Best" Event Record

- For events that match, the "best" event is selected based on level of confidence, completeness of data, and specificity of data. The event is used as the basis for an updated event
- This step can be preformed manually or by the system

5. Update Vaccine Event Records

- All available information is aggregated from the duplicate events into an updated event
- Both the updated event and the "best" event (reported "as-is") can be made available to view and utilize
- All reported events should be kept and an audit trail documented so de-duplication decisions can be analyzed
- Viewing of retained events should be limited to administrative roles

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Vaccine De-Duplication	Identify Groups of Vaccination Events for Evaluation	Have ability to identify new vaccine events	
2	Vaccine De-Duplication	Identify Groups of Vaccination Events for Evaluation	Have ability to automatically identify new vaccine events as duplicates or possible duplicates	
3	Vaccine De-Duplication	Identify Groups of Vaccination Events for Evaluation	Have ability to automatically identify existing vaccine events as duplicates	
4	Vaccine De-Duplication	Identify Groups of Vaccination Events for Evaluation	Allow users to manually flag duplicate events	
5	Vaccine De-Duplication	Identify Groups of Vaccination Events for Evaluation	Have ability to display to the end user the vaccine type, manufacturer, admin date, eligibility, and who entered the dose for manual vaccine de-duplication review	
6	Vaccine De-Duplication	Evaluate Vaccine Event Records	Support a rules based algorithm to evaluate duplicate events	
7	Vaccine De-Duplication	Evaluate Vaccine Event Records	Allow rules to be easily editable by IIS staff (add, remove, modify), when appropriate	Many States rely on vendors for this role
8	Vaccine De-Duplication	Duplicate Events?	Support probabilistic algorithm to determine and flag when duplicate events need manual review	
9	Vaccine De-Duplication	Duplicate Events?	Allow user to manually flag events for manual review	
10	Vaccine De-Duplication	Duplicate Events?	Have ability to alert user of events pending for manual review	
11	Vaccine De-Duplication	Duplicate Events?	Allow user to view events simultaneously for decision to merge	i.e., 2 or more
12	Vaccine De-Duplication	Duplicate Events?	Allow user to open multiple screens at once within the application when manually reviewing duplicate vaccine event records	
13	Vaccine De-Duplication	Duplicate Events?	Allow user to navigate the system while reviewing possible duplicates	
14	Vaccine De-Duplication	Select the "Best" Event Record	Have ability to select the 'best" vaccination event automatically that does not require manual review	

Functional Requirements for IIS Collaborative Requirements Development Project

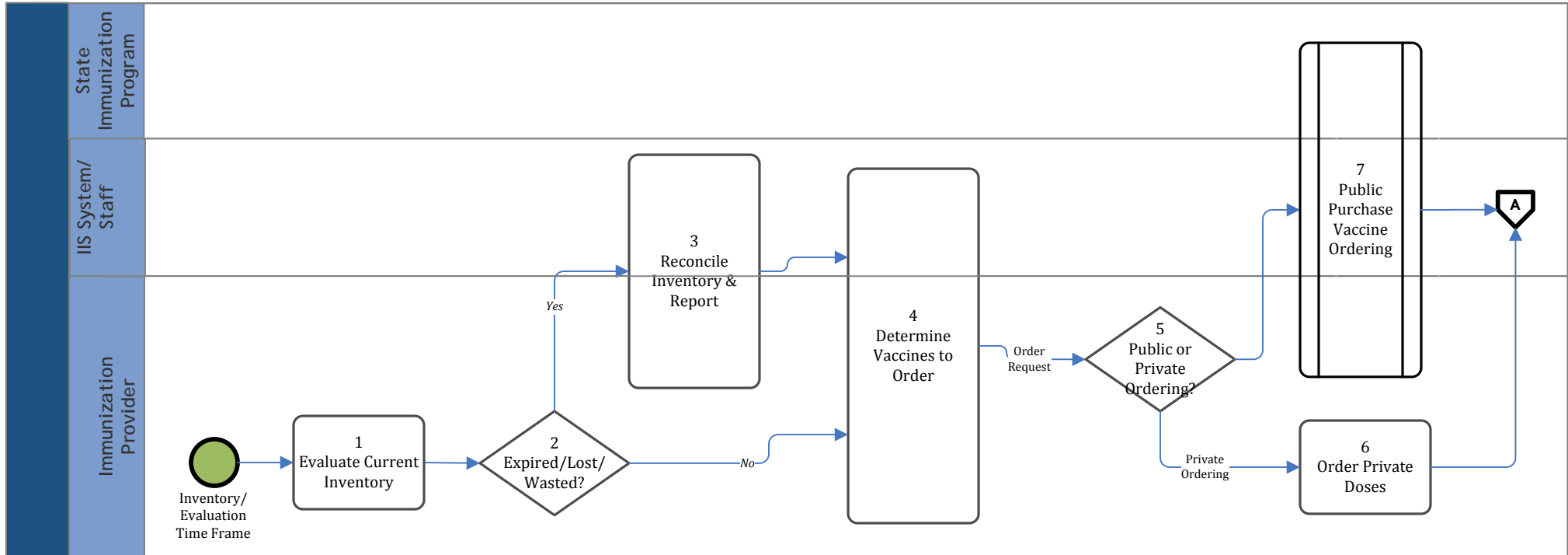
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
15	Vaccine De-Duplication	Update Vaccine Event Records	Allow user to select data elements to merge into a consolidated event record	
16	Vaccine De-Duplication	Update Vaccine Event Records	Have ability to combine two or more duplicate event records according to business rules	
17	Vaccine De-Duplication	Update Vaccine Event Records	Support an audit trail when event records are merged	
18	Vaccine De-Duplication	Update Vaccine Event Records	Have ability to retain "pre-merged" event records	
19	Vaccine De-Duplication	Update Vaccine Event Records	Allow user to delete a duplicate vaccine event	

IIS Collaborative Requirements Development Project

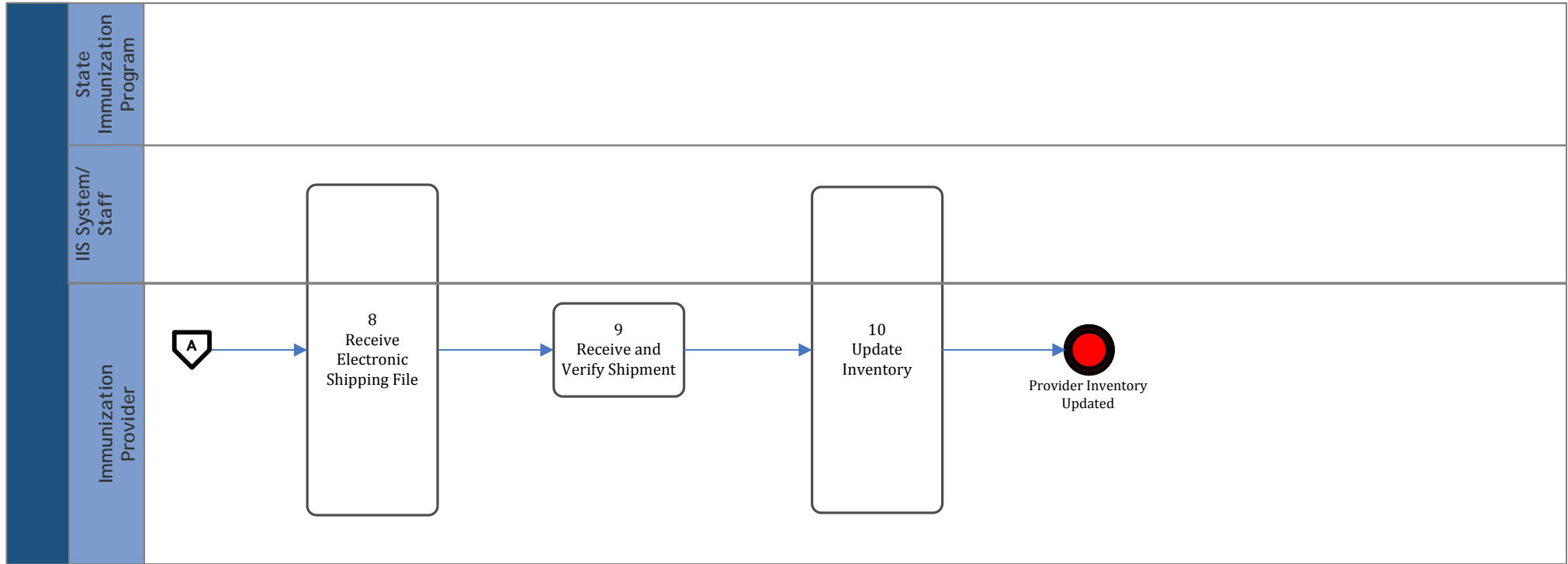
Business Process Matrix

Manage Inventory

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> To maintain an adequate vaccine inventory for privately/publicly purchased vaccine ordering and accountability 	<ul style="list-style-type: none"> State and local rules and regulations State/local immunization program criteria and protocol Publicly purchased vaccines, VFC and 317 program rules, regulations, and protocol CDC vaccine distribution center rules and regulations 	<ul style="list-style-type: none"> Inventory/ evaluation time frame Vaccine shortage Public health event Alerts 	<ol style="list-style-type: none"> Evaluate Current Inventory Expired/Lost/Wasted? Reconcile Inventory & Report Determine Vaccines to Order Public or Private Ordering? Order Private Doses Public Purchase Vaccine Ordering Receive Electronic Shipping File Receive and Verify Shipment Update Inventory 	<ul style="list-style-type: none"> Vaccine inventory Immunization forecasts 	<ul style="list-style-type: none"> Inventory report Private vaccine order Updated vaccine inventory Receipt of order Inventory reconciled between IIS and provider 	<ul style="list-style-type: none"> Number of vaccine stock outs Percentage increase or decrease of expired inventory Number of urgent (expedited) orders Number or percentage increase or decrease in number of urgent orders



Activity Details / Narrative	<p>General Process Notes</p> <p>Objective:</p> <ul style="list-style-type: none"> To maintain an adequate vaccine inventory for privately/publicly purchased vaccine ordering and accountability <p>Measurable Outcomes:</p> <ul style="list-style-type: none"> Number of vaccine stock outs Percentage increase or decrease of expired inventory Number of urgent (expedited) orders Number or percentage increase or decrease in number of urgent orders <p>General Notes:</p> <ul style="list-style-type: none"> Immunization needs are assessed based on historical usage reporting. These reports along with current inventory levels are used to create inventory forecasts Inventory forecasts help prevent issues of vaccine shortages or situations where demand is not sufficient to support inventory Immunization providers may include Physicians, Nurses, Pharmacists, Nurse Practitioners, Physician's Assistants, etc. 	<p>Activity Description:</p> <p>1. Evaluate Current Inventory, 2. Expired/Lost/Wasted?</p> <ul style="list-style-type: none"> Current inventory is physically evaluated to verify counts, check temperature logs, confirm the refrigerator/freezer were within the allowable temperatures, and identify expired or spoiled vaccines Vaccines that exceed the expiration date or where approved cold chain procedures were violated (improper temperature setting, natural disaster/power outages, spoiled in transport) must be removed from inventory Providers new to managing inventory in an IIS, would need to enter current inventory into the IIS <p>3. Reconcile Inventory & Report</p> <ul style="list-style-type: none"> Expired/lost/wasted public vaccines must be reported using the approved return form and inventory must be reconciled to adjust for the affected doses 	<p>3. Reconcile Inventory & Report, cont.</p> <ul style="list-style-type: none"> Vaccines expired/lost/wasted may have to be reimbursed according to local/state public health department guidelines Vaccines may be borrowed from various funding sources according to local/state public health department guidelines IIS may automatically recommend vaccine order quantity <p>4. Determine Vaccines to Order</p> <ul style="list-style-type: none"> Usage reporting and current inventory levels are used to assess inventory needs and identify gaps <p>5. Public or Private Ordering?</p> <ul style="list-style-type: none"> The provider determines if the vaccines to be ordered are VFC vaccines or private vaccines <p>6. Order Private Doses</p> <ul style="list-style-type: none"> The provider places an order for vaccines through a private vaccine distributor <p>7. Public Purchase Vaccine Ordering</p> <ul style="list-style-type: none"> Predefined process
	<p>State Immunization Program</p>	<p>IIS System/ Staff</p>	<p>Immunization Provider</p>



Activity Details / Narrative	<p>8. Receive Electronic Shipping File</p> <ul style="list-style-type: none"> The IIS and provider receive the electronic shipping file from the vaccine distributor <p>9. Receive and Verify Shipment</p> <ul style="list-style-type: none"> Immunization provider receives the approved doses and verifies the shipment against the electronic packing slip <p>10. Update Inventory</p> <ul style="list-style-type: none"> The provider updates the inventory in their system and in IIS with data for the received doses (e.g., vaccine, lot number, expiration, & quantity of doses) and reports any discrepancies
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Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Manage Inventory	Evaluate Current Inventory	Have ability to print current inventory list	Use to match physical with virtual inventory (May include: current vaccine inventory, lot number, and count that is in the system)
2	Manage Inventory	Evaluate Current Inventory	Have ability to display alerts/notifications for vaccines nearing expiration	
3	Manage Inventory	Evaluate Current Inventory	Have ability to track borrowed doses of vaccines with reclassified funding sources	Vaccines borrowed from other funding sources
4	Manage Inventory	Expired/Lost/Wasted?	Allow user to assign/modify quantity for expired/lost/wasted inventory using inventory adjustment codes	
5	Manage Inventory	Reconcile Inventory & Report	Ability to produce an inventory reconciliation report	
6	Manage Inventory	Reconcile Inventory & Report	Allow the user to attach usage reports to an inventory reconciliation report	
7	Manage Inventory	Determine Vaccines to Order	Ability to display current system inventory	
8	Manage Inventory	Determine Vaccines to Order	Ability to calculate and display suggested order based on provider usage, wastage, order history, etc.	
9	Manage Inventory	Determine Vaccines to Order	Alert user during vaccine ordering if provider current on-site inventory is above threshold for ordering	
10	Manage Inventory	Determine Vaccines to Order	Have ability to display all open orders (in transit, or orders in process)	
11	Manage Inventory	Public or Private Ordering?	Allow user to select funding source for vaccine	For differently public funded programs and then private
12	Manage Inventory	Public or Private Ordering?	Have the ability to prompt user to select vaccine funding source	
13	Manage Inventory	Order Private Doses	Allow user to place order with private vaccine distributor	This is to support orders separate from publicly funded vaccines
14	Manage Inventory	Order Private Doses	Support user ordering of private vaccine	i.e., Utilize ordering systems, export vaccine order list, etc.
15	Manage Inventory	Order Private Doses	Have ability to display order status, approval status, and shipping status	

Functional Requirements for IIS Collaborative Requirements Development Project

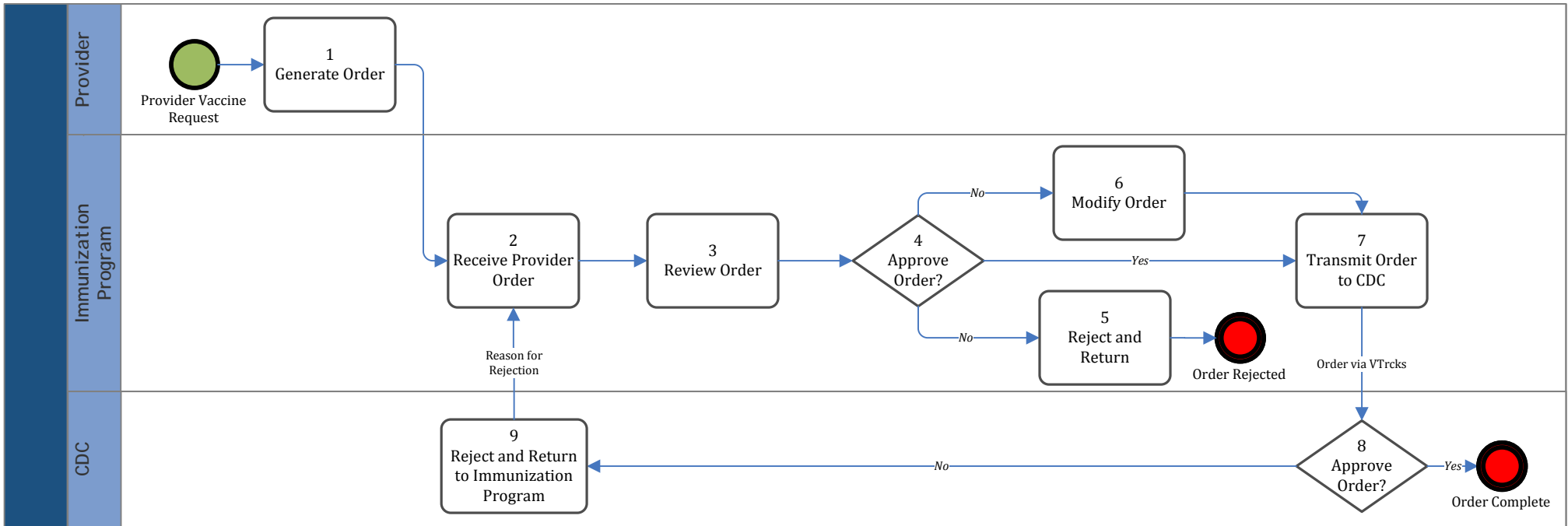
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
16	Manage Inventory	Public Purchase Vaccine Ordering	SEE PUBLIC PURCHASE VACCINE ORDERING REQUIREMENTS	
17	Manage Inventory	Receive Electronic Shipping File	Ability to accept and log shipping file from distributors	
18	Manage Inventory	Receive Electronic Shipping File	Ability to display the shipping file	Pre-populate provider inventories with shipping file information
19	Manage Inventory	Receive Electronic Shipping File	Have ability to sum quantities from multiple shipping notices	In order to display total amount fulfilled for an order
20	Manage Inventory	Receive Electronic Shipping File	Have ability to flag a shipping file as incorrect	Ex. If difference between notified order and shipment order
21	Manage Inventory	Receive Electronic Shipping File	Have ability to notify distributor of an incorrect shipping file	According to local and state public health department guidelines
22	Manage Inventory	Receive and Verify Shipment	Allow user to send acknowledgement of order receipt	
23	Manage Inventory	Receive and Verify Shipment	Have ability to flag order by vaccine type as over order quantity, under order quantity, or damaged	
24	Manage Inventory	Receive and Verify Shipment	Have ability to inform distributor of over order quantities received, under order quantities received, or damaged order	According to local and state public health department guidelines
25	Manage Inventory	Receive and Verify Shipment	Ability to accept and/or reject all or portions of an order and inform distributor	According to local and state public health department guidelines
26	Manage Inventory	Update Inventory	Allow user to edit inventory data elements in the case of discrepancies in the shipping file	
27	Manage Inventory	Update Inventory	Allow back order inventory to be accounted for in the system	Prevent reordering of already ordered inventory

IIS Collaborative Requirements Development Project

Business Process Matrix

Public Purchase Vaccine Ordering

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To enable publicly purchased vaccine ordering 	<ul style="list-style-type: none"> • Immunization program level rules and regulations • Publicly purchased vaccines protocol • CDC protocol 	<ul style="list-style-type: none"> • Public health event • Low inventory • New vaccine/ recommendations • Economic Order Quantity (EOQ) • Newly enrolled provider • Receipt of a grant 	<ol style="list-style-type: none"> 1. Generate Order 2. Receive Provider Order 3. Review Order 4. Approve Order? 5. Reject and Return 6. Modify Order 7. Transmit Order to CDC 8. Approve Order? 9. Reject and Return to Immunization Program 	<ul style="list-style-type: none"> • Usage reports: <ul style="list-style-type: none"> ○ Doses administered, expired, wasted • Inventory • Publicly purchased vaccines order forms. Possible fields: <ul style="list-style-type: none"> ○ Storage capacity ○ Shipping hours ○ Shipping demographics (address, phone #, etc.) • Temperature log 	<ul style="list-style-type: none"> • Completed publicly purchased vaccines order form • Electronic packing slip • Vaccines shipped • Vaccine order recommendations • Tracking number • Confirmation of order • State approval/ rejection of order 	<ul style="list-style-type: none"> • Order received by IIS • Number of successful orders sent to VTrcks • Reduction of transfer/ borrowing, expired and wasted vaccines



<p>Activity Details / Narrative</p>	<p>General Process Notes</p> <p>Objective:</p> <ul style="list-style-type: none"> To enable publicly purchased vaccine ordering <p>Measurable Outcomes:</p> <ul style="list-style-type: none"> Order received by IIS Number of successful orders sent to VTTrcks Reduction of transfer/ borrowing, expired and wasted vaccines <p>General Notes:</p> <ul style="list-style-type: none"> State immunization programs must approve all orders from providers and submit to the CDC for further approval Vaccine needs are assessed based on usage or historical reporting to create inventory forecasts The act of administering a vaccination in a clinic under the IIS triggers decrement of that dosage in the inventory system 	<p>Activity Description:</p> <p>1. Generate Order</p> <ul style="list-style-type: none"> The providers generate a vaccine order, based on their usage history and current inventory, and submit it to the state immunization program for purchasing <p>2. Receive Provider Order</p> <ul style="list-style-type: none"> The immunization program receives a vaccine order from a provider in their jurisdiction The provider also submits usage reports, end inventory, and temperature logs to accompany the order <p>3. Review Order</p> <ul style="list-style-type: none"> Usage reporting, provider patient profile, and inventory reports are used to assess inventory needs and identify gaps with order request <p>4. Approve Order?</p> <ul style="list-style-type: none"> Based on evaluation of the provider's current inventory, forecasted needs, and order history, the immunization program decides if the provider's request is within the ordering parameters 	<p>5. Reject and Return</p> <ul style="list-style-type: none"> If the immunization program determines that current inventory levels are sufficient, or order is not within normal ordering parameters, the order is rejected The VFC Program can review the Spend Plan, a projection of the aggregate number of vaccines by National Drug Code number to be ordered by the immunization program, to verify program orders and spending In the case where the provider has exceeded the maximum allowed number of ordered vaccines, the immunization program will inform the provider and suggest the appropriate amount <p>6. Modify Order</p> <ul style="list-style-type: none"> If the issue with the order is minor, the immunization program could make changes to the order and then submit it to the CDC for approval 	<p>7. Transmit Order to CDC</p> <ul style="list-style-type: none"> If the immunization program determines that the provider's need is sufficient to justify the order, they will transmit the order electronically to the CDC <p>8. Approve Order?</p> <ul style="list-style-type: none"> The CDC evaluates each order and determines whether to transmit the order to the distributor <p>9. Reject and Return to Immunization Program</p> <ul style="list-style-type: none"> If the CDC does not approve the order to be transmitted to the distributor, it is returned to the immunization program to either return to the provider or modify and resubmit to the CDC
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Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Public Purchase Vaccine Ordering	Generate Order	Have ability to display current provider inventory	
2	Public Purchase Vaccine Ordering	Generate Order	Have ability to display minimum order increments	e.g., Quantity in a bottle or box
3	Public Purchase Vaccine Ordering	Generate Order	Have ability to calculate and display IIS recommended order quantities	Ex. Vtrcks, etc.
4	Public Purchase Vaccine Ordering	Generate Order	Support the use of an ordering system/module	
5	Public Purchase Vaccine Ordering	Generate Order	Have ability for provider to access and place order through the IIS system	
6	Public Purchase Vaccine Ordering	Receive Provider Order	Allow provider to attach files of various formats to the vaccine order	i.e., Temperature logs, etc.
7	Public Purchase Vaccine Ordering	Receive Provider Order	Allow only specific users to order vaccines, delete and edit orders, and view order statuses for a clinic based on assigned user permissions	
8	Public Purchase Vaccine Ordering	Review Order	Allow user to view order on the screen and print	
9	Public Purchase Vaccine Ordering	Review Order	Allow user to view and print the attachments	
10	Public Purchase Vaccine Ordering	Review Order	Allow user to assign funding source/product intent at the vaccine order line level	
11	Public Purchase Vaccine Ordering	Approve Order?	Have ability to display the order history of a provider	i.e., Previous order history, doses administered, etc.
12	Public Purchase Vaccine Ordering	Approve Order?	Have ability to display order	
13	Public Purchase Vaccine Ordering	Approve Order?	Have ability to capture and display provider refrigeration storage capacity/capability	
14	Public Purchase Vaccine Ordering	Approve Order?	Support a rules-based algorithm to decide to approve or reject order	
15	Public Purchase Vaccine Ordering	Approve Order?	Alert user for the need for manual intervention	
16	Public Purchase Vaccine Ordering	Reject and Return	Allow user to select the reason code for rejection	i.e., Order number, order date, provider name, order status, and change to order status

Functional Requirements for IIS Collaborative Requirements Development Project

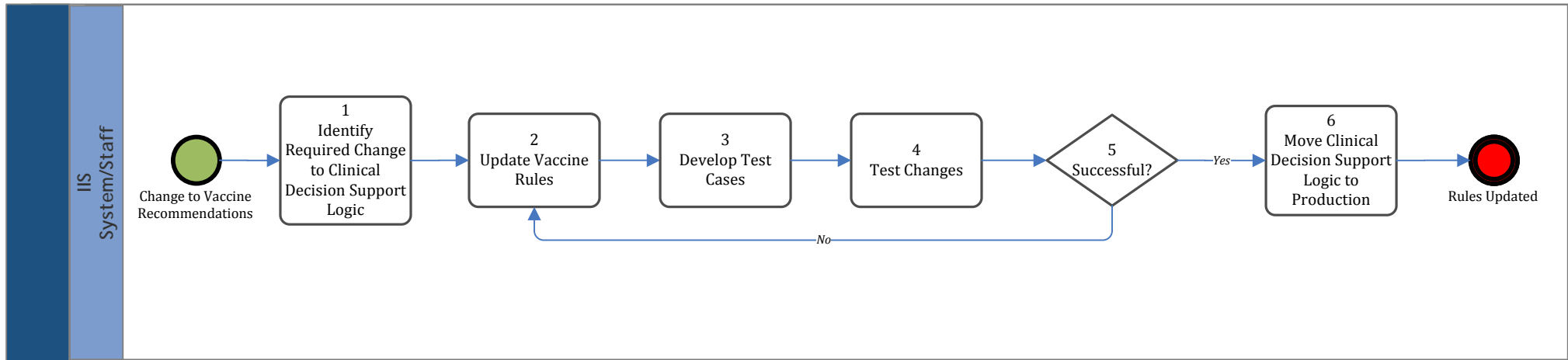
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
17	Public Purchase Vaccine Ordering	Reject and Return	Have ability to communicate order status or an audit log to the provider	Possible ways to provide order status: email, fax, phone, web portal, etc.
18	Public Purchase Vaccine Ordering	Reject and Return	Support reason codes for rejection	
19	Public Purchase Vaccine Ordering	Modify Order	Allow user to edit, save, and resubmit order after rejection	
20	Public Purchase Vaccine Ordering	Transmit Order to CDC	Have ability to transmit order to the CDC	
21	Public Purchase Vaccine Ordering	Approve Order?	Support an interface allowing an immunization program to view order confirmations	
22	Public Purchase Vaccine Ordering	Reject and Return to Immunization Program	Have ability to reject order	
23	Public Purchase Vaccine Ordering	Reject and Return to Immunization Program	Have ability to return order to the immunization program	
24	Public Purchase Vaccine Ordering	Reject and Return to Immunization Program	Support order rejection codes	
25	Public Purchase Vaccine Ordering	Reject and Return to Immunization Program	Allow immunization program to edit, save, and resubmit vaccine order after rejection	
26	Public Purchase Vaccine Ordering	Reject and Return to Immunization Program	Allow immunization program to view error message from CDC	
27	Public Purchase Vaccine Ordering	Reject and Return to Immunization Program	Have ability to send rejection notification back to IIS program	

IIS Collaborative Requirements Development Project

Business Process Matrix

Manage Forecasting Rules

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To create or update IIS immunization Clinical Decision Support (CDS) logic 	<ul style="list-style-type: none"> • ACIP recommendations • Immunization program protocols for changes and parameter testing • Clinical Decision Support (CDS) Project • Federal, state, and local law, regulations, or policies 	<ul style="list-style-type: none"> • Updated ACIP recommendations • Change in federal, state, and local policy • Outputs from CDS project workgroup • Public health emergency • Feedback from IIS users 	<ol style="list-style-type: none"> 1. Identify Required Change to Clinical Decision Support Logic 2. Update Vaccine Rules 3. Develop Test Cases 4. Test Changes 5. Successful? 6. Move Clinical Decision Support Logic to Production 	<ul style="list-style-type: none"> • ACIP recommendations • IIS forecasting logic 	<ul style="list-style-type: none"> • Updated IIS vaccine forecasting logic 	<ul style="list-style-type: none"> • Completed IIS testing with updated vaccine CDS logic • Updated vaccine CDS logic is moved to production



Activity Details / Narrative	<p><u>General Process Notes</u> Objective:</p> <ul style="list-style-type: none"> To create or update IIS immunization Clinical Decision Support (CDS) logic <p>Measurable Outcomes:</p> <ul style="list-style-type: none"> Completed IIS testing with updated vaccine CDS logic Updated vaccine CDS logic is moved to production <p>General Notes:</p> <ul style="list-style-type: none"> Immunization information systems contain information about available vaccines and recommended schedules As clinical trials inform changes to the Advisory Committee on Immunization Practices (ACIP) recommendations, vaccine rules in the IIS must be updated to match the revised recommendation The IIS must keep this information updated in order to ensure the immunization forecasts are accurate Typical changes include additions of vaccines, changes in forecasts, and removal of vaccines Depending on the jurisdiction, the IIS can have multiple version schedules (schools and daycare) Applies to both managing forecasting rules and vaccine data validation 	<ul style="list-style-type: none"> The CDC is currently conducting a workgroup, Clinical Decision Support Project, around the creation of “computable” business rules based on ACIP recommendations <p>Activity Description:</p> <p>1. Identify Required Change to Clinical Decision Support Logic</p> <ul style="list-style-type: none"> As vaccination recommendations change or new vaccinations are accepted, information in the IIS must be updated to reflect the changes in clinical decision support logic IIS staff must identify specifically what needs to be changed to align with updated recommendations <p>2. Update Vaccine Rules</p> <ul style="list-style-type: none"> When ACIP recommendations for a specific vaccine change (e.g., a booster recommended after 10 years), vaccine rules in the system must be updated to reflect the revised recommendation For new vaccines (e.g., vaccine for HPV prevention), ACIP recommendations for targeted population, dosage scheduling, etc. must be added into the system to provide the basis for patient vaccination forecasts. These rules inform IIS users what vaccine to administer and when 	<p>3. Develop Test Cases</p> <ul style="list-style-type: none"> Once changes have been made in the system, substantial testing must be performed in a test environment prior to transition to production Test cases are developed to test the interaction between the new or modified vaccine data and existing immunization data to ensure expected results are achieved <p>4. Test Changes; 5. Successful?; 6. Move Clinical Decision Support Logic to Production</p> <ul style="list-style-type: none"> Once the test cases are successfully completed and effectiveness and stability are demonstrated, the clinical decision support logic can be moved over to the production environment and incorporated into vaccine forecasts If one or more test cases failed, the coding is updated and the test cases are completed again
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Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Manage Forecasting Rules	Update Vaccine Rules	Support a rules based vaccine clinical decision support algorithm	Algorithm must be able to support minimal intervals, recommended intervals, overdue intervals, and both vaccine specific recommendations from ACIP but also general recommendations
2	Manage Forecasting Rules	Update Vaccine Rules	Have ability to apply effective dates to vaccine rules	Utilizing effective beginning and end dates, and accommodating for previous and future timeframes
3	Manage Forecasting Rules	Update Vaccine Rules	Have ability to sort rules by category	i.e., Family, vaccine, date added, etc.
4	Manage Forecasting Rules	Update Vaccine Rules	Have ability to maintain historical records of effective dates of previous forecast schedules	
5	Manage Forecasting Rules	Update Vaccine Rules	Have ability to review/apply an immunization schedule that was appropriate at the time of administration	Immunization schedules change over time
6	Manage Forecasting Rules	Update Vaccine Rules	Allow IIS system staff to update the rules based on vaccine clinical support logic	The capability for immunization program staff to add or modify schedules in the IIS
7	Manage Forecasting Rules	Update Vaccine Rules	Have the ability to incorporate new vaccine codes into the IIS and the forecasting algorithm	
8	Manage Forecasting Rules	Update Vaccine Rules	Generate an accurate and immediate forecast based on patient age and immunizatory history contained in the IIS	The patient-specific forecast is generated 'fresh' each time the record is opened; i.e., forecasts are dynamic displays, not static or saved from one record viewing to the next
9	Manage Forecasting Rules	Develop Test Cases	Allow user to create and save test cases for reuse	Most test changes are manually performed during user acceptance testing
10	Manage Forecasting Rules	Test Changes	Exist in a test environment that exactly mirrors the production environment	Ideally, the vendor provides four instances of the IIS application, all in environments as nearly identical as possible: development, testing, training and production. In addition, you may have a data warehouse or other secondary database for generating large reports.
11	Manage Forecasting Rules	Test Changes	Allow IIS staff access to test environment	
12	Manage Forecasting Rules	Successful?	Allow user to compare the expected results of the test case to the results observed by the tester	

Functional Requirements for IIS Collaborative Requirements Development Project

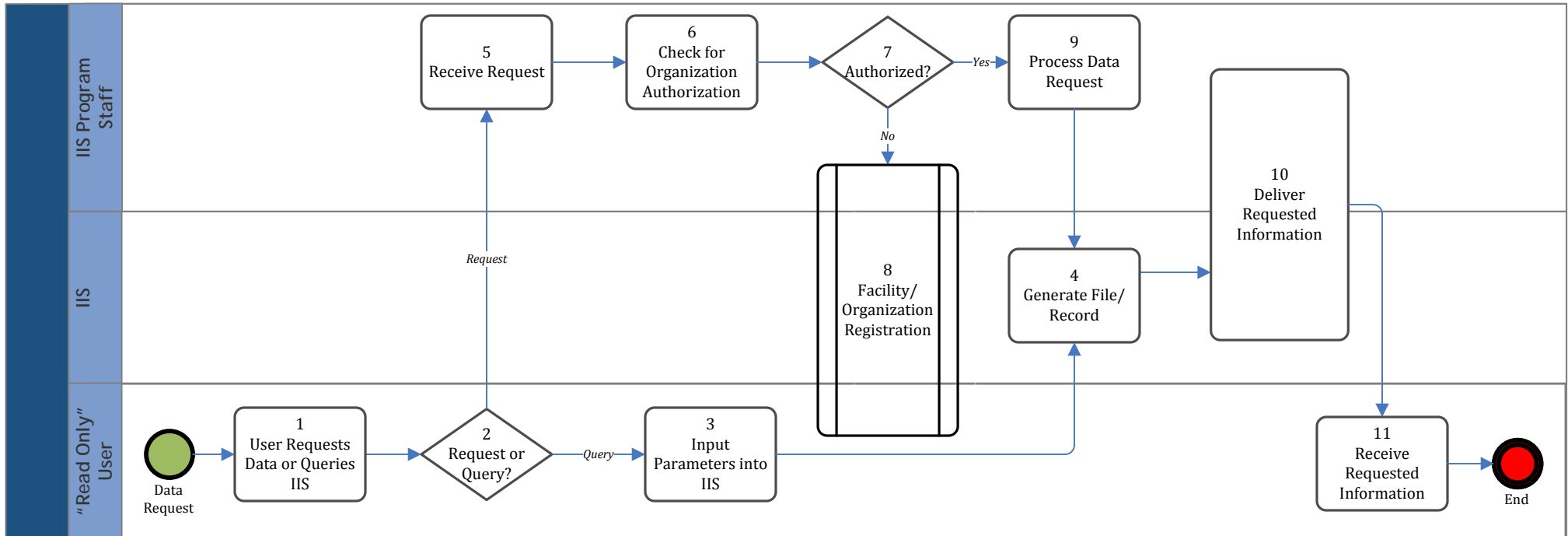
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
13	Manage Forecasting Rules	Move Clinical Decision Support Logic to Production	Have ability to deploy updated/new clinical decision support logic to production environment in a timely way	
14	Manage Forecasting Rules	Move Clinical Decision Support Logic to Production	Support ability to notify end users of updated/new clinical decision support logic according to federal, state, and local laws, regulations and policies	i.e., Email, posting on user home page, etc.

IIS Collaborative Requirements Development Project

Business Process Matrix

“Read Only” Data Exchange

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To provide authorized users with appropriate access to data elements based on user roles 	<ul style="list-style-type: none"> • User authorization • User roles • Legal authority • State/local policies 	<ul style="list-style-type: none"> • Data request • HEDIS reporting • Compliance by schools • CDC sentinel • AFIX CoCASA assessment • Research • Outbreak investigation • Perinatal Hep B follow-up • School users (query only) • WIC/child welfare programs 	<ol style="list-style-type: none"> 1. User Requests Data or Queries IIS 2. Request or Query? 3. Input Parameters into IIS 4. Generate File/Record 5. Receive Request 6. Check for Organization Authorization 7. Authorized? 8. Facility/ Organization Registration 9. Process Data Request 10. Deliver Requested Information 11. Receive Requested Information 	<ul style="list-style-type: none"> • Data parameters • Completed data request forms 	<ul style="list-style-type: none"> • Report generation 	<ul style="list-style-type: none"> • Number of records appropriately viewed or successful queries • Appropriate users receive accurate, timely data to meet their needs • Match rate with patient data is determined • Number of successful patient record searches • Percentage of active authorized users within a certain timeframe



Activity Details / Narrative

General Process Notes
Objective:

- To provide authorized users with appropriate access to data elements based on user roles

Measurable Outcomes:

- Number of records appropriately viewed or successful queries
- Appropriate users receive accurate, timely data to meet their needs
- Match rate with patient data is determined
- Number of successful patient record searches
- Percentage of active authorized users within a certain timeframe

General Notes:

- Immunization providers may include Physicians, Nurses, Pharmacists, Nurse Practitioners, Physician’s Assistants, Medical Students, etc.

Activity Description:

- User Requests Data or Queries IIS**
 - A “Read Only” user submits a specific electronic request for data, including the particular parameters they want
- Request or Query?**
 - The user will decide if they are going to perform the action as a query within the IIS or if they need to submit a data request to the IIS system staff to retrieve the data
- Input Parameters into IIS**
 - The user inputs their chosen parameters into the system
- Generate File/Record**
 - Using the parameters defined either by IIS staff or by the “Read Only” user, the IIS will generate the requested file/report
- Receive Request**
 - IIS staff receives the data request submitted by the “Read Only” user
- Check for Organization Authorization**
 - The IIS staff verifies that the user making the request is an authorized IIS enrolled user and/or has an up-to-date data sharing agreement in place
- Authorized?**
 - Based on the review of the current list of authorized users, the IIS staff determines if the user is authorized and is able to receive requested data or if they must first be registered through the facility/ organization registration process
- Facility/Organization Registration**
 - Predefined process
- Process Data Request**
 - IIS staff processes the data request and defines the parameters of the report to be generated
- Deliver Requested Information**
 - The IIS system and/or staff delivers the file/report to the requesting user
 - The file could be sent to the requestor to display in a new window, be deposited in a secure “inbox” for later pick-up, or by means based on local IIS policies and preferences
- Receive Requested Information**
 - The “Read Only” user receives the file/ report

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	"Read Only" Data Exchange	User Requests Data or Queries IIS	Have ability to perform a patient record query based on one or multiple user-defined parameters	
2	"Read Only" Data Exchange	User Requests Data or Queries IIS	Support a maximum query response time of (X) seconds	
3	"Read Only" Data Exchange	User Requests Data or Queries IIS	Have ability to produce an exact patient record match using user defined criteria	
4	"Read Only" Data Exchange	User Requests Data or Queries IIS	Have ability to display or print record	The printed report should not include patient address or SSN
5	"Read Only" Data Exchange	User Requests Data or Queries IIS	Support a patient record query algorithm to return "best matches"	
6	"Read Only" Data Exchange	User Requests Data or Queries IIS	Have ability to display possible matches	As allowed by local policy
7	"Read Only" Data Exchange	User Requests Data or Queries IIS	Allow user to re-query for a patient record by modifying current query parameters	
8	"Read Only" Data Exchange	User Requests Data or Queries IIS	Allow user to query using a search string and/or filter	
9	"Read Only" Data Exchange	User Requests Data or Queries IIS	Allow user to select a patient record from the list of possible matches	
10	"Read Only" Data Exchange	User Requests Data or Queries IIS	Support an online data request form	Data request from a "read only" user
11	"Read Only" Data Exchange	User Requests Data or Queries IIS	Provide online instructions to "read only" user on how to create and submit a data request	
12	"Read Only" Data Exchange	Input Parameters into IIS	Have ability to store report templates using past user defined parameters or IIS defined parameters	
13	"Read Only" Data Exchange	Input Parameters into IIS	Allow user to select from a list of predefined reports	
14	"Read Only" Data Exchange	Input Parameters into IIS	Allow user to choose parameters for reports	Can be used to create a custom report or as additional parameters for predefined reports
15	"Read Only" Data Exchange	Generate File/Record	Have ability to generate file/record in format specified by user defined parameters	

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
16	"Read Only" Data Exchange	Receive Request	Have ability to receive an electronic data request	Includes justification for request, match file, and required parameters
17	"Read Only" Data Exchange	Check for Organization Authorization	Have ability to query and view the system's existing users/authorization agreements	
18	"Read Only" Data Exchange	Check for Organization Authorization	Allow IIS program staff to send unauthorized users referral communications to facility/organization registration	
19	"Read Only" Data Exchange	Facility/Organization Registration	SEE FACILITY/ORGANIZATION REGISTRATION REQUIREMENTS	
20	"Read Only" Data Exchange	Process Data Request	Have ability to generate an ad hoc report based upon selected parameters	
21	"Read Only" Data Exchange	Process Data Request	Have ability to display and/or aggregate data based on user role	
22	"Read Only" Data Exchange	Process Data Request	Have ability to perform a statistical analysis on existing data	
23	"Read Only" Data Exchange	Deliver Requested Information	Support secure file transfer	
24	"Read Only" Data Exchange	Deliver Requested Information	Have ability to display data on user's screen	
25	"Read Only" Data Exchange	Deliver Requested Information	Have ability to send or export multiple file formats	HL7, CSV, PDF
26	"Read Only" Data Exchange	Deliver Requested Information	Have ability to deliver/export graphical data displays	
27	"Read Only" Data Exchange	Receive Requested Information	Have ability to receive and log message in multiple formats	HL7, ACKs
28	"Read Only" Data Exchange	Receive Requested Information	Have ability to run and save multiple file formats	HL7, CSV, PDF
29	"Read Only" Data Exchange	Receive Requested Information	Have ability to log user receipt of files	

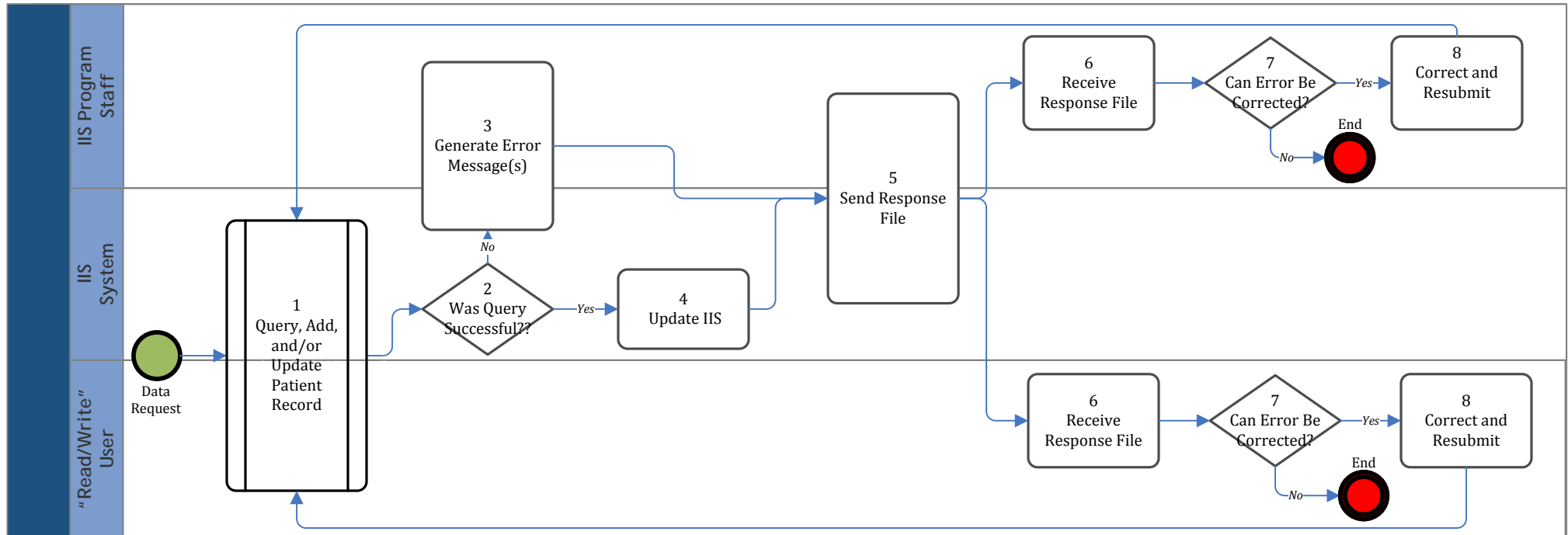
IIS Collaborative Requirements Development Project

Business Process Matrix

Data Exchange Response/Output

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To provide to and/or receive data from authorized users based on user roles • To accept data from data sharing partners (i.e. vital records, birthing hospitals, DOE, etc.) 	<ul style="list-style-type: none"> • User authorization • User roles • Legal authority • State/local policies 	<ul style="list-style-type: none"> • Administer vaccine • Enter patient history • New record • Patient record update • Vital records amendment • Change in patient status (change in provider jurisdiction) • Adverse event 	<ol style="list-style-type: none"> 1. Query, Add, and/or Update Patient Record 2. Was Query Successful? 3. Generate Error Message(s) 4. Update IIS 5. Send Response File 6. Receive Response File 7. Can Error Be Corrected? 8. Correct and Resubmit 	<ul style="list-style-type: none"> • Data request form • Core data elements • Consent indicators 	<ul style="list-style-type: none"> • Immunization record and forecast • Reports • ACK/error messages 	<ul style="list-style-type: none"> • Number of appropriately filled requests • Number of records appropriately viewed or successful queries • Appropriate users receive accurate, timely data to meet their needs • Match rate with patient data is determined • Number of successful patient record searches • Percentage of active authorized users within a certain timeframe • Number of records added

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
						<ul style="list-style-type: none">• Number of records updated• Number of data elements deleted



Activity Details / Narrative

General Process Notes

Objective:

- To provide to and/or receive data from authorized users based on user roles
- To accept data from data sharing partners (i.e. vital records, birthing hospitals, DOE, etc.)

Measurable Outcomes:

- Number of appropriately filled requests
- Number of records appropriately viewed or successful queries
- Appropriate users receive accurate, timely data to meet their needs
- Match rate with patient data is determined
- Number of successful patient record searches
- Percentage of active authorized users within a certain timeframe
- Number of records added
- Number of records updated
- Number of data elements deleted

General Notes:

- Immunization providers may include Physicians, Nurses, Pharmacists, Nurse Practitioners, Physician's Assistants, DoD Paraprofessionals, Medical Students, etc.

Activity Description:

1. Query, Add, and/or Update Patient Record

- Predefined process

2. Was Query Successful?

- The IIS determines if the user query was successful and yielded results

3. Generate Error Message(s)

- If the query was unsuccessful, the IIS system or staff will create an error message to inform the user of their query results and how to fix the issue

4. Update IIS

- If the query was successful, the IIS is updated with the new information and it is displayed to the user

5. Send Response File

- The IIS system and or staff sends the response file
- The response file includes an error message and how to correct the error

6. Receive Response File

- The "read/write" user receives the response file and analyzes it to determine next steps

7. Can Error Be Corrected?

- The user determines if the error indicated in the error message can be corrected by user staff
- If the error cannot be corrected, the user may have the vendor staff come in to attend to the issue

8. Correct and Resubmit

- This task can include data quality work by IIS and user staff to correct both consistent or episodic problems

Functional Requirements for IIS Collaborative Requirements Development Project

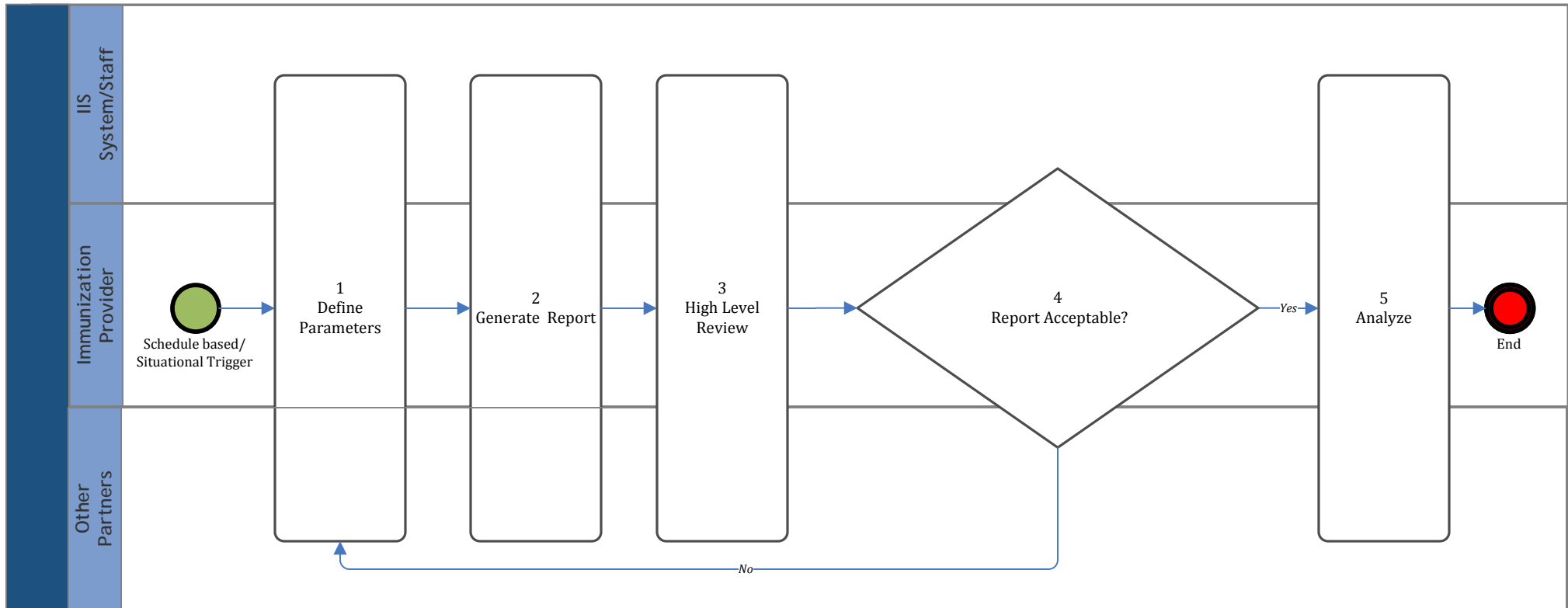
ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Data Exchange Response/Output	Query, Add, and/or Update Patient Record	SEE QUERY, ADD, AND/OR UPDATE PATIENT RECORD	
2	Data Exchange Response/Output	Generate Error Message(s)	Have the ability to generate accurate error message in appropriate format in case of a record query failure	
3	Data Exchange Response/Output	Update IIS	Have ability to automatically accept data and update a patient record	
4	Data Exchange Response/Output	Send Response File	Have ability to create and send error messages in designated formats	HL7, etc. Successful and unsuccessful messages, types of errors identified, etc.
5	Data Exchange Response/Output	Send Response File	Have ability to log error or acknowledgement messages	
6	Data Exchange Response/Output	Send Response File	Have ability to filter or sort error or acknowledgement messages	
7	Data Exchange Response/Output	Receive Response File	Have ability to view response files	
8	Data Exchange Response/Output	Receive Response File	Have ability to log user views of received response files	
9	Data Exchange Response/Output	Can Error Be Corrected?	Allow IIS staff to view current and past error message(s) for a user	Used to evaluate if the user needs training to Query, Add, and/or Update Patient Record or to read error messages
10	Data Exchange Response/Output	Correct and Resubmit	Allow user to manually modify a data error in the IIS and resubmit the record	

IIS Collaborative Requirements Development Project

Business Process Matrix

User Report Generation

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To provide the ability to access and analyze data to improve immunization coverage and meet other programmatic goals 	<ul style="list-style-type: none"> • Federal, state, and local rules • Immunization program rules • User permissions • Provider rules 	<ul style="list-style-type: none"> • Request for data (ex. IIS Annual Report) • Grant application • Progress report • Scheduled reports (ex. monthly, quarterly, etc.) • Site visit • Public health emergency • Publicly purchased vaccines audit 	<ol style="list-style-type: none"> 1. Define Parameters 2. Generate Report 3. High Level Review 4. Report Acceptable? 5. Analyze 	<ul style="list-style-type: none"> • Parameters/ criteria 	<ul style="list-style-type: none"> • Reports 	<ul style="list-style-type: none"> • Increased coverage rates • Provision of reports/ response to requests from partners and other public health agencies in a timely manner • Identification of data trends (i.e., data quality, program measures, etc.)



Activity Details / Narrative	<p>General Process Notes</p> <p>Objective:</p> <ul style="list-style-type: none"> To provide the ability to access and analyze data to improve immunization coverage and meet other programmatic goals <p>Measurable Outcomes:</p> <ul style="list-style-type: none"> Increased coverage rates Provision of reports/response to requests from partners and other public health agencies in a timely manner Identification of data trends (i.e., data quality, program measures, etc.) <p>General Notes:</p> <ul style="list-style-type: none"> This process outlines the general process to generate a variety of reports that are routinely needed by IIS, providers, and other partners <ul style="list-style-type: none"> Examples of reports include: Coverage/ Pocket of Need, Reminder/Recall, VFC Doses Administered, Patient List, Ad Hoc, Vaccine Uptake, Public vs. Private Doses, School Reports, Research Project Reports, Organization Participation, A133 <p>Activity Description:</p> <p>1. Define Parameters</p> <ul style="list-style-type: none"> Provider organizations, IIS, or other partners may define specific parameters such as: age groups, vaccine series, a specific vaccine grouping (such as 4th Dtap), or other parameters <p>2. Generate Report</p> <ul style="list-style-type: none"> The immunization program or other partners query the IIS with the defined criteria and receive a report from the IIS <p>3. High Level Review</p> <ul style="list-style-type: none"> Immunization program staff or other users with appropriate role based access review the report to validate the information <p>4. Report Acceptable?</p> <ul style="list-style-type: none"> Immunization program staff, provider, or other partners determine if the report meets their objective/purpose and is correct <p>5. Analyze</p> <ul style="list-style-type: none"> Provider, immunization program staff, or other partners analyze the data. The data is then leveraged to increase coverage rates, evaluate providers, reallocate vaccines, etc.
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Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	User Report Generation	Define Parameters	Allow user to select parameters	Time, age, race/ethnicity, jurisdiction, vaccine grouping (vaccine grouping of failing codes), vaccine dose count, specific program codes, other program codes, etc.
2	User Report Generation	Define Parameters	Allow user to select report output parameters	Display options, summary vs. detail report, sort options, alphanumeric vs. date, etc.
3	User Report Generation	Define Parameters	Allow user to choose a report generation timeframe	i.e., Run now or set the time for later
4	User Report Generation	Define Parameters	Have ability for system to determine if the report can be immediately generated or if it must be delayed based on size	i.e., Based on types of criteria, based on size of data, etc.
5	User Report Generation	Define Parameters	Have ability to prompt user to confirm the generation of a report at a later time if required	
6	User Report Generation	Generate Report	Have ability to save, display, or print report	
7	User Report Generation	Generate Report	Have ability to produce reports in multiple formats	i.e., Text delimited file, etc.
8	User Report Generation	Generate Report	Allow user to delete a report	Based on user roles
9	User Report Generation	Generate Report	Allow user to delete and/or modify data elements within a report	Lets the user modify report based on the audience
10	User Report Generation	Generate Report	Have ability to generate the report based on the parameters set	
11	User Report Generation	Report Acceptable?	Allow user to return to and modify report criteria	
12	User Report Generation	Analyze	Have ability to verify that the report is in the correct format	
13	User Report Generation	Analyze	Have ability to send by email	Regular and secure email
14	User Report Generation	Analyze	Have ability to export data in selected file formats	
15	User Report Generation	Analyze	Be interoperable with a statistical analysis software	

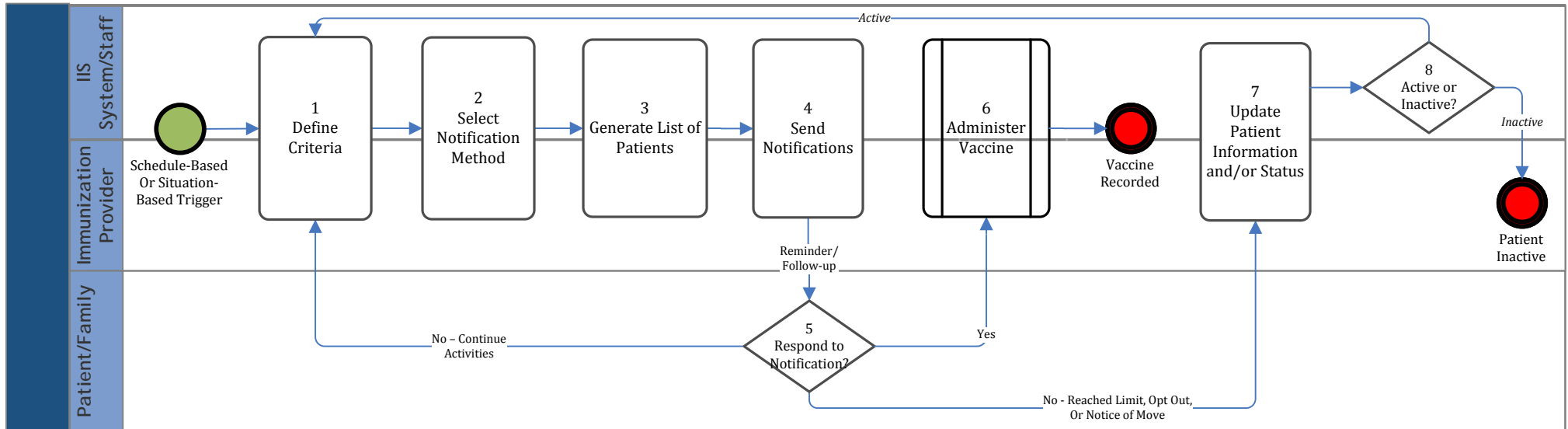
IIS Collaborative Requirements Development Project

Business Process Matrix

Patient Reminder/Recall

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • For an immunization program to communicate if a patient is due now, due on future date, or past due for an immunization to the patient or parent/guardian • For a provider or other organization to communicate if a patient is due now, due on future date, or past due for an immunization, based on the patient's population, to the patient or parent/guardian 	<ul style="list-style-type: none"> • ACIP recommendations • MMWR publications • Provider protocol • State and local protocol • Federal, state, and local policies and regulations • MIROW guidelines 	<ul style="list-style-type: none"> • Occurrence of a public health event • Recommended immunization time frames • Immunization program initiatives • School requirements • Vaccine shortages • Vaccine recall • Revaccination • Low population coverage rates 	<ol style="list-style-type: none"> 1. Define Criteria 2. Select Notification Method 3. Generate List of Patients 4. Send Notifications 5. Respond to Notification? 6. Administer Vaccine 7. Update Patient Information and/or Status 8. Active or Inactive? 	<ul style="list-style-type: none"> • Patient immunization history and/or forecast • Public health event information • Patient demographics • Patient status (death, opt out, MOGE) 	<ul style="list-style-type: none"> • Notification of candidates • Lists of immunization candidates • Reports 	<ul style="list-style-type: none"> • Number of notifications sent • Percentage of patients that receive an immunization • Number of patient status changes to inactive (MOGE) • Number of providers or organizations generating reminder/recalls from the IIS • Percentage of increase of coverage for target populations • Number of patients who receive vaccine versus number of notifications • Number of patients who

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
						have not responded to X number of follow-up notification attempts



Activity Details / Narrative

General Process Notes

Objective:

- For an immunization program to communicate if a patient is due now, due on future date, or past due for an immunization to the patient or parent/guardian
- For a provider or other organization to communicate if a patient is due now, due on future date, or past due for an immunization, based on the patient's population, to the patient or parent/guardian

Measurable Outcomes:

- Number of notifications sent
- Percentage of patients that receive an immunization
- Number of patient status changes to inactive (MOGE)
- Number of providers or organizations generating reminder/recalls from the IIS
- Percentage of increase of coverage for target populations
- Number of patients who receive vaccine versus number of notifications
- Number of patients who have not responded to X number of follow-up notification attempts

General Notes:

- Immunization reminders and recalls communicate to an individual or responsible party that the individual is due, due on a future date, or past due for an immunization
- The process can be initiated by a provider, a health plan, or a state or local public health entity
- One reminder and up to three follow-up notifications may be sent
- A reminder/recall notification may be sent with up to three follow up notifications per patient

Activity Description:

1. Define Criteria

- The provider can set filter criteria in the IIS system to identify patients who are due or overdue for vaccinations. Such filters could include age range, physician, vaccine type, vaccine lot number or geographic area
- Situation-based triggers can also be used to identify priority groups as a result of a public health event (e.g. measles outbreak), patients that are overdue for a vaccine as a result of a shortage, those recommended to receive a new vaccine, individuals residing in a specified geographic area (zip code, city boundaries), or populations with a high risk status

2. Select Notification Method

- Notification method is selected for the whole list of candidates or separately for individual patients in the list. Methods could include text messages, emails, letters, calls, postcards, or home visits
- Some IISs only have a single notification method, eliminating the need for this step

3. Generate List of Patients

- A target list of potential patients is created based on the filter criteria
- If resources are limited, patient lists can be further filtered using additional criteria

4. Send Notifications

- Notifications are distributed to designated recipients

5. Respond to Notification?

- If no response is received within X number of days, another reminder can be sent out
- Lack of response may result in the patient remaining on the list as a candidate and receiving follow-up notifications
- If the patient responds to the notification, an appointment for past due vaccinations is scheduled or patient status is updated

5. Respond to Notification? Cont.

- After a set number of notifications, activities will cease due to inactivity and the patient's status will be updated. If a patient moves outside of the jurisdiction or does not provide a forwarding address, a status change to "inactive" will be triggered as well

6. Administer Vaccine

- Pre-defined process

7. Update Patient Information and/or Status

- When attempts have been made to contact the patient but no documented response is received or documentation is received that the patient is no longer in the jurisdiction, the patient's status is changed to inactive in the IIS, which stops future contact attempts

8. Active or Inactive?

- The IIS determines from the patient record update whether to inactivate the record, or if the record remains active, to cycle the patient record back to the beginning of this process

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Patient Reminder/Recall	Define Criteria	Allow user to select reminder/recall parameters	May include but not limited to: age range, vaccine type(s)/series, lot number, geographic area, etc.
2	Patient Reminder/Recall	Define Criteria	Have ability to associate a patient with a clinic/site	To generate a provider based reminder/recall
3	Patient Reminder/Recall	Select Notification Method	Allow user to select one or more notification methods	Telephone call, "robo call", text message, letter, postcard, labels, email, etc.
4	Patient Reminder/Recall	Generate List of Patients	Have ability to produce a list of patients according to user defined parameters	
5	Patient Reminder/Recall	Generate List of Patients	Have ability to print the list of patients	
6	Patient Reminder/Recall	Generate List of Patients	Have ability to log each time a user generates a list of patients	
7	Patient Reminder/Recall	Generate List of Patients	Have the ability to display the date the reminder/recall notice was sent to a patient	Including date
8	Patient Reminder/Recall	Generate List of Patients	Allow the end user to set and/or modify the reminder/recall count limit	Limits the number of times a patient receives a reminder/recall per year
9	Patient Reminder/Recall	Generate List of Patients	Allow user or system administrator to set upper limit for the number of times a reminder/recall will be generated and sent without a patient response	
10	Patient Reminder/Recall	Generate List of Patients	Prevent sending notifications to patients who have met the "count" limit of reminder/recall	
11	Patient Reminder/Recall	Generate List of Patients	Prevent all records given an inactive status from being included in the list of patients for reminder/recall	
12	Patient Reminder/Recall	Send Notifications	Have ability to generate electronic notifications	
13	Patient Reminder/Recall	Send Notifications	Have ability to send electronic notifications	
14	Patient Reminder/Recall	Send Notifications	Use list to print mail labels, letters, postcards based on user choice	
15	Patient Reminder/Recall	Administer Vaccine	SEE ADMINISTER VACCINE REQUIREMENTS	

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
16	Patient Reminder/Recall	Update Patient Information and/or Status	Have ability to track notification attempts and log back to a patient's record	
17	Patient Reminder/Recall	Update Patient Information and/or Status	Allow user to select notification opt out on a patient record	
18	Patient Reminder/Recall	Update Patient Information and/or Status	Have ability to update/save patient status	Including change of address. Status should comply with AIRA/MIROW guide for active/inactive status
19	Patient Reminder/Recall	Active or Inactive?	Have ability to recognize and include active records for future notifications	

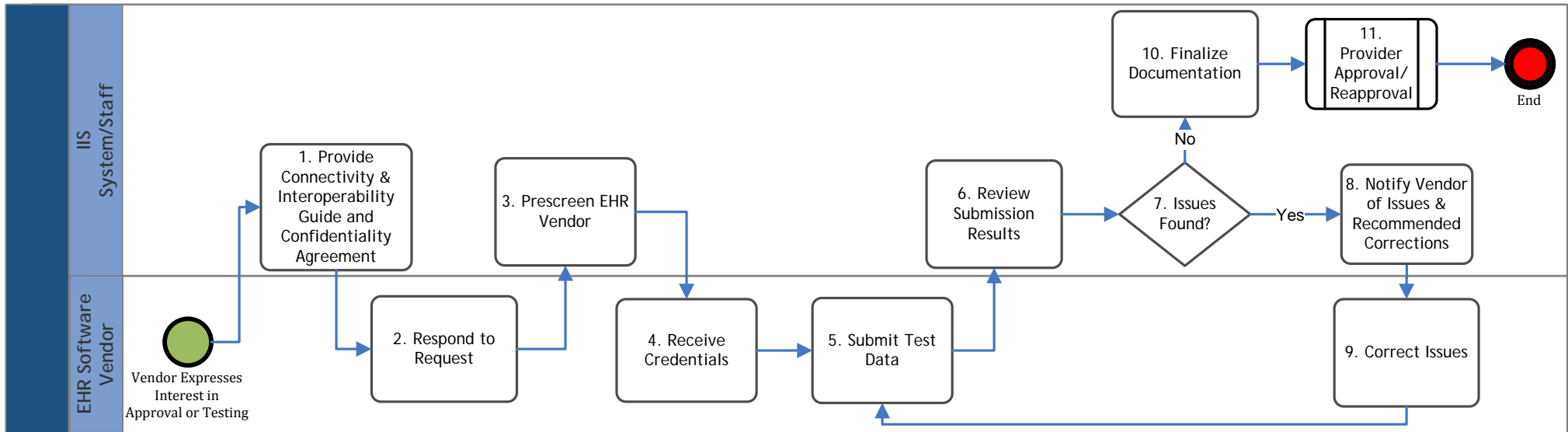
IIS Collaborative Requirements Development Project

Business Process Matrix

EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To approve an EHR system for exchanging data with an IIS on a bidirectional and real-time basis • To test EHR data files submitted by pilot sites and correct issues identified in the test files • To verify that the message transport operates correctly and is supported by the EHR • To ensure that HL7 messages are formatted correctly • To ensure that the EHR can provide information needed for the provider using the EHR • To verify the EHR 	<ul style="list-style-type: none"> • Standards-based implementation guides, profiles or interoperability specifications for immunization data • AIRA/CDC/MIROW functional standards and best practice guidelines for IIS • Patient data security and privacy (state/ local immunization data sharing laws; HIPAA, FERPA) • Data sharing agreements between entities • National immunization policy recommendations and guidelines (ACIP, NVAC, CDC, AAP, AAFP, ONC) • IIS local rules (e.g., 	<ul style="list-style-type: none"> • EHR vendor or provider expresses interest in testing/approval by an IIS • EHR migration to a new version of HL7 implementation guide • Significant change in the EHR functional interface • Significant increase in errors of provider production data • Significant change to IIS functionality 	<ol style="list-style-type: none"> 1. Provide Connectivity & Interoperability Guide and Confidentiality Agreement 2. Respond to Request 3. Prescreen EHR Vendor 4. Receive Credentials 5. Submit Test Data 6. Review Submission Results 7. Issues Found? 8. Notify Vendor of Issues & Recommended Corrections 9. Correct Issues 10. Finalize Documentation 11. Provider Approval/ Reapproval 	<ul style="list-style-type: none"> • Vaccine data from pilot sites • EHR Vaccine data from the IIS • Vendor data • Access credentials • Confidentiality agreement • Implementation guides • National standards • List of providers that are using the EHR software version in a jurisdiction 	<ul style="list-style-type: none"> • Error report/feedback from IIS to the EHR vendor • EHR vendor approval 	<ul style="list-style-type: none"> • Number of EHR vendors that successfully complete testing • Number of successful EHR system approvals • Annual percentage of providers in a jurisdiction using an approved EHR system

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<p>system can support acknowledgements, responses, and errors</p> <ul style="list-style-type: none"> • To verify that an EHR can display a consolidated record • To verify that an EHR can integrate and de-duplicate data • To verify that an EHR can display vaccine forecast information 	<p>do not accept adults)</p>					



Activity Details / Narrative	<p>General Process Notes</p> <p>Objective:</p> <ul style="list-style-type: none"> To approve an EHR system for exchanging data with an IIS on a bidirectional and real-time basis To test EHR data files submitted by pilot sites and correct issues identified in the test files To verify that the message transport operates correctly and is supported by the EHR To ensure that HL7 messages are formatted correctly To ensure that the EHR can provide information needed for the provider using the EHR To verify the EHR system can support acknowledgements, responses, and errors To verify that an EHR can display a consolidated record To verify that an EHR can integrate and de-duplicate data To verify that an EHR can display vaccine forecast information <p>Measurable Outcomes:</p> <ul style="list-style-type: none"> Number of EHR vendors that successfully complete testing Number of successful EHR system approvals Annual percentage of providers in a jurisdiction using an approved EHR system 	<p>Activity Description:</p> <p>1. Provide Connectivity & Interoperability Guide and Confidentiality Agreement</p> <ul style="list-style-type: none"> The IIS staff will provide the vendor with the information to create the systems connectivity & interoperability guide and a confidentiality agreement Documents that may be included are: HL7 Implementation Guide, Recommended Fields, Validation Recommendations, Coding Samples, Installation Use Examples, etc. The signing of a confidentiality agreement may not occur in this step if the testing occurs in a test environment The systems interoperability plan may include: recommended field inclusion, decision support inclusion, error message management, etc. The vendor is informed of the specific transport/certificate that is required <p>2. Respond to Request</p> <ul style="list-style-type: none"> The vendor signs the confidentiality agreement and returns it to IIS The vendor may also submit a completed connectivity & interoperability plan and materials to receive connection credentials (e.g., digital certificate request) <p>3. Prescreen EHR Vendor</p> <ul style="list-style-type: none"> In this process the IIS system/staff will collect initial data about the EHR's processes If the EHR vendor has passed the NIST Certification (National Institute of Standards and Technology) they may skip this activity The IIS system/staff will provide the credentials to the EHR vendor needed for the user interface once the prescreen is passed <p>4. Receive Credentials</p> <ul style="list-style-type: none"> The EHR software vendor receives the credentials necessary from the IIS for the EHR user interface to submit data to the IIS The EHR will then establish connectivity with IIS (e.g., ping the server) <p>5. Submit Test Data</p> <ul style="list-style-type: none"> Once the transport mechanism is operational and has been tested with the IIS, the vendor may begin to submit data based on IIS guidelines Data is directly sent to a test environment. The data may be a copy of production data or test data only If an error is found during the data review, the vendor must correct the error and submit new test data Reapproval begins in this step <p>6. Review Submission Results</p> <ul style="list-style-type: none"> The IIS reviews the submitted test data for various formatting and quality measures, including verifying all recommended fields are included, and the number of successful/partial/failed messages are recorded <p>7. Issues Found?</p> <ul style="list-style-type: none"> During the review, the IIS staff will determine if there are errors found in the test data <p>8. Notify Vendor of Issues & Recommended Corrections</p> <ul style="list-style-type: none"> If errors are present, the IIS staff will notify the vendor of the specific issue(s) found and may suggest possible solutions to correct the errors <p>9. Correct Issues</p> <ul style="list-style-type: none"> The vendor will correct the issue(s), then submit new test data for review <p>10. Finalize Documentation</p> <ul style="list-style-type: none"> The IIS system/staff will finalize any documentation regarding the EHR vendor's processes and test data review results <p>11. Provider Approval/Reapproval</p> <ul style="list-style-type: none"> Predefined Process

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Provide Connectivity & Interoperability Guide and Confidentiality Agreement	Have ability to display applicable interoperability guides to the vendor	Could be supplied via email, fax, hosted website, etc. Information that could be included: message types, supported delivery methods, transport layer development guide, etc.
2	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Provide Connectivity & Interoperability Guide and Confidentiality Agreement	Have ability to display agreements to vendor	Agreements could include: confidentiality agreements, etc.
3	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Respond to Request	Have ability to support correspondence between the IIS staff and the vendor	
4	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Respond to Request	Allow the vendor to send documents to the IIS	
5	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Respond to Request	Have ability to request and receive additional information	
6	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Prescreen EHR Vendor	Have ability to capture EHR system details	System detail examples: message type, transport layer detail, error handling, the number of providers currently in the IIS that use this vendor's EHR, completed agreements, other documented reviews by other jurisdictions or NIST, the version of the software to be tested, etc.
7	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Prescreen EHR Vendor	Have ability to view vendor system details	
8	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Receive Credentials	Have ability to create and assign a unique username and password to the vendor and its test facilities	

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
9	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Receive Credentials	Have ability to associate attributes with each unique user name and password to allow the association of individual facilities back to a parent organization	
10	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Receive Credentials	Have ability to provide a digital certificate to each vendor test facility	Can be a manual process
11	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Receive Credentials	Have ability to provide information to populate facility specific data segments in HL7 messages	Can be a manual process. Example data segments: MSH, RX1, etc.
12	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Receive Credentials	Allow user to apply and install credentials for each vendor test facility	Can be a manual process
13	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Receive Credentials	Have ability to validate credentials	
14	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Receive Credentials	Have ability to store transport certificate information	Including expiration date, etc.
15	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Receive Credentials	Have the ability to validate that the transport layer is functional	
16	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Receive Credentials	Have ability to alert the vendor/provider when the certificate for transport is going to expire in X time period	
17	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Submit Test Data	Have ability to validate system connectivity prior to the submission of test data	

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
18	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Submit Test Data	Have ability to receive test data messages from the test facilities	
19	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Review Submission Results	Have ability to replicate the production environment within a test environment	"Clone" the production environment
20	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Review Submission Results	Have ability to create and display test submission summaries	
21	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Review Submission Results	Have ability to document test data submissions	
22	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Review Submission Results	Have ability to make available test data submissions	Can be used to refer back to determine the source of a message error
23	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Review Submission Results	Have ability to identify data formatting errors	
24	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Review Submission Results	Have ability to correct errors	
25	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Notify Vendor of Issues & Recommended Corrections	Have the ability to send back multiple errors in one message to the vendor test facilities	This should occur as soon as the message formatting error is detected by the system. Will quickly allow the vendor to recognize a message error, correct it, and resend the message.
26	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Notify Vendor of Issues & Recommended Corrections	Have ability to provide the vendor with a test message submission summary report	Displays total number of messages submitted, total message submitted with errors, total messages submitted without errors, etc. Can be provided via HL7 message, email, web portal, etc.

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
27	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Notify Vendor of Issues & Recommended Corrections	Allow the vendor to see the detail regarding the processing of test data	Including data rejected due to errors, and data accepted with no errors
28	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Finalize Documentation	Have the ability to display a document of suggested questions to ask the vendor prior to finalizing approval documentation	
29	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Finalize Documentation	Have ability to display an error message to the user if any required data fields are not completed in the final documentation of the vendor's product	
30	EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange	Provider Approval/Reapproval	SEE PROVIDER APPROVAL/REAPPROVAL FOR BIDIRECTIONAL IIS DATA EXCHANGE REQUIREMENTS	

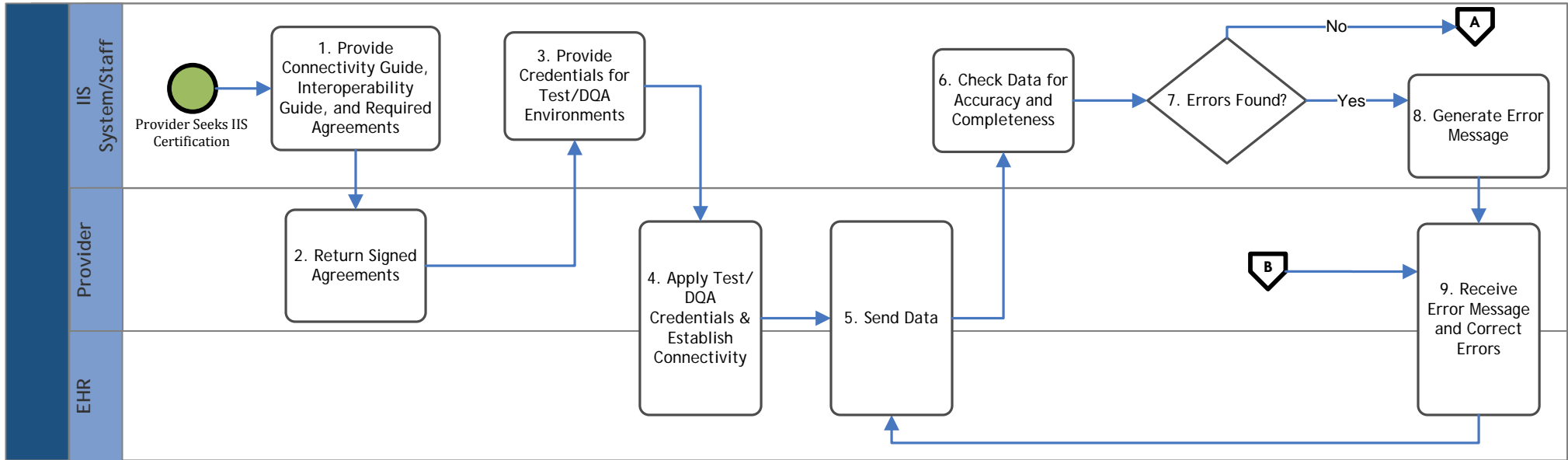
IIS Collaborative Requirements Development Project

Business Process Matrix

Provider Approval/Reapproval for Bidirectional IIS Data Exchange

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To ensure the quality of data loaded into the IIS • To ensure providers are consistently submitting complete and accurate data to the IIS • To examine data for accuracy and completeness • To allow the provider an opportunity to correct errors in the EHR • To approve the provider to begin/continue submitting data to the production IIS database 	<ul style="list-style-type: none"> • Standards-based implementation guides, profiles or interoperability specifications for immunization data • AIRA/CDC/MIROW functional standards and best practice guidelines for IIS • Patient data security and privacy (state/local immunization data sharing law; HIPAA) • Data sharing agreements between entities • National immunization policy recommendations and guidelines (ACIP, NVAC, CDC, AAP, AAFP) • IIS local rules (e.g., do not accept adults) 	<ul style="list-style-type: none"> • A provider expresses interest in participating in an IIS • EHR system updates/new version 	<ol style="list-style-type: none"> 1. Provide Connectivity Guide, Interoperability Guide, and Required Agreements 2. Return Signed Agreements 3. Provide Credentials for Test/DQA Environments 4. Apply Test/DQA Credentials & Establish Connectivity 5. Send Data 6. Check Data for Accuracy and Completeness 7. Errors Found? 8. Generate Error Message 9. Receive Error Message and Correct Errors 10. Conduct Clinical Review Between 	<ul style="list-style-type: none"> • Patient demographics and vaccine data • HL7 messages • Access credentials (organization & site specific) • User and confidentiality agreements • HL7 implementation guide • EHR vendor process documentation • Vendor accountability guides 	<ul style="list-style-type: none"> • Data can be exchanged bidirectionally and in real-time between the IIS and a provider's EHR • Most errors are determined and the provider is informed of the issue(s) • The provider addresses errors 	<ul style="list-style-type: none"> • Number of successful provider certifications within X time period • Percentage of providers that correct all data/vaccination errors following a failed data check • Percentage of providers that complete approval/reapproval • Percentage of providers approved but not yet submitting data • Number of days between approval and first submission

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
			Provider and IIS 11. Clinically Correct and Complete? 12. Generate DQA Report 13. Ready for Production? 14. Notify Provider of Approval 15. Provide Credentials for Production Environment 16. Apply Production Credentials & Establish Connectivity 17. Inform IIS of Go Live Date 18. Go Live 19. IIS Initial Data Quality Monitoring 20. Provider Ongoing Data Quality Monitoring			



Activity Details / Narrative

General Process Notes

Objective:

- To ensure the quality of data loaded into the IIS
- To ensure providers are consistently submitting complete and accurate data to the IIS
- To examine data for accuracy and completeness
- To allow the provider an opportunity to correct errors in the EHR
- To approve the provider to begin/continue submitting data to the production IIS database

Measurable Outcomes:

- Number of successful provider certifications within X time period
- Percentage of providers that correct all data/vaccination errors following a failed data check
- Percentage of providers that complete approval/reapproval
- Percentage of providers approved but not yet submitting data
- Number of days between approval and first submission

Activity Description:

- 1. Provide Connectivity Guide, Interoperability Guide, and Required Agreements**
 - The IIS staff will provide the provider with the information to create the systems connectivity & interoperability plan and confidentiality and user agreements
 - Documents that may be included are: HL7 Implementation Guide, Recommended Fields, Validation Recommendations, etc.
- 2. Return Signed Agreements**
 - The provider signs the confidentiality and user agreements and returns them to IIS
- 3. Provide Credentials for Test/DQA Environments**
 - The IIS staff creates credentials for the provider to use to connect to the test/DQA (Data Quality Assurance) environment
- 4. Apply Test/DQA Credentials & Establish Connectivity**
 - The provider receives the test/DQA credentials and applies them to connect to the IIS system

5. Send Data

- The provider/EHR chooses data/test data and sends the test file to the IIS for review
- A minimum number of messages, determined by jurisdiction, must be submitted and reviewed before approval
- Reapproval begins at this step
- When beginning reapproval, the IIS chooses a subset of data for review that has already been submitted to the IIS

6. Check Data for Accuracy and Completeness

- The IIS reviews the data submitted for accuracy and completeness
- Possible checks include: inclusion of expected data, use of appropriate codes, vaccinations match the appropriate age groups, provider conformity to its individual vaccine distribution, etc.

7. Errors Found?

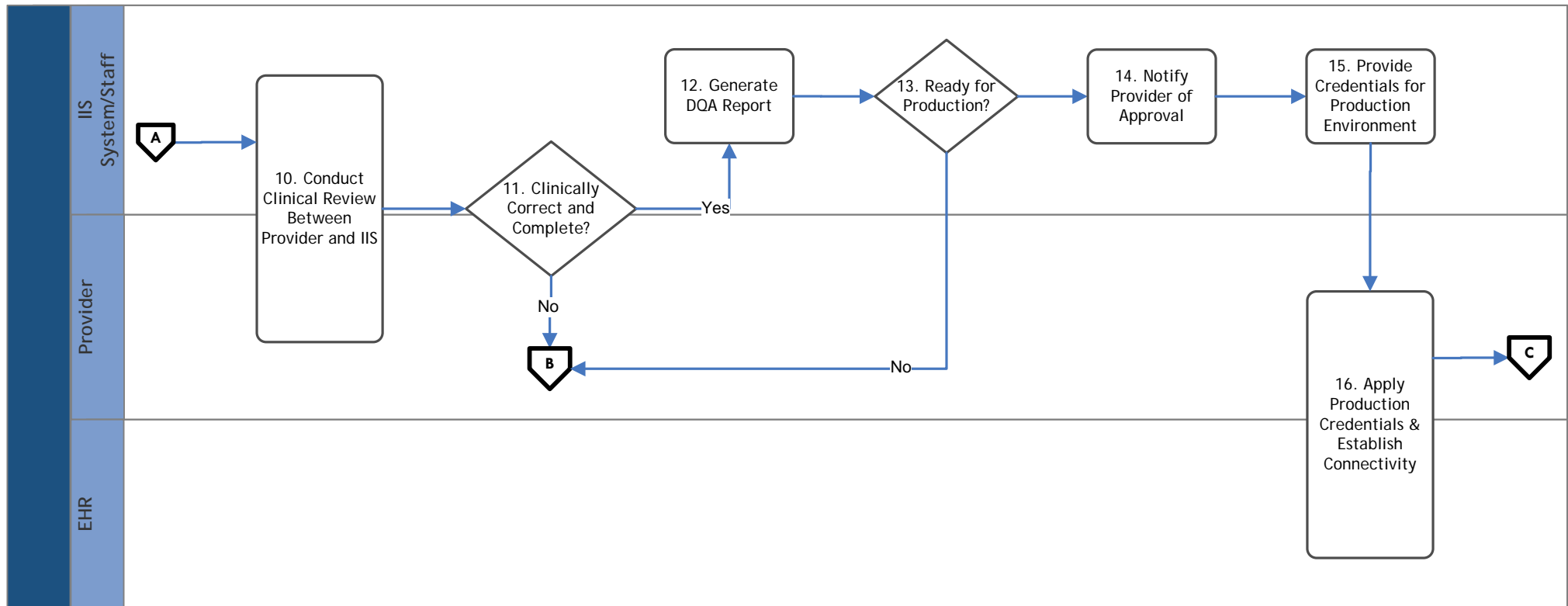
- The IIS determines if any errors are present in data/test data
- Possible error types may include: soft errors, or errors that are recognized but do not prevent the data from being accepted into the IIS database, and hard errors, or errors that require corrections to the data before being accepted into the database

8. Generate Error Message

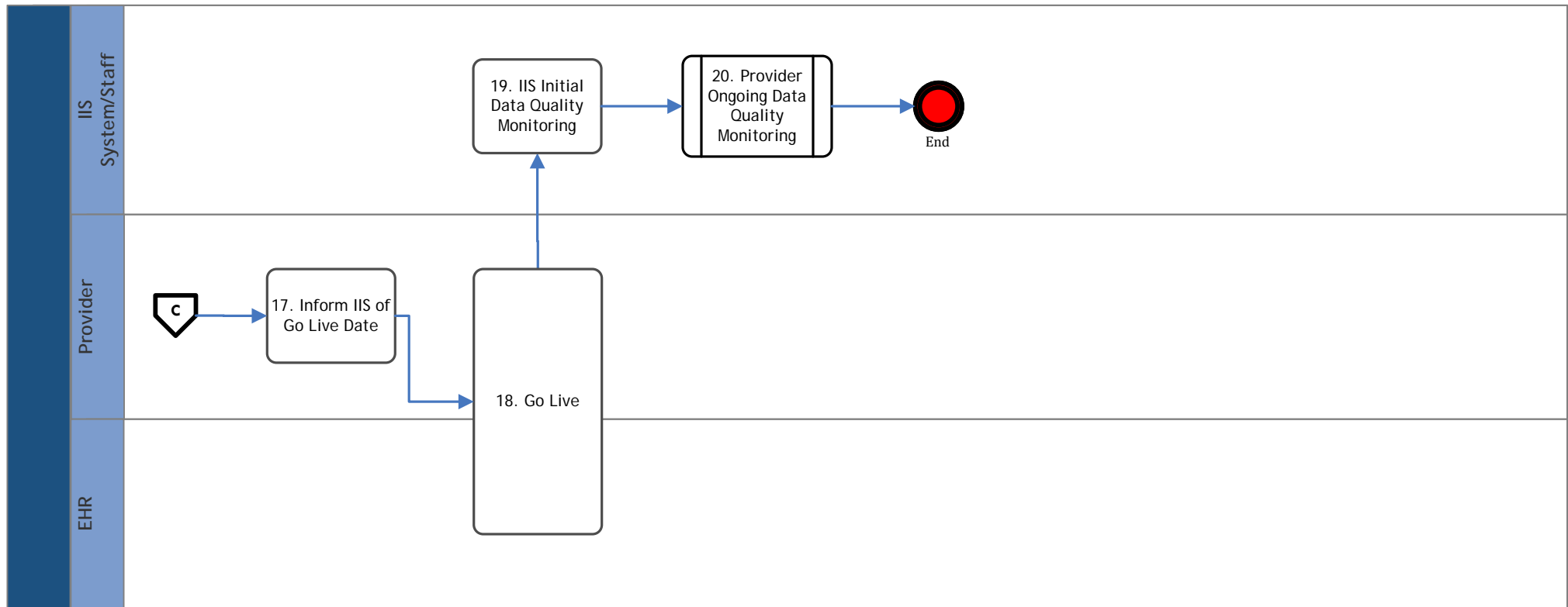
- If errors are found in the data/test data, the IIS generates an error message and sends it to the provider/EHR

9. Receive Error Message and Correct Errors

- The provider/EHR receives the error message and corrects the errors indicated in the message. New data/test data is then submitted for review



Activity Details / Narrative	<p>Activity Description, Cont.:</p> <p>10. Conduct Clinical Review Between Provider and IIS</p> <ul style="list-style-type: none"> Together the IIS staff and provider review the data submitted to the database and compare it to patient clinical records to ensure accuracy The review can consist of reviewing mandatory/optional fields The review may be accomplished by having the provider query specific records within the test environment to verify that the query function is working properly and all data is complete and accurate A minimum number of records, as determined by the jurisdiction, must be thoroughly reviewed before approval 	<p>11. Clinically Correct and Complete?</p> <ul style="list-style-type: none"> The IIS determines if the data is correct and complete based on the clinical review If errors are found, the IIS generates an error message and sends it to the provider <p>12. Generate DQA Report</p> <ul style="list-style-type: none"> The IIS system/staff generate a DQA report. This report is used to further verify completeness and accuracy of data submitted to the IIS by the provider/EHR by locating any remaining issues <p>13. Ready for Production?</p> <ul style="list-style-type: none"> The IIS determines if the provider/EHR are ready for production (i.e., begin submitting data to the production database) 	<p>13. Ready for Production? Cont.</p> <ul style="list-style-type: none"> This decision is based on the accuracy and completeness of data, the clinical review, and the results from the DQA report If the IIS determines the provider/EHR is not ready to go into production based on all evidence, the IIS notifies the provider <p>14. Notify Provider of Approval</p> <ul style="list-style-type: none"> If the IIS determines the provider/EHR is ready for production, the IIS staff notifies the provider of the approval <p>15. Provide Credentials for Production Environment</p> <ul style="list-style-type: none"> The IIS staff creates and sends credentials for the provider/EHR to use to connect to the production database 	<p>16. Apply Production Credentials & Establish Connectivity</p> <ul style="list-style-type: none"> The provider/EHR receives the production credentials and applies them to connect to the IIS system The provider/EHR will send one or more test records to ensure that data is transmitting properly
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Activity Details / Narrative	<p>Activity Description, Cont.:</p> <p>17. Inform IIS of Go Live Date</p> <ul style="list-style-type: none"> The provider determines when they will begin submitting data to the IIS in the approved format and informs the IIS system/staff There is a time-period, determined by jurisdiction, that a provider must apply credentials and begin submitting data to the IIS. If this time period lapses, the provider may be required to go through the approval process again The provider is also informed that no more test data is to be submitted once they go live. This is to prevent test data from being incorrectly classified as production data 	<p>18. Go Live</p> <ul style="list-style-type: none"> The provider/EHR begin submitting data to the production database Legacy data is loaded into the production database at this time The DQA/test credentials are set to expire on the production go live date In some cases, the provider will participate in unidirectional exchange for a period of time, as determined by jurisdiction, to ensure data quality. They can move to bidirectional exchange once the IIS has ensured proper EHR functionality and acceptable data quality <p>19. IIS Initial Data Quality Monitoring</p> <ul style="list-style-type: none"> Once the provider/EHR begin submitting data to the production database, the IIS will continue to monitor the data for accuracy and completeness for a period of time as determined by jurisdiction 	<p>20. Provider Ongoing Data Quality Monitoring</p> <ul style="list-style-type: none"> Pre-defined Process
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Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Connectivity Guide, Interoperability Guide, and Required Agreements	Have the ability to capture vendor and provider information	i.e., Contact information, status of interface development, follow-up activities checklist and support needs, primary contact for HL7 development
2	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Connectivity Guide, Interoperability Guide, and Required Agreements	Have the ability to update and display information	i.e., HL7 interface documentation, provider and vendor information, etc., via website, etc.
3	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Return Signed Agreements	Have the ability to receive and manage signed agreements	i.e., Paper and electronic
4	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Credentials for Test/DQA Environments	Have ability to create and assign a unique username and password for the test/DQA environment	Can be a manual process
5	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Credentials for Test/DQA Environments	Have ability to provide a digital certificate to the provider for the test/DQA environment	Can be a manual process
6	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Credentials for Test/DQA Environments	Have the ability to provide the credentials for the test/DQA environment in a secure message	
7	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Credentials for Test/DQA Environments	Have the ability to provide specific connectivity documentation to the provider/EHR vendor	For the test/DQA environment
8	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Apply Test/DQA Credentials & Establish Connectivity	Allow user to apply and install the test/DQA environment credentials for each provider	Can be a manual process. The IIS can supply technical resources to assist with connectivity
9	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Apply Test/DQA Credentials & Establish Connectivity	Have ability to validate credentials	

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
10	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Send Data	Have ability to validate system connectivity prior to the submission of data	
11	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Send Data	Have ability to receive data messages from the provider	
12	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Check Data for Accuracy and Completeness	Have the ability to process data	Following the HL7 standards and local implementation guidelines
13	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Check Data for Accuracy and Completeness	Have the ability to receive and process data in real-time	
14	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Check Data for Accuracy and Completeness	Have ability to replicate the production environment within a test environment	"Clone" the production environment
15	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Check Data for Accuracy and Completeness	Have ability to create and display test submission summaries	
16	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Check Data for Accuracy and Completeness	Have ability to document test data submissions	
17	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Check Data for Accuracy and Completeness	Have ability to make available test data submissions	Can be used to refer back to determine the source of a message error
18	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Check Data for Accuracy and Completeness	Have ability to identify message errors	

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
19	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Generate Error Message	Have the ability to send back multiple errors in one message to the vendor test facilities	This should occur as soon as the message formatting error is detected by the system. Will quickly allow the vendor to recognize a message error, correct it, and resend the message. Can be provided via HL7 message, email, web portal, etc.
20	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Generate Error Message	Have the ability to report back non-fatal errors to the vendor test facilities	
21	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Generate Error Message	Have ability to provide a test message summary report	Can be provided via HL7 message, email, web portal, etc.
22	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Receive Error Message and Correct Errors	Allow the provider to see the detail regarding the processing of test data	Including data rejected due to errors, data accepted with non fatal errors, and data accepted with no errors
23	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Receive Error Message and Correct Errors	Allow the provider to correct errors	
24	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Conduct Clinical Review Between Provider and IIS	Have the ability to create and display a report of all data in a registry for a patient	"Patient Reconciliation Page" used to compare to provider EHR data to ensure IIS accuracy
25	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Conduct Clinical Review Between Provider and IIS	Have the ability to utilize web conference technology	Used to allow IIS staff and providers to review patient data from different locations
26	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Conduct Clinical Review Between Provider and IIS	Have the ability to display the required data fields	

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
27	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Generate DQA Report	Have ability to create Data Quality Assurance Reports (DQA)	Examples of reports: ad hoc, timed reports, automated, aggregate reports, single patient reports, etc. Possible data to be included: patient vaccinations, inventory management, transport layer, end-user data evaluations, etc.
28	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Generate DQA Report	Have ability to store reports in the IIS	Via email, IIS web portal, etc.
29	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Generate DQA Report	Have ability to display/deliver reports	Via email, IIS web portal, etc.
30	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Ready for Production?	Have the ability to display a report for user review	
31	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Ready for Production?	Have ability to identify errors in a report	i.e., Are there consistent anomalies, has the provider reviewed the report and acted on them, are they re-querying when they do not receive an exact match, etc.
32	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Ready for Production?	Have ability to alert IIS staff if errors are found in a report	
33	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Ready for Production?	Allow user to decide if a report error is an issue that prevents the provider from going live	
34	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Notify Provider of Approval	Allow user to send provider an approval notification	Includes letter of approval, next steps, provider association with other facilities
35	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Credentials for Production Environment	Have ability to create and assign a unique username and password to the provider for the production environment	Can be a manual process

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
36	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Credentials for Production Environment	Have ability to provide a digital certificate to the provider for the production environment	Can be a manual process
37	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Credentials for Production Environment	Have ability to provide information to populate provider specific data segments in HL7 messages	Can be a manual process. Example data segments: MSH, RX1, etc.
38	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Credentials for Production Environment	Have the ability to provide additional information to connect to the production environment	i.e., Production connectivity link, documentation for the production server, etc.
39	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provide Credentials for Production Environment	Have the ability to provide the credentials for the production environment in a secure message	
40	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Apply Production Credentials & Establish Connectivity	Have the ability to provide specific connectivity documentation for the production environment to the provider/EHR vendor	
41	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Apply Production Credentials & Establish Connectivity	Allow user to apply and install production environment credentials for each provider	Can be a manual process. The IIS can supply technical resources to assist with connectivity
42	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Apply Production Credentials & Establish Connectivity	Have ability to validate the correct installation of production environment credentials for the provider	
43	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Apply Production Credentials & Establish Connectivity	Have the ability to receive test messages	Used to ensure messages are transmitting properly
44	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Inform IIS of Go Live Date	Allow provider to determine and submit their chosen go live date to the IIS	The provider can only decide a go live date within IIS criteria (ex: Go Live within X days past applying credentials)

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
45	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Go Live	Have ability to accept data being submitted by the provider/EHR	
46	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Utilize monitoring tools to ensure provider data is being submitted	
47	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Have ability to prompt the provider to begin submitting data	i.e., After X number of days have passed the go live date without data being submitted
48	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Have the ability to shut off the go live data feed	
49	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Allow user to determine if a provider interface should be retested after X days of inactivity	
50	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Have ability to detect errors in production data	
51	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Have ability to document and notify user of failed, partially failed, and accepted messages	
52	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Have ability to notify provider of any issues	Ex. Data quality errors, gaps in connectivity, etc.
53	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Allow user to monitor provider data for X time period	The monitoring time period may vary according to jurisdictional requirements

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
54	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Allow user to create a data quality monitoring plan	
55	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	IIS Initial Data Quality Monitoring	Have ability to document the provider acceptance of a data quality monitoring plan	
56	Provider Approval/Reapproval for Bidirectional IIS Data Exchange	Provider Ongoing Data Quality Monitoring	SEE PROVIDER ONGOING DATA QUALITY MONITORING FOR BIDIRECTIONAL IIS DATA EXCHANGE REQUIREMENTS	

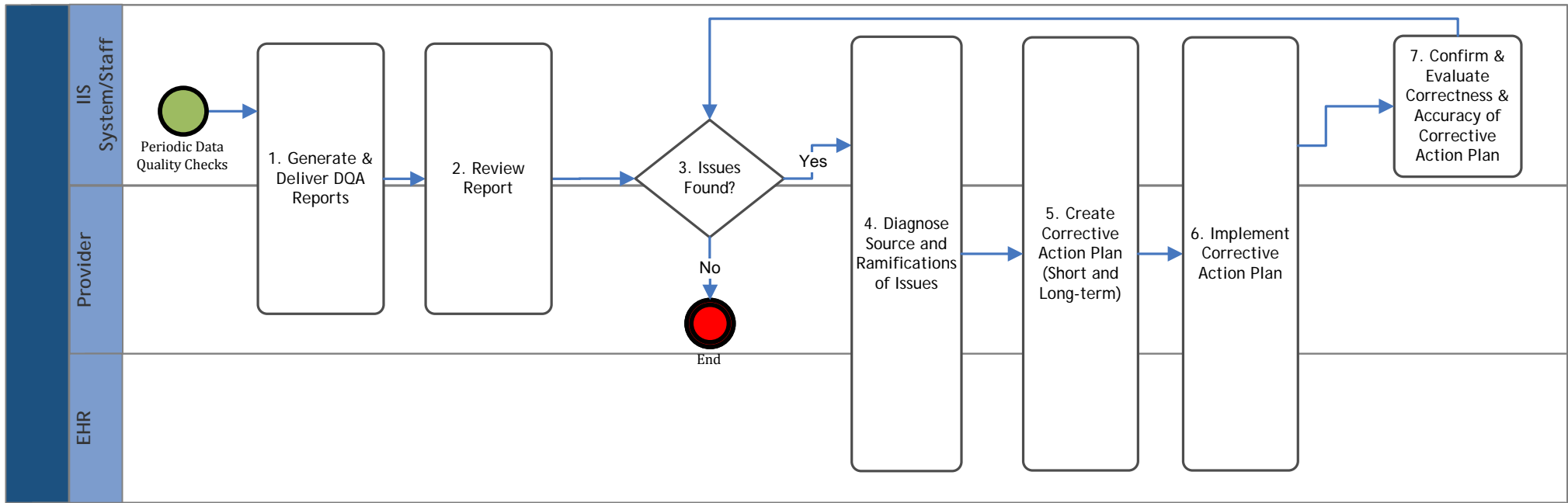
IIS Collaborative Requirements Development Project

Business Process Matrix

Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To communicate with a provider when data quality issues are found • To check for changes to the providers data submission (sudden stops, missing vaccine/vaccine groups, new vaccines not being included) • To verify that IIS data quality changes have been incorporated into the EHR by the provider/EHR vendor • To utilize AFIX measures for data quality control • To evaluate provider query usage 	<ul style="list-style-type: none"> • Standards-based implementation guides, profiles or interoperability specifications for immunization data • AIRA/CDC/MIROW functional standards and best practice guidelines for IIS • Patient data security and privacy (state/local immunization data sharing law; HIPAA) • Data sharing agreements between entities • National immunization policy recommendations and guidelines (ACIP, NVAC, CDC, HIMSS, AAP, AAFP) • IIS local rules (e.g., do not accept adults) 	<ul style="list-style-type: none"> • New vaccines, age groups, or policies are introduced • Periodic data quality checks • EHR system updates/new version • New version of HL7 implementation guides 	<ol style="list-style-type: none"> 1. Generate & Deliver DQA Reports 2. Review Report 3. Issues Found? 4. Diagnose Source and Ramifications of Issues 5. Create Corrective Action Plan (Short and Long-term) 6. Implement Corrective Action Plan 7. Confirm & Evaluate Correctness & Accuracy of Corrective Action Plan 	<ul style="list-style-type: none"> • Patient demographics and vaccine data • HL7 messages • Access credentials (organization & site specific) • User and confidentiality agreements • IIS implementation guide • EHR vendor documentation of processes • Vendor accountability guides 	<ul style="list-style-type: none"> • DQA reports are delivered or pushed to providers via email, web page, HL7 message, etc. • Follow-up from DQA reports • Provider access is suspended; requirement to repeat initial approval and testing of the EHR system • Communicate with provider (i.e., error messages, acknowledgements, etc.) • Submission reminder • Creation of a plan of action for corrective action 	<ul style="list-style-type: none"> • A provider meets minimum standards for IIS data submission in X number of days • Number of times a provider connects to the IIS in X days • Percentage of error free data submitted by providers • Percentage of providers that fail ongoing data quality monitoring checks • Number of providers that have viewed their data quality reports in X days • Percentage of providers that have viewed their data quality reports in X days • Percentage of providers that are suspended from

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
						submitting data in X days <ul style="list-style-type: none"> • Percentage of providers that require follow-up concerning suspect data quality in X days • Percentage of providers that require a corrective action plan to address poor data quality in X days • Percentage of providers that need to take action to improve data quality • Percentage of providers that took action to improve data quality



Activity Details / Narrative	<p>General Process Notes</p> <p>Objective:</p> <ul style="list-style-type: none"> To communicate with a provider when data quality issues are found To check for changes to the providers data submission (sudden stops, missing vaccine/ vaccine groups, new vaccines not being included) To verify that IIS data quality changes have been incorporated into the EHR by the provider/EHR vendor To utilize AFIX measures for data quality control To evaluate provider query usage <p>Measurable Outcomes:</p> <ul style="list-style-type: none"> A provider meets minimum standards for IIS data submission in X number of days Number of times a provider connects to the IIS in X days Percentage of error free data submitted by providers Percentage of providers that fail ongoing data quality monitoring checks Number of providers that have viewed their data quality reports in X days 	<p>Measurable Outcomes, Cont.:</p> <ul style="list-style-type: none"> Percentage of providers that have viewed their data quality reports in X days Percentage of providers that are suspended from submitting data in X days Percentage of providers that require follow-up concerning suspect data quality in X days Percentage of providers that require a corrective action plan to address poor data quality in X days Percentage of providers that need to take action to improve data quality Percentage of providers that took action to improve data quality <p>Activity Description:</p> <p>1. Generate & Deliver DQA Reports</p> <ul style="list-style-type: none"> The IIS system/staff and/or the provider generate a Data Quality Assurance (DQA) report. This report is used to verify completeness and accuracy of data submitted to the IIS by the provider/EHR 	<p>2. Review Report</p> <ul style="list-style-type: none"> The IIS system/staff and/or the provider review the report and determine if there are errors (consistent or one-time) in the data submitted during a specified time frame <p>3. Issues Found?</p> <ul style="list-style-type: none"> The IIS system/staff determine if there are data quality issues that need correcting based on the review of the DQA report or the evaluation of the corrective action plan If no issues are found, ongoing data quality monitoring is suspended until the process is triggered again <p>4. Diagnose Source and Ramifications of Issues</p> <ul style="list-style-type: none"> The IIS staff/provider determine the source of the issues found in the DQA report and the severity of the ramifications of the issue. In some cases the issues are simple, and can be quickly and easily corrected. However, in other cases, the issue is complicated and will require extensive corrections by the IIS system/staff and/or the provider/EHR 	<p>5. Create Corrective Action Plan (Short and Long-term)</p> <ul style="list-style-type: none"> The IIS staff and/or the provider/EHR work to create a corrective action plan. Depending on the extent of the issue, a short and/or long-term plan may be required <p>6. Implement Corrective Action Plan</p> <ul style="list-style-type: none"> The IIS system/staff and/or the provider/EHR implement activities outlined in the corrective action plan <p>7. Confirm & Evaluate Correctness & Accuracy of Corrective Action Plan</p> <ul style="list-style-type: none"> The IIS system/staff evaluate the results of the corrective action plan and determine if the issues have been corrected and the ramifications have been avoided

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
1	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Generate & Deliver DQA Reports	Have ability to create Data Quality Assurance Reports (DQA)	Examples of reports: ad hoc, timed reports, automated, single patient, etc.
2	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Generate & Deliver DQA Reports	Allow user to specify data criteria for the DQA report	Possible data to be included: patient vaccinations, inventory management, transport layer, end-user data evaluations, etc.
3	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Generate & Deliver DQA Reports	Have ability to store reports in the IIS	Via email, IIS web portal, etc.
4	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Generate & Deliver DQA Reports	Have ability to deliver reports	Via email, IIS web portal, etc.
5	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Review Report	Have ability to utilize an algorithm to identify data that is outside of defined parameters	
6	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Review Report	Have ability to alert IIS staff of data outside of defined parameters	
7	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Review Report	Have the ability to display a report for user review	
8	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Diagnose Source and Ramifications of Issues	Allow user to document details about the data issue	Ex. The underlying caused the issue, which entity is responsible, and the extent that the issue has impacted the IIS data (The issue has caused only one record to be incorrect and will require an easily applied correction, or the issue has caused all records from a specific provider to be incorrect and will require the vendor to modify the EHR system)

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
9	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Create Corrective Action Plan (Short and Long-term)	Allow user to document a corrective action plan	Examples of what may be included in a corrective action plan: who will have to correct the issue, will it require one correction or multiple steps, how long will it take to implement the corrective action, does the issue affect others outside of the IIS/provider/EHR world, how will you determine if the issue has been corrected?
10	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Implement Corrective Action Plan	Allow user to provide instruction/facilitate the provider on how to implement the corrective action plan	i.e., Web portal, email, phone, etc. This could also require manual assistance
11	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Implement Corrective Action Plan	Provide the vendor or provider access to the IIS test environment to test if the issue has been corrected	
12	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Implement Corrective Action Plan	Have ability to remove/suspend a provider's access to the production environment	
13	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Implement Corrective Action Plan	Have ability to log all corrective action plans	
14	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Implement Corrective Action Plan	Have ability to measure and document progress in the corrective action plan	
15	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Confirm & Evaluate Correctness & Accuracy of Corrective Action Plan	Allow user to access the original DQA report, original diagnosis, and the corrective action plan	
16	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Confirm & Evaluate Correctness & Accuracy of Corrective Action Plan	Allow user to run additional ad hoc DQA/other reports	

Functional Requirements for IIS Collaborative Requirements Development Project

ID	BUSINESS PROCESS	ACTIVITY	REQUIREMENT (The system must or should...)	COMMENTS
17	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Confirm & Evaluate Correctness & Accuracy of Corrective Action Plan	Have ability to utilize analytical tools/software	
18	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Confirm & Evaluate Correctness & Accuracy of Corrective Action Plan	Have ability to update the DQA report fields based on evaluation of the Corrective Action Plan	
19	Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange	Confirm & Evaluate Correctness & Accuracy of Corrective Action Plan	Have ability to identify if the issue has not been adequately corrected	

Appendix A

The Collaborative Requirements Development Methodology™

Defining requirements is a critical step in developing or acquiring an information system that will effectively support the work of the organization. If the requirements are not correctly defined, the system will not meet the needs of the users. Describing requirements for the way in which an information system should function involves first analyzing how the work gets done, by clearly defining the processes involved.

The Institute engaged 11 public health practitioners from 10 local and state health agencies, and applied a facilitated collaborative approach to developing requirements for reportable conditions surveillance information systems. Through use of our Collaborative Requirements Development Methodology (CRDM), the Institute assisted practitioners in analyzing the tasks and processes performed; defining better ways to perform those processes; and documenting the requirements for the ways in which information systems should support that work. The information system requirements they defined will enable other public health agencies to communicate with vendors and developers about how to meet their specific software needs, rather than having to buy off-the-shelf products that may not meet those needs, or settle for a vendor recommendation based on arbitrary likes or dislikes, as opposed to one based on product appropriateness.

To learn more about the Institute's CRDM, visit the "How We Work" page at www.PHII.org.

Appendix B

Functional Standard – Business Process Crosswalk for Immunization Information Systems

This appendix connects the business processes documented in this work with the related functional standards for Immunization Information Systems (IIS).¹ For each functional standard, the business processes that most directly relate to that standard are as listed as “Primary Processes.” Other processes that play a more auxiliary role in achieving the standard are listed as “Supporting Processes.”

Business Processes by Functional Standard

1.1 The IIS provides individual immunization records accessible to authorized users at the point and time where immunization services are being delivered.

Primary Process(es)

- Query, Add, and/or Update Patient Record
- Administer Vaccine

Supporting Process(es)

- Patient De-Duplication
- Vaccine De-Duplication
- Manage Forecasting Rules
- Facility/Organization Registration
- “Read Only” Data Exchange
- Data Exchange Response/Output

1.2 The IIS has an automated function that determines vaccines due, past due, or coming due (“vaccine forecast”) in a manner consistent with current ACIP recommendations. Any deficiency is visible to the clinical user each time an individual’s record is viewed.

Primary Process(es)

- Query, Add, and/or Update Patient Record
- Manage Forecasting Rules

Supporting Process(es)

- Patient De-Duplication
- Vaccine De-Duplication
- Data Exchange Response/Output

1.3 The IIS automatically identifies individuals due/past due for immunization(s), to enable the production of reminder/recall notifications from within the IIS itself or from interoperable systems.

Primary Process(es)

¹ At the time of the initial publication of this document, the functional standards were provisional (not yet approved) by the National Vaccine Advisory Committee (NVAC). This version of the functional standards was sent review and comment to the IIS community in May of 2012 by the Immunization Information Systems Support Branch (IIS SB).

- Patient Reminder/Recall

Supporting Process(es)

- Query, Add, and/or Update Patient Record
- Patient De-Duplication
- Vaccine De-Duplication
- Manage Forecasting Rules

1.4 When the IIS receives queries from other health information systems, it can generate an automatic response in accordance with interoperability standards endorsed by CDC for message content/format and transport.

Primary Process(es)

- “Read Only” Data Exchange
- Data Exchange Response/Output
- EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange
- Provider Approval/Reapproval for Bidirectional IIS Data Exchange
- Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange

Supporting Process(es)

- Query, Add, and/or Update Patient Record
- Patient De-Duplication
- Vaccine De-Duplication
- Facility/Organization Registration

1.5 The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport.

Primary Process(es)

- Query, Add, and/or Update Patient Record
- Data Exchange Response/Output
- EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange
- Provider Approval/Reapproval for Bidirectional IIS Data Exchange
- Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange

Supporting Process(es)

- Patient De-Duplication
- Vaccine De-Duplication
- Facility/Organization Registration
- Administer Vaccine

2.1 The IIS has a vaccine inventory function that tracks and decrements inventory at the provider level according to VFC program requirements.

Primary Process(es)

- Manage Inventory

Supporting Process(es)

- Query, Add, and/or Update Patient Record
- Vaccine De-Duplication
- Administer Vaccine
- Determine Vaccine Funding Source (Sub-process of Administer Vaccine)
- Data Exchange Response/Output

2.2 The IIS has a vaccine inventory function that automatically decrements as vaccine doses are recorded, whether through the user interface or an EHR system.

Primary Process(es)

- Manage Inventory

Supporting Process(es)

- Query, Add, and/or Update Patient Record
- Vaccine De-Duplication
- Administer Vaccine
- Determine Vaccine Funding Source (Sub-process of Administer Vaccine)
- Data Exchange Response/Output

2.3 The IIS has a vaccine inventory function that is available to direct data entry users and can interoperate with EHR or other inventory systems.

Primary Process(es)

- Manage Inventory

Supporting Process(es)

- Query, Add, and/or Update Patient Record
- Vaccine De-Duplication
- Administer Vaccine
- Determine Vaccine Funding Source (Sub-process of Administer Vaccine)
- Data Exchange Response/Output
- EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange
- Provider Approval/Reapproval for Bidirectional IIS Data Exchange
- Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange

2.4 Eligibility is tracked at the dose level for all doses administered.

Primary Process(es)

- Determine Vaccine Funding Source (Sub-process of Administer Vaccine)

Supporting Process(es)

- Query, Add, and/or Update Patient Record
- Administer Vaccine
- Data Exchange Response/Output

2.5 The IIS interfaces with the national vaccine ordering, inventory, and distribution system (currently VtrckS).

Primary Process(es)

- Public Purchase Vaccine Ordering
- Manage Inventory

Supporting Process(es)

- Administer Vaccine
- Determine Vaccine Funding Source (Sub-process of Administer Vaccine)

2.6 The IIS can provide data and/or produce management reports for VFC and other public vaccine programs.

Primary Process(es)

- User Report Generation
- Determine Vaccine Funding Source (Sub-process of Administer Vaccine)

Supporting Process(es)

- Query, Add, and/or Update Patient Record
- Patient De-Duplication
- Vaccine De-Duplication
- Public Purchase Vaccine Ordering
- Administer Vaccine
- Manage Inventory

3.1 The IIS provides consolidated demographic and immunization records for persons of all ages in its geopolitical area, except where prohibited by law, regulation, or policy.

Primary Process(es)

- Patient De-Duplication
- Vaccine De-Duplication

Supporting Process(es)

- Query, Add and/or Update Patient Record
- Facility/Organization Registration
- Create Newborn Record
- Vital Record Amendments

3.2 The IIS can regularly evaluate incoming and existing patient records to identify, prevent, and resolve duplicate and fragmented records.

Primary Process(es)

- Patient De-Duplication

Supporting Process(es)

- Query, Add and/or Update Patient Record

3.3 The IIS can regularly evaluate incoming and existing immunization information to identify, prevent, and resolve duplicate vaccination events.

Primary Process(es)

- Query, Add and/or Update Patient Record

Supporting Process(es)

- Patient De-Duplication
- Vaccine De-Duplication
- Administer Vaccine

3.4 The IIS can store all IIS Core Data Elements.

Primary Process(es)

- [None]

Supporting Process(es)

- Query, Add and/or Update Patient Record
- Public Purchase Vaccine Ordering
- Manage Forecasting Rules
- Facility/Organization Registration
- Administer Vaccine
- Determine Vaccine Funding Source (Sub-process of Administer Vaccine)
- Manage Inventory
- Create Newborn Record

3.5 The IIS can establish a record in a timely manner from sources such as Vital Records for each newborn child born and residing at the date of birth in its geopolitical area.

Primary Process(es)

- Create Newborn Record

Supporting Process(es)

- Query, Add and/or Update Patient Record
- Patient De-Duplication
- Vaccine De-Duplication
- Vital Record Amendments
- EHR Vendor/Data Submitter Testing, Approval, and Reapproval for Bidirectional IIS Data Exchange
- Provider Approval/Reapproval for Bidirectional IIS Data Exchange
- Provider Ongoing Data Quality Monitoring for Bidirectional IIS Data Exchange

3.6 The IIS records and makes available all submitted vaccination and/or demographic information in a timely manner.

Primary Process(es)

- Query, Add and/or Update Patient Record
- Administer Vaccine

Supporting Process(es)

- Patient De-Duplication
- Vaccine De-Duplication
- Manage Forecasting Rules
- Facility/Organization Registration

- “Read Only” Data Exchange
- Data Exchange Response/Output
- Create Newborn Record
- Vital Record Amendments

3.7 The IIS documents active/inactive status of individuals at both the provider organization/site and geographic levels.

Primary Process(es)

- Query, Add and/or Update Patient Record

Supporting Process(es)

- User Report Generation
- Patient Reminder/Recall
- Create Newborn Record
- Vital Record Amendments

4.1 The IIS program has written confidentiality and privacy practices and policies based on applicable law or regulation that protect all individuals whose data are contained in the system.

Primary Process(es)

- Facility/Organization Registration

Supporting Process(es)

- [None]

4.2 The IIS has user access controls and logging, including distinct credentials for each user, least-privilege access, and routine maintenance of access privileges.

Primary Process(es)

- Facility/Organization Registration

Supporting Process(es)

- [None]

4.3 The IIS is operated or hosted on secure hardware and software in accordance with industry standards for protected health information, including standards for security/encryption, uptime and disaster recovery.

Primary Process(es)

- [None]

Supporting Process(es)

- [None]

5.1 The IIS can provide immunization data access to healthcare providers, public health, and other authorized stakeholders (e.g., schools, public programs, payers) according to law, regulation, or policy.

Primary Process(es)

- Query, Add and/or Update Patient Record

Supporting Process(es)

- Facility/Organization Registration
- “Read Only” Data Exchange
- Data Exchange Response/Output

5.2 The IIS can generate predefined and/or ad hoc reports (e.g., immunization coverage, vaccine usage, and other important indicators by geographic, demographic, provider, or provider groups) for authorized users without assistance from IIS personnel.

Primary Process(es)

- User Report Generation

Supporting Process(es)

- Patient De-Duplication
- Vaccine De-Duplication
- Manage Forecasting Rules

5.3 With appropriate levels of authentication, IIS can provide copies of immunization records to individuals or parents/guardians with custodial rights.

Primary Process(es)

- Query, Add and/or Update Patient Record

Supporting Process(es)

- Patient De-Duplication
- Vaccine De-Duplication
- Manage Forecasting Rules
- Facility/Organization Registration
- Data Exchange Response/Output

5.4 The IIS can produce an immunization record acceptable for official purposes (e.g., school, child care, camp).

Primary Process(es)

- Query, Add and/or Update Patient Record
- User Report Generation

Supporting Process(es)

- Patient De-Duplication
- Vaccine De-Duplication
- Manage Forecasting Rules
- Facility/Organization Registration
- “Read Only” Data Exchange

6.1 Provide the necessary reports and/or functionality to facilitate vaccine recalls when necessary, including the identification of recipients by vaccine lot, manufacturer, provider, and/or time frame.

Primary Process(es)

- User Report Generation

Supporting Process(es)

- Manage Inventory

6.2 *Facilitate reporting and/or investigation of adverse events following immunization.*

Primary Process(es)

- User Report Generation

Supporting Process(es)

- Query, Add and/or Update Patient Record
- Patient De-Duplication
- Vaccine De-Duplication

Appendix C

Provider Registration Data Elements

This appendix contains the recommended data set for an Immunization Information System (IIS) to collect when enrolling a new facility, organization, or private provider to record and access information regarding administered immunizations and other health-related data by healthcare providers.

- Date (*Facility/Organization/Private Provider Applied for Registration*)
- In-charge Physician's: Last Name
- In-charge Physician's: First Name
- In-charge Physician's: Middle Initial
- In-charge Physician's: NPI number
- Full Name of Private Provider/Group Practice/Facility/Organization
- Facility/Organization/Private Provider: Building # and Street Number/Name
- Facility/Organization/Private Provider: City
- Facility/Organization/Private Provider: State
- Facility/Organization/Private Provider: Zip Code + 4 digits
- Facility/Organization/Private Provider: Telephone
- Facility/Organization/Private Provider: Email Address
- Facility/Organization/Private Provider: Fax Number
- Contact Person Name: Last Name
- Contact Person Name: First Name
- Contact Person Name: Middle Initial
- Contact Person Name: Email address
- Shipping Contact: Last Name
- Shipping Contact: First Name
- Shipping Contact: Building # and Street Number/Name
- Shipping Contact: City
- Shipping Contact: State
- Shipping Contact: Zip Code + 4 digits
- Facility operating hours (*Specifically for shipping purposes*)
- Facility/Organization/Private Provider: VFC PIN (*As assigned by the IIS*)
- Facility/Organization/Private Provider: Taxpayer ID
- Facility/Organization/Private Provider: Medicaid Provider #
- Primary Population Served (*Check all that apply: Adults, 19 years and above; Children, under 19 years; Medical Speciality [e.g., Internal Medicine; Ob/Gyn; etc.]*)
- Facility Type (*Private Hospital; Public Hospital; Private provider; Community Health Center; School; etc.*)
- How will the practice report to the Registry? (*Online; Electronically [clinical/billing system]*)
- Facility/Organization/Private Provider: Current VFC Provider?
- List of all MDs/DOs, PAs, NPs providing immunization services (Collect for each: Last Name; First Name; Title, MD/DO/PA/NP [specify]; Email address; Provider License Number)

Appendix D

EHR-HIE-IIS Data Exchange Business Process

The following pages contain the business process matrix and task flow for the EHR-HIE-IIS Data Exchange business process. This business process demonstrates what immunization data exchange might look like using a Health Information Exchange (HIE)/Health Information Organization (HIO) as an intermediary; a model in which the HIE/HIO does not transform the message but simply passes it through.

IIS Collaborative Requirements Development Project

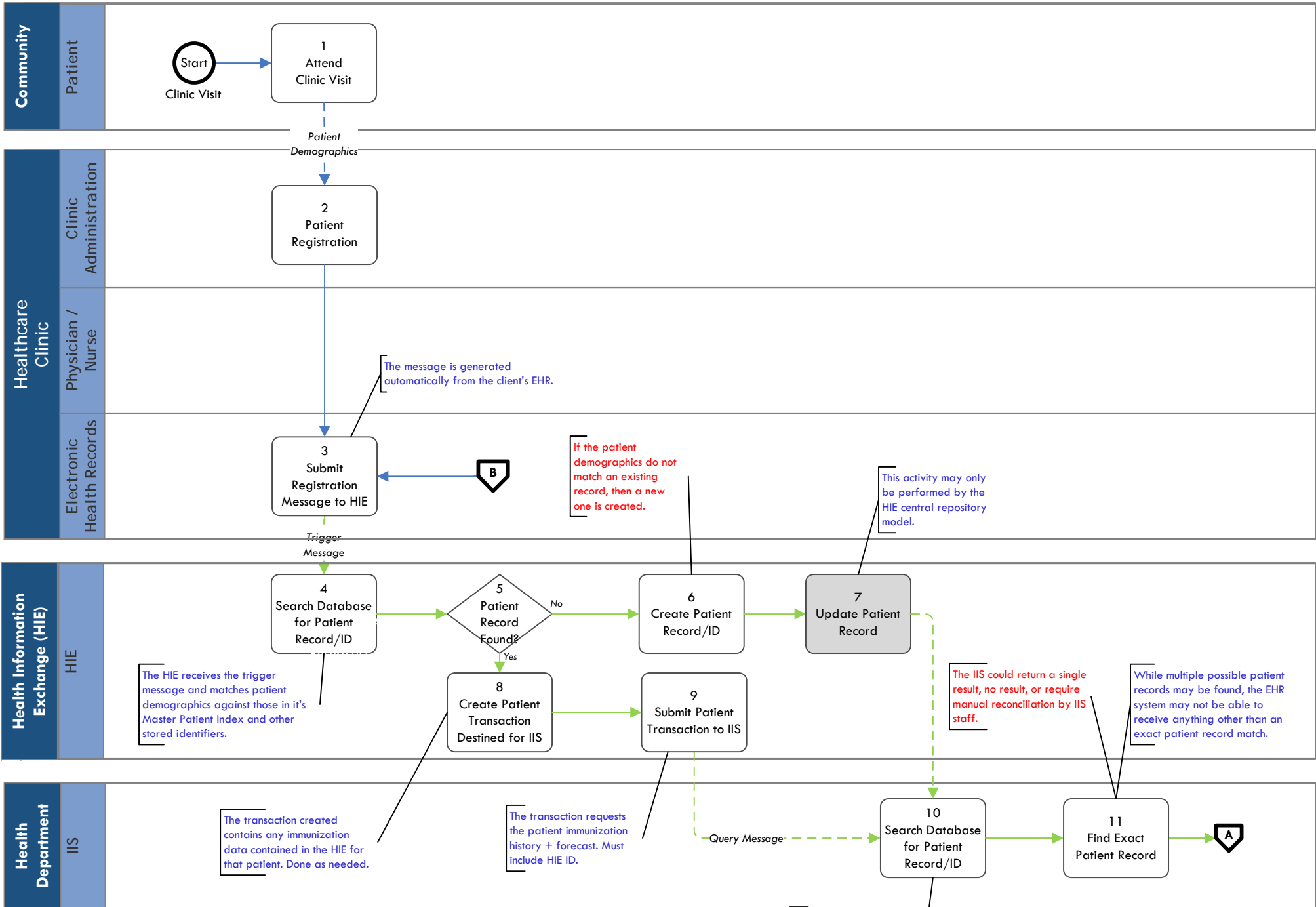
Business Process Matrix

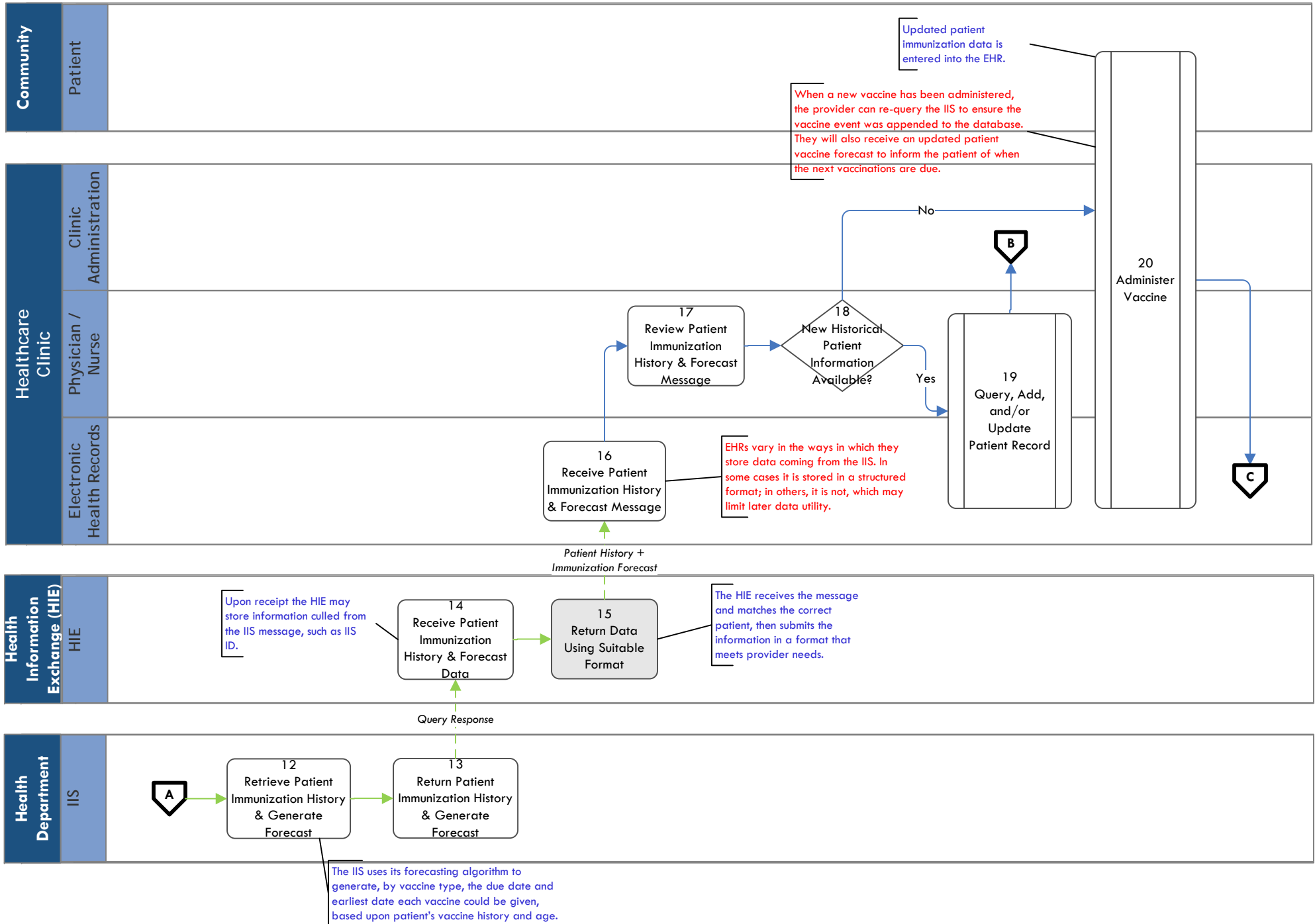
EHR-HIE-IIS Data Exchange

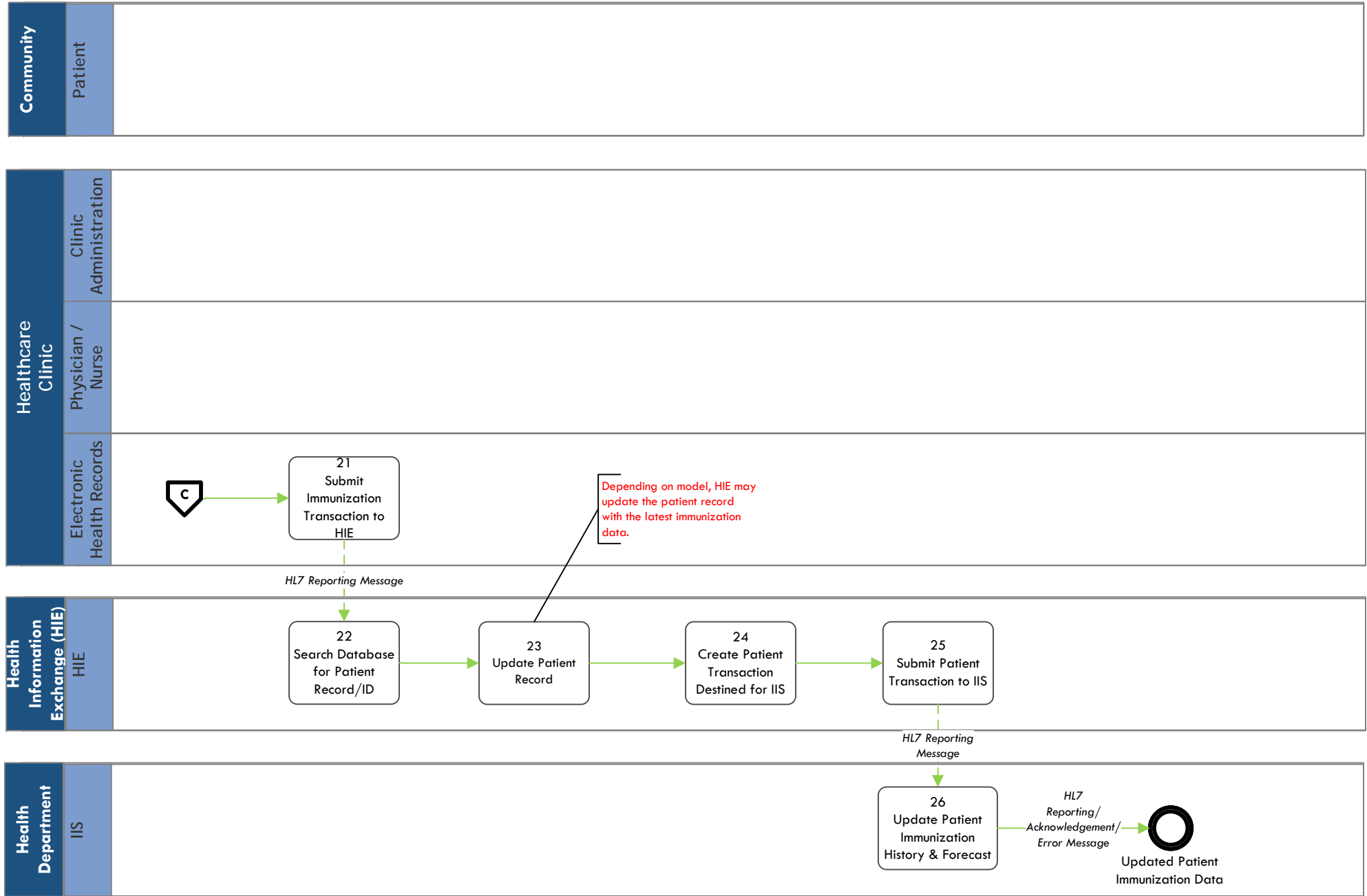
GOALS	OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
<ul style="list-style-type: none"> • To ensure immunization providers can access complete and accurate immunization history and recommendations in real time • One point of connection for public health 	<ul style="list-style-type: none"> • Ensure immunization providers have accurate, complete, patient-specific information to support immunization decisions • Reduce the manual data entry burden for multiple providers • Reduce the cost of developing/maintaining system interfaces • Leverage HIE infrastructure 	<ul style="list-style-type: none"> • Patient data security and privacy (state/local immunization data sharing law; HIPAA) • Data sharing agreements between entities • National immunization policy recommendations and guidelines (ACIP, NVAC, CDC, HIMSS, AAP, AAFP) • Standards-based implementation guides, profiles or interoperability specifications for 	<ul style="list-style-type: none"> • Patient presents for or schedules a clinical encounter (e.g., clinic appointment) • Patient needs certificate for school, child care, or camp • Immunization occurs at another provider site 	<ol style="list-style-type: none"> 1. Attend Clinic Visit 2. Patient Registration 3. Submit Registration Message to HIE 4. Search Database for Patient Record/ID 5. Patient Record Found? 6. Create Patient Record/ID 7. Update Patient Record (Optional) 8. Create Patient Transaction Destined for the IIS 9. Submit Patient Transaction to IIS 10. Search Database for Patient Record/ID 11. Find Exact Patient Record 12. Retrieve Patient Immunization History & Generate 	<ul style="list-style-type: none"> • Immunization data coming into the HIE and the IIS from an EHR system, including the core data elements 	<ul style="list-style-type: none"> • Consolidated, patient immunization record • Patient immunization recommendations based on known immunization history and patient age • Synchronized immunization record across EHR, HIE, and IIS in real time • Updated vaccine forecast for patient 	<ul style="list-style-type: none"> • Proportion of a clinic's patient population age-appropriately immunized • Proportion of a population in a geographic area age-appropriately immunized • Proportion of record queries to the HIE for which a match is found • Proportion of record queries from the HIE to the IIS for which a match is found • Number of transactions exchanged among IIS, HIE, and EHR • Completeness of core data elements in IIS • Acknowledgement from IIS of receipt

GOALS	OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
		immunization data <ul style="list-style-type: none"> • AIRA/CDC/MIROW functional standards and best practice guidelines for IIS • National HIE policy recommendations and guidelines (ONC) 		Forecast 13. Return Patient Immunization History & Generate Forecast 14. Receive Patient Immunization History & Forecast Data 15. Return Data Using Suitable Format (Optional) 16. Receive Patient Immunization History & Forecast Message 17. Review Patient Immunization History & Forecast Message 18. New Historical Patient Information Available? 19. Query, Add, and/or Update Patient Record 20. Administer Vaccine 21. Submit Immunization Transaction to HIE 22. Search Database for Patient Record/ID			of record <ul style="list-style-type: none"> • Proportion of records returned to provider from the IIS in less than or equal to four seconds on average • Proportion of provider interfaces that flowed through HIEs

GOALS	OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUTS	OUTPUTS	MEASURABLE OUTCOMES
				23. Update Patient Record 24. Create Patient Transaction Destined for IIS 25. Submit Patient Transaction to IIS 26. Update Patient Immunization History & Forecast			







General Process Notes**Objective:**

- Ensure immunization providers have accurate, complete, patient-specific information to support immunization decisions
- Reduce the manual data entry burden for multiple providers
- Reduce the cost of developing/maintaining system interfaces
- Leverage HIE infrastructure

Measurable Outcomes:

- Proportion of a clinic's patient population age-appropriately immunized
- Proportion of a population in a geographic area age-appropriately immunized
- Proportion of record queries to the HIE for which a match is found
- Proportion of record queries from the HIE to the IIS for which a match is found
- Number of transactions exchanged among IIS, HIE, and EHR
- Completeness of core data elements in IIS
- Acknowledgement from IIS of receipt of record
- Proportion of records returned to provider from the IIS in less than or equal to four seconds on average
- Proportion of provider interfaces that flowed through HIEs

General Notes:

- This business process describes one model for how immunization information can be reported from an EHR system to an IIS using a Health Information Exchange organization (sometimes referred to as a Health Information Organization or HIO) as an intermediary. Among the challenges in documenting such exchanges is that HIOs can be based on different models of operation. Some include repositories of patient demographic and clinical data (a central repository model), while others mostly contain demographic information (often called a Record Locator Service model).
- This task flow diagram assumes that the IIS and HIE operate under the same patient consent requirements; that is, both operate with implicit patient consent as an "opt out" system. Differences in data disclosure and patient consent laws/regulations/policies are one of the many complexities of public health reporting through an HIO.

General Notes, Cont.

- The task flow diagrams highlight the large number of complex tasks which must be performed by three or more information systems at the clinic, HIO and public health levels. It's critical that these systems perform the tasks instantaneously so that the data captured can be retrieved by the clinician and used in determining what vaccines to administer.
- The issue of how to communicate and display multiple possible record matches to a query still needs to be resolved with today's technologies. An IIS can readily do this when clinicians query through the user interface (unless prohibited by local law). But queries from an EHR system through an HIE to the IIS mean that both the HIE and IIS may find possible matching records. Few of today's EHR systems can display messages about possible record matches, or enable the clinician to choose from among the records as a way to re-submit the query through the HIO to the IIS.

Activity Description:**1. Attend Clinic Visit**

- Depending on the clinic's workflow and policy, the electronic reconciliation and sharing of vaccine data and the creation and sharing of the immunization forecast may begin prior to the patient visit, when the appointment is scheduled, or when the patient arrives at the clinic. For pediatric patients still receiving their primary vaccination series, which are very time-sensitive, the healthcare provider should obtain an up-to-date forecast based on the date of the actual clinic visit, and not rely on a forecast generated at an earlier time, such as when the clinic appointment was made.

2. Patient Registration

- In most outpatient clinical care settings, patient demographic data are entered electronically well before the actual visit. Therefore, there is ample time to submit a transaction to the HIE and the IIS to retrieve any missing data. However, outpatient EHR systems may lack mechanisms that allow a preemptive query or trigger message to be sent. Trigger messages are commonly sent at the time the patient arrives. Consequently, there is a need for fast-turnaround, low-latency responses from the systems being queried, so that the information is available at the point of care when the patient is being seen. Alternatively, EHR systems may implement appropriate batch-mode immunization data transfer processes on a routine (e.g., nightly) basis.

3. Submit Registration Message to HIE

- Patient-identifying information and vaccine administration data are sent from the EHR to the HIE. This information should be sent in real time.
- There are multiple ways to accomplish this task (ex. PIX, unsolicited VXU, VXQ, XDS, etc.).

4. Search Database for Patient Record/ID

- The HIE searches its database for an exact patient record then uses its MPI to include the IIS identifier in the message.

5. Patient Record Found?

- The system determines if a patient record is found. The next step depends on whether a record is found. If no, a new record is created, and if yes, the process continues to create a transaction destined for the IIS.

6. Create Patient Record/ID

- If patient demographics do not match an existing record in the HIE, a new patient record and ID will be automatically created. Processes for creating a new patient record and adding or updating clinical data for that patient record are distinct activities. A new patient record and ID must be created before clinical data can be added to, or updated for that record.

7. Update Patient Record (Optional)

- If immunization data is contained in the notification message, those data are added to the HIE's clinical data repository. This step is included because updating clinical data for an existing patient record is distinct from creating a new patient record. This is an unlikely scenario, but is included for the sake of completeness.
- This activity may only be preformed by the HIE central repository model.

Activity Description, Cont.:

8. Create Patient Transaction Destined for the IIS

- This transaction can occur in tandem with the creation of a new record in the EHR. For a central repository HIE, the transaction will contain demographic data destined for the IIS, as well as any updated immunization data, according to the business rules. An example business rule is that the immunization date must include the day it was given, not just month and year.
- For optimal performance in patient record matching, both the HIE and IIS must store each other's local unique patient identifiers, and include these in all transactions. If the HIE supports a Master Patient Index (MPI), the IIS identifiers would be among those referenced and matched against the MPI.

9. Submit Patient Transaction to IIS

- Query transactions containing patient demographic data are transmitted to the IIS.

10. Search Database for Patient Record/ID

- The IIS system searches for an existing patient.
- If no patient record/ID is found in the IIS, a message will be returned to the EHR prompting the need for the creation of an IIS patient record.

11. Find Exact Patient Record

- The IIS must establish business rules to accommodate the case when a unique record match cannot be made. For example, options may include returning an "insufficient data to match" message; return a list of possible matches (although the IIS and HIE may have the capability to return multiple match, an EHR may not be able to receive and process the return of multiple matches); or simply respond with "no record found." The business rules should not be so strict that users will become frustrated and not use the system, nor should they be too loose and risk the proliferation of duplicate records.

12. Retrieve Patient Immunization History & Generate Forecast

- Combining information from the IIS, EHR and HIE, the IIS will create a list of forecasted immunizations (that is, what vaccines could be given today or, the earliest date on which they could be given) based on the known immunization history and patient age. Forecasting business rules are informed by recommendations from the Advisory Committee on Immunization Practices, as accepted by the Centers for Disease Control and Prevention (CDC).

12. Retrieve Patient Immunization History & Generate Forecast, cont.

- While immunization forecasting may be closely coupled to the IIS as described in this workflow, close coupling is not necessary. Some immunization stakeholders contemplate a universal forecasting service that could exist independently of any particular IIS and may service a broader constituency. A variety of IISs may desire to use such a system, and other entities such as HIEs and EHR systems may also seek to access a loosely-coupled forecasting system. This particular workflow action will change if a more loosely-coupled forecasting system is desired.

13. Return Patient Immunization History & Generate Forecast

- The IIS sends the immunization history and immunization forecast in response to a query message.

14. Receive Patient Immunization History & Forecast Data

- Depending on the system, forecast data may be returned in many different formats including structured, unstructured, pdf file, text file, etc.

15. Return Data Using Suitable Format (Optional)

- The HIE transforms data into a suitable format and then delivers immunization forecast and history data to the requesting healthcare clinic.

16. Receive Patient Immunization History & Forecast Message

- This step assumes that the EHR receives the data, but neither assumes nor excludes the possibility that the provider views the data at this point.

17. Review Patient Immunization History & Forecast Message

- Provider will review current immunization status and assess need for further immunizations.

18. New Historical Patient Information Available?

- The provider will determine from the forecast and patient interview if there is additional information that needs to be added to the patient's record.

19. Query, Add, and/or Update Patient Record

- The provider will update the patient record and then query for a new forecast based on the most up-to-date information.

20. Administer Vaccine

- Predefined Process

21. Submit Immunization Transaction to HIE

- This transaction will update the HIE, and subsequently the IIS, following a clinic visit where new vaccines are administered. This requirement suggests that an automated process within the EHR can identify newly entered vaccination information.

22. Search Database for Patient Record/ID

- The HIE searches its database for an exact patient record match.

23. Update Patient Record

- If immunization data is contained in the update message, that data is added to the HIE's clinical data repository. This step is included because updating clinical data for an existing patient record is distinct from creating a new patient record. This is an unlikely scenario, but is included for the sake of completeness.

24. Create Patient Transaction Destined for IIS

- The transaction will contain demographic data destined for the IIS, as well as any appropriate updated immunization data, according to the business rules agreed upon by the EHR stakeholders, the HIE, and the IIS. An example business rule is that the immunization date must include the day it was given, not just month and year.
- For optimal performance in patient record matching, both the HIE and IIS must store each other's local unique patient identifiers, and include these in all transactions. If the HIE supports a Master Patient Index (MPI), the IIS identifiers would be among those referenced and matched against the MPI.

25. Submit Patient Transaction to IIS

- Query transactions containing patient demographic data are transmitted to the IIS.

26. Update Patient Immunization History & Forecast

- After the patient record is updated by the provider, they may then choose to re-query the IIS for an updated patient history and forecast.

Appendix E

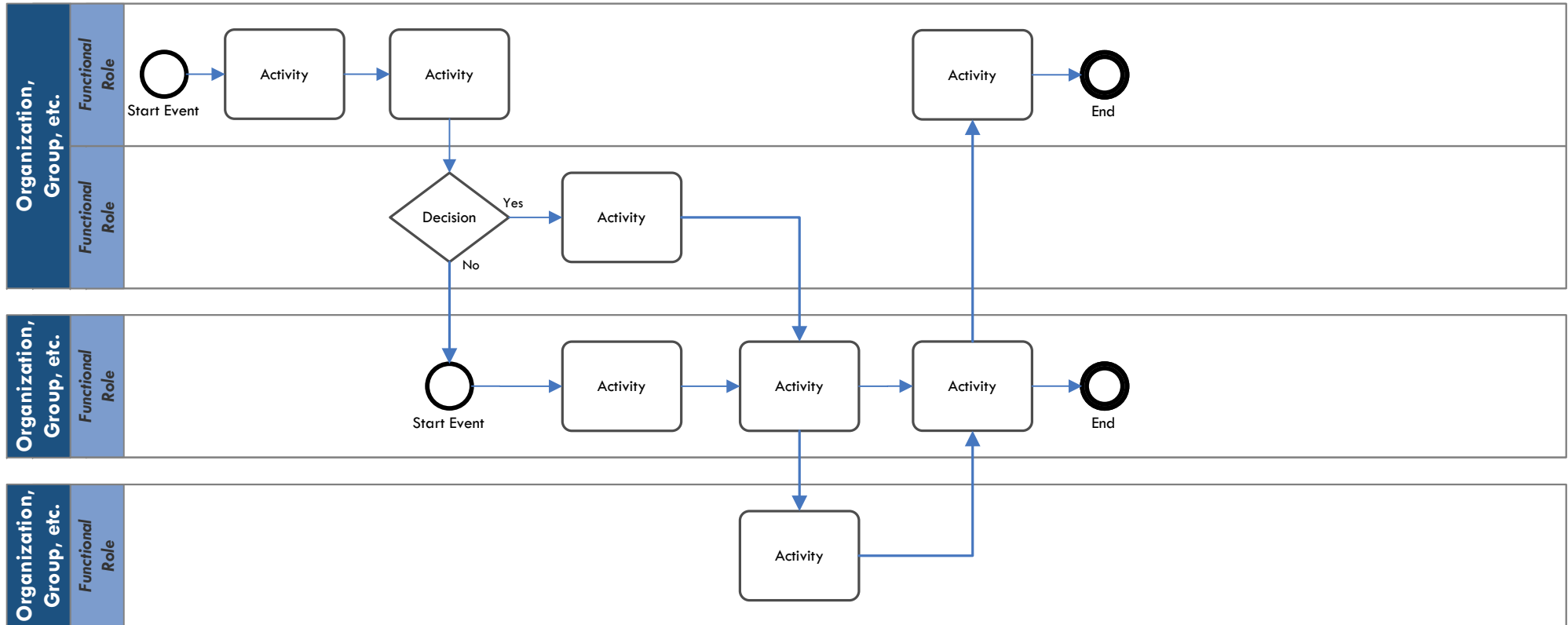
Example Business Process Matrix, Task Flow, and Requirements Document

The following pages contain example forms with explanatory language for each of the business process tools.

Business Process Matrix

Name of Business Process

OBJECTIVES	BUSINESS RULES	TRIGGER	TASK SET	INPUT	OUTPUTS	MEASURABLE OUTCOMES
A concrete statement describing what the business process seeks to achieve. A well-worded objective will be SMART: Specific, Measurable, Attainable/Achievable, Realistic, and Timebound.	A set of criteria that defines or constrains some aspect of the business process. Business rules are intended to assert business structure or to control or influence the behavior. Examples in healthcare and public health include laws, standards, and guidelines.	An event, action or state that indicates the first course of action in a business process. In some cases, a trigger is also an input.	The key set of activities that are carried out in a business process.	Information received by the business process from external sources. Inputs are not generated within the process.	Information transferred out from a process. The information may have been the resulting transformation of an input, or it may have been information created within the business process.	The resulting transaction of a business process that indicates the goal(s) and objectives have been met.



General Process Notes

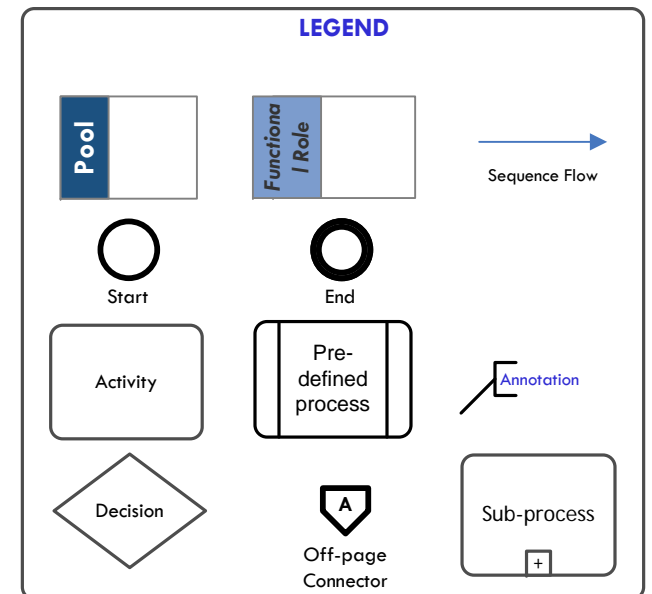
- General notes regarding the task flow

1. Identify Business Need for Data

- Details

2. Identify Potential Data Requirements

- Details



ID	BUSINESS PROCESS	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should...)	COMMENTS
1.1.1	Business Process #1	Activity #1	Entity or Functional Role performing the activity	Requirement #1	
1.1.2	Business Process #1	Activity #1	Entity or Functional Role performing the activity	Requirement #2	
1.1.3	Business Process #1	Activity #1	Entity or Functional Role performing the activity	Requirement #3	
1.1.4	Business Process #1	Activity #1	Entity or Functional Role performing the activity	Requirement #4	
1.1.5	Business Process #1	Activity #1	Entity or Functional Role performing the activity	Requirement #5	
1.1.6	Business Process #1	Activity #1	Entity or Functional Role performing the activity	Requirement #6	
1.1.7	Business Process #1	Activity #1	Entity or Functional Role performing the activity	Requirement #7	
1.2.1	Business Process #1	Activity #2	Entity or Functional Role performing the activity	Requirement #1	
1.2.2	Business Process #1	Activity #2	Entity or Functional Role performing the activity	Requirement #2	
1.2.3	Business Process #1	Activity #2	Entity or Functional Role performing the activity	Requirement #3	
1.3.1	Business Process #1	Activity #3	Entity or Functional Role performing the activity	Requirement #1	
1.3.2	Business Process #1	Activity #3	Entity or Functional Role performing the activity	Requirement #2	
1.3.3	Business Process #1	Activity #3	Entity or Functional Role performing the activity	Requirement #3	
1.3.4	Business Process #1	Activity #3	Entity or Functional Role performing the activity	Requirement #4	
2.1.1	Business Process #2	Activity #1	Entity or Functional Role performing the activity	Requirement #1	
2.1.2	Business Process #2	Activity #1	Entity or Functional Role performing the activity	Requirement #2	

Appendix F

Request for Proposal

Preparing a Request for Proposal (RFP)

Preparing a Request for Proposal can be a challenging process. It is important that you properly prepare and allow sufficient time to fully understand your business requirements and your jurisdiction’s procurement policies, and to thoroughly evaluate potential software vendors. Typically, it takes from six to twelve months to complete the RFP process, depending on the complexity of the information system.

The RFP begins with understanding your business requirements and categorizing them as “need to have” versus “nice to have”. There may be additional technical requirements or constraints that must be articulated to the vendors, so it is best to involve your IT department early in this process.

Most jurisdictions also have an RFP/RFQ template which you may be required to use as the basis for your solicitation. Numerous state/local regulations are likely to govern the sequence, timing, publication and communications requirements of your competitive solicitation. Be sure to connect with your procurement, legal and other departments early to understand these requirements. For example, to what extent can you communicate with potential respondents, if at all? Can you send a notice to vendors that the RFP has been published in the state register or on jurisdiction’s web site? If a respondent asked you a question about your RFP, how are you to respond? Are you required to publish the question and response to all other respondents?

Vendor Selection

Be sure to allow enough time for respondents to prepare thorough responses to the RFP. Responses will then be evaluated and ranked on the basis of how closely they align with your “need to have” and technical requirements, with consideration given to “nice to have” as a further ranking criteria. Based on this evaluation, you may select one or more respondents to perform live demonstrations of their systems, incorporating several use cases that you will provide ahead of time. Depending on the breadth of the functionality, it will be best to allot half- or full-day sessions for these use-case demonstrations.

The value of your RFP and the resulting demonstrations in making the best vendor selection will depend on the clarity and applicability of the use cases you define, and on determining prior to the demonstration how – based on what criteria – the use-case demonstrations will be judged. Take time immediately following each presentation to evaluate the strengths, weaknesses and/or scores for each use case, based on the judgment criteria previously established.

In addition to evaluating the ability of the vendor to address your specific business and technical requirements, several additional factors should be considered. It will be important to understand the overall cost of owning the software, including start-up and maintenance costs, and to ascertain the vendor’s customer service capability, both their track record of customer satisfaction, as well as their strategy for maintaining and upgrading their software. Along these lines, it is equally important to assess the vendor’s financial viability. It would be unfortunate indeed to purchase software with all of the correct functionality from a vendor on the verge of bankruptcy, which could leave you with no one to turn to for support or maintenance of your software.

Although the RFP and vendor selection process requires significant effort and due diligence, the result will be a well-organized and documented approach that allows you to select the most appropriate software application and vendor to meet your business needs.

RFP Table of Contents

Project Overview

- Provide a brief high-level description of the organization, purpose of the project and what you plan to achieve by implementing the new information system. Typically 1 – 2 pages in length.

Project Background and Goals

- Provide details on how and why the project was conceived and the specific goals that the project has set out to accomplish. Typically 1 – 2 pages in length.

Scope of Project

- Describe the details of the scope of the project. It is also helpful to provide insight to what is defined as out-of-scope. The more clarity provided here, the better the vendor can assess their ability to meet your needs. Typically 1 – 3 pages in length.

Project Deliverables

- Describe the specific project deliverables that the vendor will be responsible for completing as part of this project. This section typically details expectations related to implementing the information system, user testing, system documentation, system maintenance, and technical support.

Evaluation Selection Criteria

- Describe in detail the criteria, along with weighting factors, that will be used to evaluate the vendor. This is typically laid out in a matrix or table structure, along with a scoring scheme. More weight is given to those areas of highest importance.

Attachments

- Requirements
- General System Assessment
- Vendor Assessment

Appendix G

General System Assessment

1. General System Characteristics
 - 1.1 Describe the basic system architecture (e.g., host-based, client/server, multi-tiered, etc.) and operating architecture (e.g., ASP, server location, etc.)
 - 1.2 Describe the operating systems supported on the client (if applicable) and the server
 - 1.3 Describe any database back-ends supported and note what type of drivers are used or other access technology
 - 1.4 Describe user interfaces supported (thin client, thick client, Web, PDA, API, ADO, DDE, etc.)
 - 1.5 If separate site servers are utilized, describe how site synchronization is achieved in the event of network failure in multi-site implementations
 - 1.6 Describe other products with which the surveillance information system is designed to integrate
 - 1.7 Describe user interfaces supported by the product that are used by two or more customers (include PDA, Web, GUI, etc.)
 - 1.8 Can a customer install multiple non-interacting instances of the information system in order to support training and testing? If so, describe approach most commonly used by customers, and give two supporting customer references.
 - 1.9 Describe the system's audit trail capability
 - 1.10 Describe the minimum requirements for workstations and associated peripherals, such as printers and barcode readers
2. Database
 - 2.1 Provide the name of the database product, if one is used
 - 2.2 Describe the data model (e.g., flat file, relational, object-oriented, proprietary, etc.)
 - 2.3 Provide the size of the largest database installed for a customer's information system (number of test records)
 - 2.4 Describe the relationship of server size to database size, and impact of server memory (all in relationship to system response time)
 - 2.5 Describe the impact of workstation sizing (if any) on response time
 - 2.6 Describe the relationship of response time to number of concurrent users

- 2.7 What is the maximum number of concurrent users that can be efficiently supported (if there is a maximum)?
- 2.8 What is the application development language?
- 2.9 Describe the database tools supplied with the application
- 2.10 Describe the archiving capability and approach utilized in your application
- 2.11 Describe the audit trail capability and approach utilized to address HIPAA requirements

Appendix H

Vendor Assessment

1. Organization History
 - 1.1 Number of years in immunization information system business
 - 1.2 Number of staff in organization
 - 1.3 Number of staff assigned to immunization information system-related operations
 - 1.4 Number of staff in immunization information system development
 - 1.5 Number of staff in immunization information system implementation and training
 - 1.6 Number of staff supporting current immunization information system installed base
 - 1.7 Describe the development history of your immunization information system
 - 1.8 Date of original version/release
 - 1.9 Date of current version/release
2. Current Installation Base
 - 2.1 Total number of unique customer installations of immunization information systems
 - 2.2 Total number of customers on latest version of immunization information system
 - 2.3 References from three customers on latest version of immunization information system, who have system needs similar those stated in this RFP
 - 2.4 References from three additional customers
 - 2.5 Total number of concurrent user licenses or workstations on which immunization information system software is installed
 - 2.6 Total revenue from immunization information systems for last fiscal year
 - 2.7 Number of new customer installations of immunization information systems
2. Product Marketing
 - 3.1 Describe the primary market for your immunization information system
 - 3.2 Is the product marketed as (indicate all that apply):
 - Part of a bundled product offering?
 - Part of multi-vendor suite?
 - A standalone product offering?

- 3.3 Describe ways in which the product can be demonstrated
- 3.4 Describe any warranty provided (i.e., length, coverage, etc.)
- 3.5 Describe the new version release strategy (i.e., how often, to whom is it available, and at what cost, if any)
4. Implementation Support (installation, training, database conversion)
 - 4.1 Describe the application and database installation procedure
 - 4.2 Describe the administrative and user training provided as a part of the implementation process
 - 4.3 Describe available customer database conversion services
 - 4.4 Describe database conversion tools/programs used for converting a legacy database
 - 4.5 Describe the project management strategy for implementation, including customer sign-offs
5. Information System Technical Support
 - 5.1 Describe Help Desk support and problem investigation including:
 - Hours of operation
 - Access method(s) (800 numbers, Internet, on site, online remote, etc.)
 - Help desk operator training and immunization information system experience
 - Problem-logging mechanism
 - Documentation of complaint history and resolution
 - 5.2 Describe strategy for system patches and fixes including:
 - Application method: individually or in groups
 - How they are applied at user site (e.g., remote, by user, etc.)
 - To whom they are distributed (e.g., entire base, version-specific users only, etc.)
 - Bug-fix prioritization and average timeframe between report and installed fix
 - 5.3 Describe continuing training opportunities and associated costs (if any)
 - 5.4 Describe how new versions and releases are deployed
6. User Groups and Other Services
 - 6.1 Provide name of user group and contact information (name, phone number, address and/or e-mail address)
 - 6.2 Describe group organizational structure and membership requirements

- 6.3 Describe group purpose and objectives
 - 6.4 Provide frequency of meetings and location(s)
 - 6.5 Provide number of members (organizations and average attendance at last two meetings)
 - 6.6 Describe other customer services and benefits
7. Vendor Risk Assessment
- 7.1 Provide Dunn and Bradstreet rating, if available
 - 7.2 Provide percent personnel turnover for last year
 - 7.3 Provide financial statement (balance sheet and income statement) for last full year
 - 7.4 Provide banking reference (name, account officer, address, and telephone number)
8. Documentation
- 8.1 Describe the level of detail addressed by the documentation (e.g., general operation, low-level configuration, report design, API access, etc.)
 - 8.2 Describe online documentation that can be accessed by the user directly from the application screens
 - 8.3 Describe how the documentation is organized and provide a hard copy version for inspection

Appendix I

Glossary

The following IIS terms are used in this document. Wherever possible, established definitions are used.

Accepted Vaccine Event Submission

A successful vaccine event data upload into the registry after confirmation of the data's conformity to the data guidelines.

ACIP (Advisory Committee on Immunization Practices)

A federally-established advisory committee that provides advice and guidance to the Secretary of HHS, the Assistant Secretary for Health, and the Director of CDC regarding the most appropriate selection of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population. The committee specifically provides advice for the control of diseases for which a vaccine is licensed in the U.S. IIS vaccine validation and forecasting logic is based upon ACIP recommendations.

AIRA (American Immunization Registry Association)

A membership organization that promotes the development and implementation of immunization information systems (IIS) as an important tool in preventing and controlling vaccine preventable diseases. The organization provides a forum through which IIS programs and interested organizations, individuals, and communities combine efforts, share knowledge, and promote activities to advance IIS and immunization programs.

Authorized User

A user who is granted access to a database and agrees to the confidentiality and security guidelines set by the owner of the system. For IIS, authorized users are generally established in statute or policy, and can include both those that submit immunization data and those that have read-only access.

Bidirectional Immunization Message

Two-way exchange of immunization information that includes an inbound vaccine query/add/update records message from an EHR or other system, and a reciprocal response that includes patient-specific vaccine history and vaccine forecasts (see below).

Data Synchronization

The process of establishing consistency among data from different sources within a centralized database.

De-Duplication

The process of identifying and eliminating redundant records or data. As a result of the de-duplication process, duplicate data is either deleted or merged, leaving only one copy of the record or data to be stored.

EHR System (Electronic Health Record System)

The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this record is patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter—as well as supporting

other care-related activities directly or indirectly via interface—including evidence-based decision support, quality management, and outcomes reporting.²

HIE (Health Information Exchange)

The electronic movement of health-related information among organizations according to nationally recognized standards.³

The mobilization of healthcare information electronically across organizations within a region or community. HIE provides the capability to electronically move clinical information between disparate healthcare information systems while maintaining the meaning of the information being exchanged. The goal of HIE is to facilitate access to and retrieval of clinical data to provide safer, more timely, efficient, effective, equitable, patient-centered care.⁴

An organization that oversees, governs, and facilitates the exchange of health information among organizations according to nationally recognized standards. Also referred to as a Health Information Organization (HIO).

IIS (Immunization Information System)

Confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area.

MIROW (Modeling of Immunization Registry Operations Workgroup)

An initiative of the CDC National Center for Immunization and Respiratory Diseases (NCIRD), in partnership with the American Immunization Registry Association (AIRA), to analyze and improve Immunization Information System (IIS) operations by developing best practice recommendations for IIS operations and processes. The initiative uses a collaborative approach, leveraging subject matter experts from the IIS community to identify and analyze current practices and in a focused, structured process, reaches consensus on best practices.

Provider

A health care provider is an individual or an organization, licensed by a state to provide preventive, curative, promotional or rehabilitative health care services in a systematic way to individuals, families or communities. Most providers are licensed to administer immunizations but it is most commonly done by family practices and pediatric practices, as well as hospitals and, increasingly, pharmacies.

Provider Organization Name

The designation for an organized group of providers. The organization may include a number of different provider offices or sites and physician groups, and is often a corporate name.

Public Health Entity

A governmental agency with public health oversight or management responsibilities over a particular public health jurisdiction and associated population.

² www.himss.org

³ The National Alliance for Health Information Technology Report to the Office of the National Coordinator for Health Information Technology on Defining Key Health Information Technology Terms, April 2008.

⁴ eHealth Initiative. "Second Annual Survey of State, Regional and Community-based Health Information Exchange Initiatives and Organizations." Washington: eHealth Initiative, 2005.

Query

The primary mechanism for retrieving information from a database. A query consists of questions presented to the database in a predefined format.

Real-time

A synchronous, reciprocal transaction sent from the provider to the IIS.

Recommended Vaccination

An immunization that is due or past due for an individual/patient per a recommended immunization schedule, and based on the patient's age and immunization history.

Rejected Vaccine Event Submission

The rejection of a vaccine event data upload into the registry when data fails to conform to the data guidelines. A rejected submission is customarily returned to the sender to be fixed and subsequently re-sent.

Reminder/Recall Protocol

A set of rules and procedures that guides the Reminder/Recall operations.

Request

See "Query."

Submitter

An entity (provider; see above) that submits immunization data to the IIS.

Vaccination Encounter Date

The date the patient received one or more doses of one or more vaccines.

Vaccination Event

Administration of one vaccine to a patient. Several vaccination events can happen during one vaccination encounter.

Vaccination Event – Compromised Dose (flag)

A Valid/Invalid flag indicating that a dose of vaccine should not be considered when generating a vaccine forecast (see below). An Invalid flag indicates that a dose administered to a patient is considered substandard and therefore not a valid dose that can be counted.

Vaccine Family/Group Name

Broad categories of vaccines that generally correspond to individual antigens and are related by vaccine type (e.g., Hib-PRP-T and Hib-HbOC have a Vaccine Family/Group Name of Hib). A Vaccine Family/Group Name may correspond to a group of multiple vaccine types that are typically given in a combination vaccine (e.g., MMR and DTP).

Vaccine Forecast

The output of an IIS's algorithm/business rules that denotes what vaccines are due, coming due, or are past due for an individual, based upon that person's age, vaccine history, and the ACIP recommendations. A vaccine forecast is a form of clinical decision support.

Vaccines for Children (VFC)

A federally funded entitlement program offering vaccines at no cost for eligible children through VFC-enrolled doctors. IISs have increasingly been engaged to assist with greater VFC vaccine accountability.

Vaccine Inventory System

A tracking system that supports accurate inventory management of vaccines within an organization, including doses on hand by vaccine lot number (see below), doses wasted or transferred, reports, and other inventory functions.

Vaccine Lot Number

The manufacturer-assigned number for a specific batch of vaccine developed and distributed. This number is the tracking number of the administered vaccine, and can be used by IIS to help recall individuals who received sub-optimal vaccine from a lot.

Vaccine Trade Name

The name under which the manufacturer copyrights a vaccine/vaccines. A trade name is usually assigned by the manufacturer to identify vaccine type. Also known as “Brand Name.”

Vaccine Type

An internationally recognized numerical code that designates a specific vaccine product. CPT and CVX codes are the two most recognized standards to designate vaccine type.

VTrckS (Vaccine Tracking System)

An information system that integrates the entire publicly-funded vaccine supply chain, from purchasing and ordering to distribution of the vaccine.

Appendix J

Explanation of Terminology

The following terms are included to clarify the meaning of words used within this document.

automating

Attempting to reduce an existing manual job to a set of computer programs that can replace the existing manual effort with the minimum of human effort or understanding.

best practice

A technique or methodology that, through experience and research, has shown to reliably lead to a desired result.

business practice

Habitual or customary actions or acts in which an organization engages. Also used in the plural to describe a set of business operations that are routinely followed.

business process

A set of related work tasks designed to produce a specific desired programmatic (business) result. The process involves multiple parties internal or external to the organization and frequently cuts across organization boundaries.

business process analysis

The effort to understand an organization and its purpose while identifying the activities, participants and information flows that enable the organization to do its work. The output of the business process analysis phase is a model of the business processes consisting of a set of diagrams and textual descriptions to be used for design or redesign of business processes.

business process redesign

The effort to improve the performance of an organization's business processes and increase customer satisfaction. Business process redesign seeks to restructure tasks and workflow to be more effective and more efficient.

business rules

A set of statements that define or constrain some aspect of the business process. Business rules are intended to assert business structure or to control or influence the behavior of the health agency (business).

context diagram (entity diagram)

Reflects relationships and boundaries that exist between individuals and groups within a work environment, and shows how they relate to one another to achieve the goals and objectives of the process. It consists of the following elements:

- (1) **entity**: a person or group of people (e.g., accounts payable clerk or accounts payable department) who performs one or more tasks involved in a process,
- (2) **transaction**: Information exchanges between entities. Entities are represented by circles and transactions are represented by arrows. A context diagram may involve all the transactions of a single user of a system or of multiple users. Usually, single-user diagrams are attempted first (for ease), but multi-user diagrams are needed to get a good look at an entire process.

critical task

An action or set of actions that adds an identifiable value to a given business process objective.

customer

Groups or individuals who have a business relationship with the organization— those who receive and use or are directly affected by the services of the organization. Customers include direct recipients of treatment and services, internal customers who provide services and resources for final recipients, and other organizations and entities that interact with an LHD to provide treatment and services.

entity

A person, group of people, or organization that performs one or more tasks involved in a process. The entities are the participants in the process. Entities are represented by circles in context diagrams.

framework

A defined support structure in which other components can be organized and developed. A logical structure for classifying and organizing complex information. A system of rules, ideas or principles that provides a unified view of the needs and functionality of a particular service.

function

A repeatable task series or operation that is used in more than one instance and can be shared across multiple business processes.

goal

The major health goal that the business process supports. The goal is the end state to be achieved by the work of the health agency and should be defined in terms of the benefits provided to the community/population or individual/client.

information system

Refers to the interaction between processes and technology, which may occur within or between organizations. It includes the information technology an organization uses, the ways the organizations interacts with the technology, and the ways technology works with the organization's business processes.

input(s)

Information received by the business process from external sources. Inputs are not generated within the process.

logical design

Logical design describes textually and graphically how an information system must be structured to support the requirements. Logical design is the final step in the process prior to physical design, and the products provide guidelines from which the programmer can work.

objective

A concrete statement describing what the business process seeks to achieve. The objective should be specific to the process such that one can evaluate the process or reengineer the process and understand how the process is performing towards achieving the specific objective. A well-worded objective will be SMART (Specific, Measurable, Attainable/Achievable, Realistic and Time-bound).

operation

A task series that completes a transaction.

outcome

The resulting transaction of a business process that indicates the objective has been met. Producing or delivering the outcome satisfies the stakeholder of the first event that triggered the business process. Often, measures can be associated with the outcome (e.g., how much, how often, decrease in incidents, etc.). An outcome can be, but is not necessarily, an output of the process.

output(s)

Information transferred out from a process. The information may have been the resulting transformation of an input, or it may have been information created within the business process.

result

A task output that may be used in one of three ways: (a) as an input to the next sequential step, (b) as an input to a downstream step within a task series; or (c) as the achievement of an organizational objective.

requirements

Define the specific tasks that need to be performed by an information system to complete a task.

requirements definition

Serves to specifically define the functionality to be supported. Requirements are also specified to ensure that activities within the business process remain within physical and operational boundaries.

Requirements definition answers the question: “How would you see information systems supporting Task X?”

requirements development methodology

A logical, step-wise approach to think through the tasks that are performed to meet the specific public health objectives (analyze business processes), rethink the tasks to increase effectiveness and efficiency (redesign business processes), and describe what the information system must do to support those tasks (define system requirements).

stakeholder

A person, group, or business unit that has a share or interest in a particular activity or set of activities.

task

A definable piece of work that can be done at one time; i.e., what happens between the in-box and the out-box on someone’s desk. A business process is made up of a series of work tasks.

task flow diagram

Graphic depiction of tasks showing inputs, processes, and results for each step that makes up a task.

task series

Any succession or progression of discrete tasks. A business process may contain more than one task series.

task set

The set of tasks that are carried out in a business process.

transaction

Information exchanges between entities. May also be the exchange of goods (e.g., a vaccine or payment) or services (e.g., an inspection) between two entities. Transactions are represented by arrows in context diagrams.

trigger

Event, action, or state that initiates the first course of action in a business process. A trigger may also be an input, but not necessarily so.