

VistA Immunizations Enhancements (VIMM 2.0)

Increment 3

Requirements Specification Document



August 2015

Version 0.2

Department of Veterans Affairs

Revision History

Note: The revision history cycle begins once changes or enhancements are requested after the Requirements Specification Document has been baselined.

Date	Version	Description	Author
27 August 2015	0.2	Added Section 2.7 Inter-operable Requirements, 2.8 Duplicate Requirements, 2.9 Non-functional Requirements, and 2.10 Out of Scope Requirements and populated appropriately (in progress)	Jacquelyn Marian Seema Chaudhry
18 August 2015	0.1	Listed requirements in Section 2.6 for increment 3	Jacquelyn Marian

Place latest revisions at top of table.

The Revision History pertains only to changes in the content of the document or any updates made after distribution. It does not apply to the formatting of the template.

Remove blank rows.

Artifact Rationale

The Requirements Specification Document (RSD) records the results of the specification gathering processes carried out during the Requirements phase. The RSD is generally written by the functional analyst(s) and should provide the bulk of the information used to create the test plan and test scripts. It should be updated for each increment.

The level of detail contained in this RSD should be consistent with the size and scope of the project. It is not necessary to fill out any sections of this document that do not apply to the project. The resources necessary to create and maintain this document during the life cycle of a large project should be acknowledged and clearly reflected in project schedules. Do not duplicate data that is already defined in another document or a section in this document; note in the section where the information can be found.

Table of Contents

1. Introduction	1
1.1. Purpose	1
1.2. Scope.....	2
1.3. References	3
2. Overall Description	4
2.1. Accessibility Specifications	4
2.2. Business Rules Specification	5
2.3. Design Constraints Specification	5
2.4. Disaster Recovery Specification	6
2.5. Documentation Specifications.....	6
2.6. Functional Specifications	7
2.7. Inter-operable Requirements	19
2.8. Duplicate Requirements.....	32
2.9. Non-Functional Requirements	33
2.10.Out of Scope Requirements.....	33
2.11.Graphical User Interface (GUI) Specifications	39
2.12.Multi-divisional Specifications	39
2.13.Performance Specifications	40
2.14.Quality Attributes Specification	41
2.15.Reliability Specifications	41
2.16.Scope Integration.....	41
2.17.Security Specifications.....	42
2.18.System Features.....	42
2.18.1. Inventory Management	43
2.18.2. Patient Education.....	43
2.18.3. Data Interchange	43
2.18.4. Computerized Provider Order Entry (CPOE)	43
2.18.5. Clinical Decision Support (CDS)	43
2.18.6. Alerts and Reminders	43
2.18.7. Reporting	43
2.18.8. Scheduling	43
2.18.9. Forecasting	44
2.18.10. Disconnected Mode	44
2.19.Usability Specifications	44
3. Purchased Components	45
4. Estimation	45

5. Approval Signatures	45
Appendix A. Non-Functional Requirements.....	46

1. Introduction

In January 2004, President George W. Bush issued an executive order encouraging the use of electronic health records by 2014 with the goal of making healthcare more efficient. The Department of Defense (DoD) and Department of Veterans Affairs (VA) responded to this challenge and have become leaders in the development and implementation of solutions enabling the sharing of electronic health data.

After a series of decision-making meetings, which began in March 2011, the Secretaries of Defense and Veterans Affairs committed their respective Departments to jointly develop and implement the next generation of electronic health record (EHR) capabilities. As part of this effort, Capability-Integrated Project Teams (C-IPT) were formed to develop and document the functional and non-functional requirements and business architecture artifacts related to each capability. The acquisition and sharing of standardized immunization data was included in the first prioritized set of capabilities to be considered for development.

As of July 2013, in response to strategic decisions made by the Interagency Program Office (IPO), VA and DoD, the direction of the Joint Immunization Capability (JIC) was altered to allow the VA to move ahead with a development effort to ensure readiness to meet Federated Data Accelerator goals for Initial Operating Capability (IOC) in September 30, 2014. These efforts, currently termed Veterans Information and Technology Architecture – 4 (VistA-4), will be separate from the DoD.

Currently, DoD and VA manage immunizations using separate Information Technology (IT) systems, with separate data repositories, and complex sharing processes. The use of multiple and disparate IT systems, non-standardized immunization data and non-standardized data management processes can lead to inconsistent or duplicative non-associated documentation within an individual's immunization record with the potential for unnecessary and excessive vaccinations, increased cost, and inventory waste. To address these challenges the VistA Immunization (VIMM) project was created to enhance VA IT systems capability to display, store and share standardized immunization data in a uniform manner. For VA, the Patient Care Encounter (PCE) system will be modernized and various other VistA applications will be modified to carry out the aforementioned objectives.

1.1. Purpose

The purpose of the Requirements Specification Document (RSD) is to document requirements for the Department of Veterans Affairs (VA) Office of Information Technology (OI&T) Office of Enterprise Development (OED) that are necessary to obtain IOC for VIMM in support of VistA-4 and Other development to support Full Operating Capability (FOC), such as updates to VistA-based Remote

Procedure Calls (RPC) to read/write within the evolved file structure, improved Electronic Health Management Platform (eHMP), improved user interface integrated to User Experience (UX) and the development of a data exchange using web-enabled decision support for bidirectional exchange of vaccine information with state registries. The intended audience includes project managers, business analysts, configuration managers and software developers that will be tasked with developing the patch.

1.2. Scope

Modernization of the VistA PCE system and modifications to other VistA applications that consume immunization data is critical to the success of VistA-4 and will be completed, in an incremental approach, with a series of development efforts that will span multiple years. The first development effort, VA Short Term Phase VIMM 1.0 aimed at obtaining IOC, included modifications to VistA immunization files that support the PCE system and a number of other VistA applications and the creation of a number of other standardized VistA supporting files. The VIMM 2.0 aimed at obtaining FOC consists of the following functionality.

- **Immunizations Standardization** – Immunization Standardization for first increment will make coded data entry and display for immunizations easier, which will enhance the integrated User Experience.
- **Interoperability** – Interoperability will allow VistA to intake immunization data from outside VA and transmit VA data to other healthcare systems and agencies. This will be enabled by updates to VistA-based Remote Procedure Calls (RPC) to read/write within the evolved file structure.
- **Meaningful Use** – Meaningful Use will enable the deployment of read/write exchange using web-enabled decision support for bidirectional exchange of vaccine information to demonstrate care coordination across sites of care and with state registries to meet Meaningful Use Stage 3 criteria.
- **Clinical Decision Support** – Clinical Decision Support will provide improved patient safety by identifying recommended immunization treatments based on nationally approved immunization schedules, notify provider and/or beneficiary of upcoming recommended or required immunizations through alerts and reminders and generating template-driven and ad-hoc reporting to manage population public health, cohort or panel immunization status.

The intended development for this phase currently includes in a VistA patch enhancement to the PX SAVE DATA RPC to capture all information sent by Walgreens / commercial immunization providers; inbound and outbound data read/write with DoD and CDC registries for Interoperability using existing VLER DAS interfaces (only one Immunization required to prove interface – select one that is either the easiest or most relevant); creation of a new Health Summary in VistA for Immunizations; work with CPRS v32 for provider read/write/edit of V-IMMUNIZATION fields; addition of all new fields to Clinical Reminders.

- Link to Business Requirements Document (BRD):
http://vaww.oed.portal.va.gov/pm/iehr/vista_evolution/immunization/Shared%20Documents/VIMM%202.0/PMAS%20Documents%20MS0/2011102_Immunization%20BRD%20adapted%20from%20VA%20iEHR%20JIC%20BRD_Signed.docx
- Link to Project Management Plan (PMP):
http://vaww.oed.portal.va.gov/pm/iehr/vista_evolution/immunization/Shared%20Documents/VIMM%202.0/PMAS%20Documents%20MS1/VEP_VIMM%202%200_PMP_20150402_PASSED.pdf

1.3. References

- JIC iBRD to support VistA-4(VA Only Use) NSR # 20130903
http://vaww.oed.portal.va.gov/pm/iehr/vista_evolution/immunization/default.aspx
- PCE V. 1.0 & Visit Tracking V. 2.0 Technical Manual
[http://www.va.gov/vdl/documents/Clinical/Patient_Care_Encounter_\(PCE\)/pxtm.doc](http://www.va.gov/vdl/documents/Clinical/Patient_Care_Encounter_(PCE)/pxtm.doc)
- Health Product Support Completion and Release Checklist
http://vaww.oed.portal.va.gov/pm/iehr/vista_evolution/immunization/default.aspx
- Application Linkages Research Immunization Files #9000010.11 and #9999999.14 – OI&T OED
http://vaww.oed.portal.va.gov/pm/iehr/vista_evolution/immunization/default.aspx
- VIMM 2 Requirements Master List
http://vaww.oed.portal.va.gov/pm/iehr/vista_evolution/immunization/Shared Documents/VIMM 2.0/Requirements
- Immunization_dependency_11182013 Spreadsheet dated November 18, 2013
http://vaww.oed.portal.va.gov/pm/iehr/vista_evolution/immunization/default.aspx
- The project repository for OED project information is at:
<http://tspr.vista.med.va.gov/warboard/anotebk.asp?proj=1714&Type=Active>

2. Overall Description

PCE, Computerized Patient Record System (CPRS) and other VistA applications that consume immunization data will undergo modifications over the next few years in order to conform to functional requirements specified by VIMM. In order for VA to be interoperable with other healthcare providers such as DoD and patient health information exchanges such as eHealth Exchange; PCE, CPRS and other VistA applications must be able to store, display and share additional data elements from Centers for Disease Control and Prevention (CDC) Immunization Information Systems (IIS), Health Level Seven (HL7) Standard Code Sets – Vaccine Administered (CVX) and Manufacturers of Vaccines (MVX). Both active and inactive vaccines available in the US will be stored in order to allow transmission of historical immunization records.

When an MVX (manufacturer) code is paired with a CVX (vaccine administered) code, the specific trade named vaccine may be indicated. Immunization data will be transmitted and shared using the International HL7 messaging. HL7 is the global authority on standards for interoperability (framework for the exchange, integration, sharing, and retrieval of electronic health information) of health information technology.

Overall, an immunization management system optimized for documenting, tracking, and reporting standard, interoperable immunization data of Service members/dependents and Veterans will enable VA to realize the following benefits:

- Optimize the quality of health care
- Reduce unnecessary immunizations
- Reduce excess costs
- Reduce inventory waste
- Improve accuracy of patient health records
- Facilitate immunizations reporting
- Decrease the risk of preventable infections by extending optimized processes and solutions to the public sphere

VA Short-Term Phase 1 is a subset of requirements to support VA's short term needs for VistA-4 to deliver standard, interoperable immunization data. This phase of development will bring VistA in compliance for immunizations per ONC EHR certification standards for 2014 (see NSR # 20110408).

2.1. Accessibility Specifications

GUI improvements will make coded data entry and display for immunizations easier, which will enhance the integrated User Experience. The development effort is inclusive of modifications to CPRS v32, Enterprise Health Management Platform (eHMP), ICE and CAT for Clinical Decision Support (CDS). VIMM will

work with the applicable GUI's to comply with applicable VA Section 508 Technical Standards, and will use VA Section 508 Checklists to validate that the application's Web interface conforms to VA Section 508 guidelines.

2.2. Business Rules Specification

Business Rules Requirement	Business Rules Specification
Patient can exchange data with community, resulting in patient-centric immunization history.	Deploy read/write/exchange with decision support for vaccines capability for coded immunizations data and that is integrated into UX. Bidirectional immunization sharing (C/MU standard of Health Level Seven (HL7) 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4.).

2.3. Design Constraints Specification

In developing any files or file modifications developers must recognize and apply the following technical constraints:

- All constraints of the current VA VistA system. See VistA Monograph (http://www.va.gov/VISTA_MONOGRAPH/index.asp) and VHA Documentation Library (VDL) (<http://www.va.gov/vdl/>).
- Application Linkages – the following application linkages must be considered in the development effort. These linkages must remain functional in order to assure continued functionality of all systems and interfaces that interoperate V IMMUNIZATION and IMMUNIZATION files.
 - Forward Pointers – Pointers in the Immunization files that point to other files.
 - Inbound References – Identifies and analyzes all references made by other applications to the legacy files; identifies applicable ICRs.
 - Backward Pointers – Pointers in other files that point to the Immunization files.
 - Integration Control Registrations (ICRs) – Lists the custodial and subscriber ICRs.
 - VistA Extracts – Identifies VistA extracts which transmit data to external systems that contain fields from either of the two files.
 - Outbound Templates – Identifies occurrences of templates that either reference the Immunization files or make relational jumps to the files.
 - Data Dictionary – The Immunization Data Dictionary identifies the contents of the Immunization files and sub-files.

- References from Data Dictionary – Identifies all of the references from the Data Dictionary to the Immunization files.
- ScreenMan – Identifies ScreenMan entries that access the Immunization files.
- Remote Procedure Calls (RPCs) – Identifies RPCs returning references to the Immunization files.
- National Capacity Planning – Capacity planning information provides site specific data for any existing VistA package.

2.4. Disaster Recovery Specification

Not applicable. There is no system development for this patch. All pre-existing VA VistA disaster recovery infrastructure established for the CPE and other VA applications that consume immunization data remains in place and in effect.

2.5. Documentation Specifications

VA requires that Operating Units (Program Managers, Project Managers, Analysts) ensure that adequate documentation for VA information systems and its constituent components is maintained, protected when required, and distributed to authorized personnel. OI&T system managers and the OI&T Chief/CIO in conjunction with the ISO must ensure that sufficient documentation is developed and maintained to formalize security and operational procedures for the Operating Unit's information systems.

Documentation developed shall comply with the specifications identified in VA ProPath artifacts and templates and/or specifications identified in other VA repositories (see Project Management Accountability System (PMAS) Guide version 5.0 June 11, 2014). Developers should reference and apply the conventions outlined in the VIMM System Design Document (SDD). Additionally, developers shall create and update as needed all documentation related to VIMM development in accordance with the following:

- All appropriate VIMM project documentation (manuals, etc.) will be updated in:
 - VistA Software Document Library (VDL)
(<http://www.va.gov/vdl/>)
 - VIMM project share point sites (both internal and external)
 - Technical Service Project Repository (TSPPR – VA Intranet)
<http://tspr.VistA.med.va.gov>
 - VA National Rational Repository for the VIMM project
- Developers shall create a System Design Document (SDD), User Guide, Technical Guide, Deployment Plan, Back Out Plan, Version Description Document (VDD) and an Installation Guide for the VIMM project.

- Analysts will create a Requirements Specification Document (RSD), Master Test Plan (MTP), Master Test Strategy, Requirements Traceability Matrix, Software Quality Assurance (SQA) Checklist, Release Notes for the VIMM Project.
- Project managers will be responsible to create, as needed, all other VIMM project documentation required to satisfy Program Management, Enterprise Testing Services (ESE) and IOC Entry Request mandates.

2.6. Functional Specifications

Req ID	Business Requirement	Elaboration/Comments
JIC-0031	The system shall capture that a user was presented with an immunization interaction / contraindication warning.	
JIC-0127	1. The system SHALL capture, display and report all immunizations associated with a patient	Testable requirement with Health Summary components.
JIC-0155	3. The system SHOULD provide the ability to document that a provider was presented with and acknowledged a drug interaction warning.	Immunization Functionality Link to JIC-0031
JIC-0203	The system SHOULD provide the ability to present the publication date of the VIS based on actual publication dates by the CDC.	Testable requirement with Health Summary components.
JIC-0207	The system shall provide the ability to capture if a patient declines an immunization.	Backend Data Dictionary structure created in PX*1.0*206. Functionality to be created in this increment. A V file would need: <ul style="list-style-type: none"> - Pointer to patient - Pointer to immunization type (9999999.14) - Pointer to IMM REFUSAL REASONS and/or IMM CONTRAINDICATION REASONS (We talked about it being a either variable pointer or two separate fields, and whether a single record could actually have both) - Some type of visit pointer to derive a date/time of the non-event - A comments field
JIC-	The system shall provide the ability	Linked to JIC-0207

Req ID	Business Requirement	Elaboration/Comments
0208	to capture the reason an immunization was not administered. (For example, Contraindications [history of anaphylaxis, fever > 104F, severe allergy to vaccine components], Refusals [parent refusal, patient refusal], or other reasons)	
JIC-0235	The system shall provide the ability to tag immunizations that are no longer in stock.	Additional work to be completed by CPRS/eHMP
JIC-0244	The system shall provide the ability to capture a patient's comments related to their immunizations concerns.	User Story: As a documenting provider I need default responses for some of the prompts (fields to be determined) for the immunization to either accept or edit values so that it saves me time. (example 'Date and Time' field to be populated with 'Today or Now' or 'Dosage' field to be populated with dose and unit '0.5 ml'). Acceptance Criteria: A documenting provider is able to view some immunization prompts with default values to accept and the ability to edit the responses if need be.
JIC-0271	The system shall provide the ability to interface between iEHR and external systems at the national and local level (For example, VA ADERS, VistA, etc.).	Identified to be VLER
JIC-0292	The system SHALL provide the ability for an authorized user to enter an immunization-specific default anatomical site where an immunization was administered on the patient. Can be done at the facility level.	
JIC-0300	The system SHALL provide the ability to tag recorded core data elements, when related to the provision of occupational health care provided to an employee-patient. Question of what occ med	

Req ID	Business Requirement	Elaboration/Comments
	information can be shared.	
JIC-0318	The system shall provide the ability to annotate an exception with the appropriate supporting policy or documentation. Clarification: For example, religious waiver	
JIC-0319	The system shall provide the ability to annotate an exemption with the appropriate supporting policy or documentation.	
JIC-0323	The system shall provide the ability to manually annotate historical immunization data for a patient.	
JIC-0324	The system shall provide the ability for the user to enter in the immunization lot number manually when transcribing historical records.	Improvements to the Field Description to provide guidance for the Lot # field when entering historical immunization information. CPRS/eHMP
JIC-0358-03	The system shall provide the ability to identify the timing of a post-administration immunization result.	
JIC-0360	The system MAY provide the ability to produce a history of all alerts that were generated for the patient in the record.	Testable
JIC-0369	The system shall provide the ability to UPDATE user role access.	No development, but testable Utilizing roles and security keys to provide appropriate level access to users.
JIC-0373	The system should capture immunization data elements presented by automated identification technologies (e.g., when a immunization's barcode is scanned, RFID). Clarification: Will capture the six data elements (as available) and demographic data.	If Barcode(BC) is the input method - then you get more than one piece of info. The sys will have to hold other pieces of info and use them to answer other fields as they come up.
JIC-0377	The system shall provide the ability to sort immunization records by all immunization data fields.	Sort on all fields is not expected. The alpha, chronologic, and reverse chronologic sorting in Health

Req ID	Business Requirement	Elaboration/Comments
		Summary is accepted as meeting this requirement.
JIC-0378	The system shall provide the ability to filter immunization records by all immunization data fields.	Same as JIC-0377.
JIC-0404	The system shall provide the ability to capture occupational series codes from the authoritative data source. Clarification: for all applicable beneficiaries	
JIC-0408	The system shall provide the ability to render a summary report of Immunity Status for an individual patient. Clarification: Immunity Status Report	Health Summary meets intent of VIMM responsibility and rest is out of scope.
JIC-0420	11. IF the system is used to extract data for analysis and reporting, THEN the system SHALL conform to function IN.2.4 (Extraction of Health Record Information), to support data extraction across the complete health record of an individual.	VLER
JIC-0426	18. IF the system exchanges data for which generally accepted interchange standards have been established, THEN the system SHALL conform to function IN.5.1 (Interchange Standards), to support interoperability.	VLER
JIC-0427	19. IF the system exchanges data for which generally accepted interchange standards have been established, THEN the system SHALL conform to function IN.5.2 (Interchange Standards Versioning and Maintenance), to accommodate the inevitable evolution of interchange standards.	VLER
JIC-0428	20. The system SHOULD conform to function IN.5.3 (Standards-based Application Integration).	VLER
JIC-0429	21. IF the system exchanges data with other systems outside itself,	VLER

Req ID	Business Requirement	Elaboration/Comments
	THEN the system SHALL conform to function IN.5.4 (Interchange Agreements), to define how the sender and receiver will exchange data.	
JIC-0430	8. IF health information has been mistakenly associated with a patient, THEN the system SHALL provide the ability to associate it with the correct patient.	We need to maintain the PCE roll and scroll interface to perform administrative corrections. This reqmt already exists in current VistA. We need to make sure we don't disable or break it (Regression Testing needs to be done on it). It is not a development but a testable reqmt
JIC-0441	1. The system SHALL provide the ability to create views that prohibit patients from accessing certain information according to organizational policy, scope of practice, and jurisdictional law.	
JIC-0442	2. The system SHOULD provide the ability to create customized views of summarized information based on sort and filter controls for date or date range, problem, or other clinical parameters.	
JIC-0443	3. The system SHOULD provide the ability to access summarized information through customized views based on prioritization of chronology, problem, or other pertinent clinical parameters.	
JIC-0469	1. The system SHOULD provide the ability to generate ad hoc query and reports of structured clinical and administrative data through either internal or external reporting tools.	No development, but is a testable requirement.
JIC-0470	2. The system MAY provide the ability to include information extracted from unstructured clinical and administrative data in the report generation process, using internal or external tools.	No development, but is a testable requirement.
JIC-	3. The system SHOULD provide the	No development, but is a testable

Req ID	Business Requirement	Elaboration/Comments
0471	ability to export reports generated.	requirement. Clinical Reminders
JIC-0472	4. The system SHOULD provide the ability to specify report parameters, based on patient demographic and/or clinical data, which would allow sorting and/or filtering of the data.	No development, but is a testable requirement. Clinical Reminders
JIC-0473	5. The system MAY provide the ability to save report parameters for generating subsequent reports.	No development, but is a testable requirement. Clinical Reminders
JIC-0474	6. The system MAY provide the ability to modify one or more parameters of a saved report specification when generating a report using that specification.	No development, but is a testable requirement. Clinical Reminders
JIC-0476	7. IF health information has been mistakenly associated with a patient, THEN the system SHALL provide the ability to mark the information as erroneous in the record of the patient in which it was mistakenly associated and represent that information as erroneous in all outputs containing that information.	Linked to JIC-0719
JIC-0488	6. The system SHOULD provide the ability to include patient identifying information on each page of reports generated.	No development, but is a testable requirement.
JIC-0492	3. The system SHOULD provide the ability to export reports generated.	
JIC-0494	5. The system (or an external application, using data from the system) MAY provide the ability to save report parameters for generating subsequent reports.	
JIC-0495	6. The system (or an external application, using data from the system) MAY provide the ability to modify one or more parameters of a saved report specification when generating a report using that specification.	

Req ID	Business Requirement	Elaboration/Comments
JIC-0501	1. The system SHALL provide the ability to create and update sets of access-control permissions granted to principals.	Linked to JIC-0369
JIC-0503	3. The system SHALL provide EHR-S security administrators with the ability to grant authorizations to principals according to scope of practice, organizational policy, or jurisdictional law.	Linked to JIC-0369
JIC-0504	4. The system SHALL provide EHR-S security administrators with the ability to grant authorizations for roles according to scope of practice, organizational policy, or jurisdictional law.	Linked to JIC-0369
JIC-0505	5. The system SHALL provide EHR-S security administrators with the ability to grant authorizations within contexts according to scope of practice, organizational policy, or jurisdictional law.	Linked to JIC-0369
JIC-0506	6. The system MAY provide the ability to define context for the purpose of principal authorization based on identity, role, work assignment, present condition, location, patient consent, or patient's present condition.	Linked to JIC-0369
JIC-0507	7. The system MAY provide the ability to define context based on legal requirements or disaster conditions.	Linked to JIC-0369
JIC-0508	1. The system SHALL conform to function IN.1.1 (Entity Authentication).	Linked to JIC-0369
JIC-0509	2. The system SHALL conform to function IN.1.2 (Entity Authorization).	Linked to JIC-0369
JIC-0510	3. The system SHALL provide the ability to define system and data access rules.	Linked to JIC-0369
JIC-	4. The system SHALL enforce	Linked to JIC-0369

Req ID	Business Requirement	Elaboration/Comments
0511	system and data access rules for all EHR-S resources (at component, application, or user level, either local or remote).	
JIC-0520	1. The system SHALL provide the ability to fully comply with the requirements for patient privacy and confidentiality in accordance with a user's scope of practice, organizational policy, or jurisdictional law.	No development, but is testable.
JIC-0523	4. The system SHALL conform to function IN.1.3 (Entity Access Control).	Linked to JIC-0369
JIC-0527	8. The system SHALL provide the ability to maintain varying levels of confidentiality in accordance with users' scope of practice, organizational policy, or jurisdictional law.	Linked to JIC-0369
JIC-0528	9. The system SHALL provide the ability to mask parts of the electronic health record (e.g. medications, conditions, sensitive documents) from disclosure according to scope of practice, organizational policy or jurisdictional law.	
JIC-0529	10. The system SHALL provide the ability to override a mask in emergency or other specific situations according to scope of practice, organizational policy or jurisdictional law.	
JIC-0579	4. The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction) to provide the ability to inactivate, obsolete, or destroy structured health record information.	Link to JIC-0719
JIC-0630	17. The system MAY provide the ability to create access privilege rules to guide system behavior.	Linked to JIC-0369
JIC-	18. The system MAY provide the ability to update access privilege	Linked to JIC-0369

Req ID	Business Requirement	Elaboration/Comments
0631	rules.	
JIC-0632	19. The system MAY provide the ability to customize access privilege rules and their components.	Linked to JIC-0369
JIC-0650	Provide enhancements to VistA/CPRS to allow modular EHR certification with the Dept. of HHS 2014 Edition Certification Criteria in both ambulatory and inpatient settings.	
JIC-0651	§170.314(b)(2) Transitions of care – create and transmit transition of care/referral summaries	
JIC-0652	Create: Provide the ability to enable a user eligible provider/ eligible hospital (EP/EH) to electronically create a transition of care/referral summary formatted in accordance with the standard § 170.205(a)(3) – HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, that includes, at a minimum Clarification: The use of the "unstructured document" document-level template is prohibited.	
JIC-0653	Immunizations: § 170.207(e)(2) – HL7 Standard Code Set CVX – Vaccines Administered, updates through July 11, 2012. Clarification: TBD during VLER requirements elaboration.	
JIC-0655	Minimum data from which to select: Provide EP the ability to select, at a minimum, the following data when creating a clinical summary:	
JIC-0656	The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future	

Req ID	Business Requirement	Elaboration/Comments
	scheduled tests; and recommended patient decision aids.	
JIC-0657	§170.314(b)(7) Data portability Clarification: See OWNR 2.6_EHR Certification of VistA for Meaningful Use RSD and BRCD. This requirement is covered.	
JIC-0658	Data portability: Provide the user (EP/EH) with the ability to electronically create a set of export summaries for all patients formatted in accordance to standard § 170.205(a)(3) – HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation., that represents the most current clinical information about each patient and includes, at a minimum: Clarification: The use of the "unstructured document" document-level template is prohibited.	
JIC-0659	The Common MU Data Set, and the following data expressed, where applicable, according to the specified standard(s).	
JIC-0660	Immunizations: § 170.207(e)(2) – HL7 Standard Code Set CVX – Vaccines Administered, updates through July 11, 2012. Clarification: See OWNR 2.6_EHR Certification of VistA for Meaningful Use RSD and BRCD. This requirement is covered.	
JIC-0660-01	§170.314(f)(2) Transmission to immunization registries Clarification: See OWNR 2.6_EHR Certification of VistA for Meaningful Use RSD and BRCD. This requirement is covered.	
JIC-0660-02	EHR technology must be able to electronically create immunization information for electronic transmission in accordance with the standard and applicable	

Req ID	Business Requirement	Elaboration/Comments
	implementation specifications specified in	
JIC-0660-03	§170.205(e)(3) – HL7 2.5.1 and the HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4.	
JIC-0660-04	§170.207(e)(2) – HL7 Standard Code Set CVX – Vaccines Administered, updates through July 11, 2012.	
JIC-0691	The system shall provide customized lists for specific needs allowing for display of a subset of immunizations or by limiting individual immunizations to a specific time period or number of instances.	Health Summary SIM component should satisfy this requirement.
JIC-0692	Provide the ability to consume a Global Trade Item Number (GTIN) as part of the data obtained by scanning a 2D barcode.	
JIC-0693	Provide the ability to extract (parse) the vaccine's lot number and expiration date from the data obtained by scanning a 2D barcode.	
JIC-0693-01	Provide the ability to record a new entry to IMMUNIZATION LOT # by scanning the product's 2D barcode	
JIC-0693-02	Provide the ability to store an immunization's NDC code as a property of the IMMUNIZATION file entry using the CODING SYSTEM multiple.	
JIC-0693-03	Provide the ability to identify an entry from the IMMUNIZATION file based on the NDC code present in the CODING SYSTEM multiple. (i.e., create a translation between NDC and CVX).	
JIC-0696	Provide the ability for authorized users to configure (i.e. view, edit, and publish) rules (e.g. Advisory Committee on Immunization Practices) for immunizations/vaccine	Task1: Create a new multiple field Vaccine Group in the Immunization File (9999999.14). It shall be a free text field with character length between 2 and 30 characters. A

Req ID	Business Requirement	Elaboration/Comments
	groups	<p>whole file cross-reference shall be created for searching and or sorting immunizations associated with the Vaccine Group Name. Like other fields this field shall also be always audited.</p> <p>User Story: As a user, I need to be able to find all immunizations associated with the Vaccine Group so that I can find a sorted list.</p> <p>Acceptance criteria: User is able to find a list of immunizations associated to the Vaccine Group.</p> <p>Task 2: TBD</p> <p>Task 3: TBD</p>
JIC-0712	The system shall provide the ability to redirect a user towards the allergy documentation interface whenever an allergy-type contraindication is recorded as a reason for not giving an immunization.	Related to patient refusal / contraindication requirements.
JIC-0719	As an immunizations user, I need the system to send an UPDATE/ENTERED-IN ERROR notification to external registries that may have received the data previously so that they can manage the update according to their organizational policy and/or jurisdictional law.	
JIC-0719-01	As an immunization user, I need the system to mark an attribute on a record that has been entered in error and shared with external entity, so that I am unable to delete references to it.	Linked to JIC-0476
JIC-0719-02	As an immunizations supervisor, I need to mark an immunization that was entered in error so that it can be excluded from reports and clinical decision support calculations but still keep the immunization as part of the record for historical purposes.	Linked to JIC-0476

2.7. Inter-operable Requirements

Req ID	Business Requirement	Elaboration/Comments
JIC-0017	The system shall be able to tag as "transcribed" historical immunization data from external systems.	VLER, DAS, and any other outside calling packages will need to include Event Information Source's appropriate code when passing data to \$\$DATA2PCE^PXAPI in order to determine historical information.
JIC-0020	The system shall provide the ability to enter comments on the immunization record for a defined group.	Immunization API/RPC and Immunization Campaign
JIC-0025	The system SHALL auto-populate selected immunization data fields with defaults when lot # for an immunization is selected. Clarification: Manufacturer, exp date.	CPRS/eHMP What we now expect in practice is that the UI will send in an identifier for an IMMUNIZATION (#9999999.14) file entry and the API (or RPC) will return non-expired entries from the IMMUNIZATION LOT (#9999999.41) file with the manufacturer and expiration date as additional data fields returned. Then when the user picks the LOT NUMBER from the returned choices, the UI will show (but not allow editing) of the manufacturer and expiration date.
JIC-0026	The system shall maintain patient immunization notifications (e.g. letters and email notifications) for reporting purposes.	Clinical Reminders
JIC-0037	The system shall provide the ability to enter the evidence for determination of a patient's immunity status (e.g., vaccination, lab test, reported history of disease, etc.)	ICE (VIMM or CR may provide the feeds to ICE) VIMM portion – Just the ability to enter historical vaccinations. Lab tests and History of disease go to someone else. Important part is being able to collate all of that in MU transmission, it is not in VIMM scope. Which pkg will take the lead (VIMM or CR) do not know that but be able to format the input to ICE.
JIC-0057	11. The system SHOULD provide the ability to receive, store and present standards-based structured, codified data received from an external	DAS (VIMM completed the changes to RPC)

Req ID	Business Requirement	Elaboration/Comments
	source.	
JIC-0060	12. The system SHOULD receive immunization histories from a public health immunization registry.	HDR (Health Data Repository)
JIC-0061	1. The system SHALL present information necessary to correctly identify the patient and accurately administer medications and immunizations such as patient name, medication name, strength, dose, route and frequency.	
JIC-0072	2. The system MAY provide the ability to automate the retrieval of formatted demographic and clinical information from local disease specific registries (and other notifiable registries).	HDR (Health Data Repository)
JIC-0093	The system shall provide the ability to enter the immunity status of a patient. Clarification: Immunity Status should be defined as: immune, vaccinated, not immune, vaccine series in progress	ICE We want to be able to record Immunity Status, but not in any of the files VIMM has. Duplicate of JIC-0182.
JIC-0094	The system shall provide the ability to capture the source of immunizations that were externally obtained.	VLER Linked to JIC-0017
JIC-0106	The system shall provide the ability to capture patient risk factors in determining an immunization schedule.	ICE Linked to JIC-0182
JIC-0112	The system SHALL provide the ability for an authorized user to render individual patient immunization exceptions.	ICE Linked to JIC-0182
JIC-0118	1. The system SHALL capture and explicitly label patient-originated data.	VLER Linked to JIC-0017
JIC-0138	The system shall provide the ability to capture patient risk factors in determining an immunization treatment plan.	ICE Linked to JIC-0182

Req ID	Business Requirement	Elaboration/Comments
JIC-0182	The system SHALL provide the ability for an authorized user to link required immunization(s) to a User-Defined Group of patients.	ICE Linked to JIC-0093, JIC-0106, JIC-0112, and JIC-0138. If someone has the immunity to a disease that has been documented by a vaccine, lab test demonstration, or by having the disease. Younger adults are immune because they had the vaccine & older adults are immune because they had the disease. If someone is immune because they had the disease then ask ICE to calculate their vaccination need. It has to be smart enough to know that you had the disease and that is why you do not need it. Decision Support belongs to eHMP so it'll be part of that discussion. How we're going to track these other things that are non-documentational given the vaccines.
JIC-0188	The system SHALL provide the ability to RENDER immunizations requirements associated to User-Defined Groups. Clarification: Defined groups include: User-defined groups, population cohorts, etc.	ICE
JIC-0200	The system shall provide the ability to render the most current printed Vaccine Information Sheet.	CPRS/eHMP
JIC-0202	The system SHALL provide the ability to capture the following data for the VIS: - VIS Name - Publication date of (applicable) VIS - Date offered to Patient - Offered to Patient (Y/N)	CPRS/eHMP VIMM part is complete with the changes to APIs and RPCs.
JIC-0229	1. The system MAY provide the ability to capture and update material that may be printed and provided to the patient at the point of care.	CPRS/eHMP
JIC-	The system shall provide the ability	CPRS/eHMP

Req ID	Business Requirement	Elaboration/Comments
0248	to capture a patient's comments related to their immunizations concerns.	
JIC-0254	The system SHALL provide the ability for an authorized user to render a schedule of immunizations for a patient, including: <ul style="list-style-type: none"> - Required immunizations - Remaining doses in an immunization series completion of series may or may not be required	ICE/HLN It is a VIMM reqmt and it stays as an ICE reqmt. ICE can handle bullet 1 – Reqd Immz. But ICE does not handle bullet 2 - remaining doses in immz series). The HLN will complete the enhancements to ICE.
JIC-0267	The system SHALL provide the ability for an authorized user to enter an immunization using the manufacturer name and generic name. Clarification: Trade name, manufacturer name, abbreviated descriptor	CPRS/eHMP
JIC-0267-01	The system shall provide the ability for an authorized clinician to document an immunization by selecting it using the generic name (CDC short description) or the trade name (CDC PRODUCT NAME)	CPRS/eHMP
JIC-0283	The system SHALL provide the ability to harmonize immunization record comments assigned to a user-defined group of patients to the individual records of all patients in the group. Meant to represent the six elements of an immunization record	Immunization Campaign
JIC-0284	The system SHALL provide the ability to capture immunization data elements associated with each specific immunization during concomitant administration of multiple immunizations.	CPRS/eHMP
JIC-0285	The system SHALL provide the ability to present predefined template documentation of immunizations	Immunization Campaign

Req ID	Business Requirement	Elaboration/Comments
	given in a mass vaccination setting. child of concomitant imm. Need to identify the data elements.	
JIC-0286	The system SHALL provide the ability to capture documentation of immunizations that are administered in a multiple dose series.	Immunization Campaign
JIC-0287	The system SHALL provide the ability, when documenting the immunization given, to store the following core data elements: <ul style="list-style-type: none"> - Vaccine type - Vaccine manufacturer - Vaccination date - Vaccination lot number - Immunization event identifiers (series) - Dose/volume - Site - Route - Expiration date - VIS documentation 	CPRS/eHMP
JIC-0290	The system shall provide the ability for the vaccinator to capture the date and time an immunization was actually administered. Clarification: Not for transcribed records. Less than or equal to current date/time	CPRS/eHMP
JIC-0291	The system shall capture the date and time of documentation of an administration of an immunization. Clarification: Equals current date/time	CPRS/eHMP
JIC-0293	The system shall provide the ability to capture that a patient received an immunization as a part of a combination immunization (e.g., Tetanus-Diphtheria) Clarification: The system will capture the documentation that administration of a combination	ICE

Req ID	Business Requirement	Elaboration/Comments
	immunization satisfies individual immunization requirements.	
JIC-0298	The system shall provide the ability to capture input from an external electronic data capture system (e.g., BCMA) to complete the documentation of immunization administration.	BCMA
JIC-0306	6. The system SHALL record as discrete data elements data associated with any immunization.	CPRS/eHMP
JIC-0317	The system shall provide the ability to transmit adverse immunization reaction information to required authorities. Clarification: Patient record, VA ADERS, VAERS, CDC, FDA	VLER
JIC-0320	The system SHALL provide the ability to present changes to a patient-specific immunization schedule Clarification: With a flag. Able to identify individual patients.	ICE/HLN
JIC-0329	6. The system MAY generate documentation of medication or immunization administration as a by-product of verification of patient, medication, dose, route and time.	BCMA
JIC-0334	1. The system SHOULD automatically transfer formatted demographic and clinical information to local disease specific registries (and other notifiable registries).	VLER
JIC-0338	11. The system SHOULD transmit required immunization information to a public health immunization registry.	VLER
JIC-0383	The system shall comply with exchange of health information according to scope of practice, organizational policy, and/or jurisdictional law.	VLER
JIC-	The system shall provide the ability to render a monthly immunization	Health Summary / Clinical Reminders

Req ID	Business Requirement	Elaboration/Comments
0385	report listing the types of immunizations given. Clarification: For fleet.	
JIC-0387	The system shall provide ability to render preventive medicine reports that contain data on immunizations required, given and to whom. Clarification: Child of ad hoc reporting.	Health Summary and CPRS/eHMP
JIC-0389	The system shall provide the ability to view online help materials for Immunization Capability Clarification: Context-sensitive, at the data element level. 11/21/13-changed JIC to Immunization capability.	CPRS/eHMP
JIC-0396	The system shall provide the ability to exchange historical data from authoritative sources.	VLER
JIC-0398	The system shall provide the ability to capture ad hoc report templates.	CPRS/eHMP and Clinical Reminders
JIC-0399	The system shall provide the ability to remove ad hoc report templates.	CPRS/eHMP and Clinical Reminders
JIC-0400	The system shall provide the ability to Store ad hoc report templates.	CPRS/eHMP and Clinical Reminders
JIC-0401	The system shall provide the ability to Store ad hoc report output.	CPRS/eHMP and Clinical Reminders
JIC-0405	The system shall provide the ability to render summary reports of immunization doses administered across a defined group (e.g., an Occupational Health Vaccination Status Report, a Military Immunization Readiness Report). Clarification: VA Vaccination Administration Report.	Clinical Reminders
JIC-0406	The system shall provide the ability to render summary reports of immunization status using the following data elements: - vaccine	Clinical Reminders

Req ID	Business Requirement	Elaboration/Comments
	<ul style="list-style-type: none"> - patient - occupation series - facility - vaccine status Clarification: Vaccination Status Report.	
JIC-0407	The system shall provide the ability to render summary report of immunizations across a patient population. Clarification: Vaccination Status Report.	Clinical Reminders
JIC-0409	The system SHALL provide the ability to render national performance monitoring reports (e.g. such as that required by VA Office of Performance Measurement) to satisfy existing quality monitors such as vaccination rates Clarification: Capture additional reports.	Clinical Reminders
JIC-0410	The system shall provide the ability to CAPTURE a denominator to facilitate ad hoc reporting. Clarification: Patient cohort or other population attribute.	Clinical Reminders
JIC-0440	10. The system SHOULD provide the ability to receive, store and present structured text-based reports received from an external source.	VLER
JIC-0445	14. The system MAY provide the ability to re-prescribe medication by allowing a prior prescription to be reordered without re-entering previous data (e.g. administration schedule, quantity).	eHMP
JIC-0446	15. The system SHOULD provide the ability to re-prescribe a medication from a prior prescription using the same dosage but allow for editing of details adequate for correct filling and administration of medication (e.g. dose, frequency, body weight).	eHMP

Req ID	Business Requirement	Elaboration/Comments
JIC-0447	1. The system SHALL provide the ability to capture non-medication patient care orders for an action or item	eHMP
JIC-0448	2. The system SHALL provide the ability to capture adequate order detail for correct order fulfillment.	eHMP
JIC-0449	3. The system SHALL track the status of the ordered action or item.	eHMP
JIC-0450	4. The system SHOULD provide the ability to capture patient instructions necessary for correct order fulfillment.	eHMP
JIC-0451	5. The system SHOULD provide the ability to present patient instructions necessary for correct order fulfillment.	eHMP
JIC-0452	6. The system SHOULD provide the ability to communicate the order to the correct recipient(s) for order fulfillment	eHMP
JIC-0453	1. The system SHALL provide the ability to capture orders for diagnostic tests.	eHMP
JIC-0454	2. The system SHALL provide the ability to capture adequate order detail for correct diagnostic test fulfillment.	eHMP
JIC-0455	3. The system SHALL provide the ability to track the status of diagnostic test(s).	eHMP
JIC-0456	4. The system SHOULD provide the ability to capture and present patient instructions relevant to the diagnostic test ordered.	eHMP
JIC-0457	5. The system SHALL communicate orders to the service provider of the diagnostic test.	eHMP
JIC-0458	6. The system SHOULD communicate supporting detailed documentation to the correct service	eHMP

Req ID	Business Requirement	Elaboration/Comments
	provider of the diagnostic test.	
JIC-0496	1. The system SHALL provide the ability to generate instructions pertinent to the patient for standardized procedures.	eHMP
JIC-0515	4. The system SHALL encrypt and decrypt EHR data that is exchanged over a non-secure link.	VLER
JIC-0516	5. The system SHALL support standards-based encryption mechanisms when encryption is used for secure data exchange.	VLER
JIC-0517	1. The system SHALL automatically route electronically exchanged EHR data only from and to known sources and destinations and only over secure networks.	VLER
JIC-0518	2. The system SHOULD route electronically exchanged EHR data only to and from authenticated sources and destinations (conform to function IN.1.1 (Entity Authentication)).	VLER
JIC-0531	2. The system SHALL provide the ability to retain inbound data or documents (related to health records) as originally received (unaltered, inclusive of the method in which they were received) for the legally organizationally prescribed time in accordance with users' scope of practice, organizational policy, or jurisdictional law.	VLER
JIC-0532	3. The system SHALL retain the content of inbound data (related to health records) as originally received for the legally prescribed time.	VLER
JIC-0564	2. The system SHOULD conform to function IN.3 (Registry and Directory Services) to enable the use of registries and directories.	VLER
JIC-0566	4. The system SHOULD store the location of each known health record	VPR

Req ID	Business Requirement	Elaboration/Comments
	component in order to enable authorized access to a complete logical health record if the EHR is distributed among several applications within the EHR-S.	
JIC-0586	1. The system SHALL provide the ability to use standard terminologies to communicate with other systems(internal or external to the EHR-S).	VLER
JIC-0588	3. The system SHOULD provide the ability to exchange healthcare data using formal standard information models and standard terminologies.	VLER
JIC-0589	4. The system SHOULD provide the ability to use a formal standard terminology model.	VLER
JIC-0605	1. The system SHALL provide the ability to use interchange standards as required by realm specific and/or local profiles.	VLER
JIC-0606	2. The system SHALL provide the ability to seamlessly perform interchange operations with other systems that adhere to recognized interchange standards.	VLER
JIC-0608	4. IF there is no standard information model available, THEN the system MAY provide a formal explicit information model in order to support the ability to operate seamlessly with other systems.	VLER
JIC-0609	5. The system SHOULD provide the ability to exchange data using an explicit and formal information model and standard, coded terminology.	VLER
JIC-0610	1. The system SHALL provide the ability to use different versions of interchange standards.	VLER
JIC-0611	2, The system SHALL provide the ability to change (reconfigure) the way that data is transmitted as an interchange standard evolves over	VLER

Req ID	Business Requirement	Elaboration/Comments
	time and in accordance with business needs.	
JIC-0612	3. The system SHOULD provide the ability to deprecate an interchange standard.	VLER
JIC-0613	4. The system SHOULD provide the ability to interoperate with other systems that use known earlier versions of an interoperability standard.	VLER
JIC-0649	Provide the ability to utilize CVX so that users will be able to document standardized immunization data 1. 170.314(b)(1) – Transitions of Care (ToC)-Receive, Display, and Incorporate Transition of Care/Referral Summaries: 2. 170.314(b)(2) – Transitions of Care-Creat and Transmit Transition of Care/Referral Summaries: 3. 170.314(f)(2) – Transmission to Immunization Registries. 4. 170.314(b)(7) – Data Portability Clarification: 170.207(e)(2) – Immunization Information System (IIS): HL7 Standard Code Set CVX – Vaccines Administered, updates through July 11, 2012.	VLER
JIC-0694	The system shall provide the ability to restrict data input for documentation of new immunization administrations to be limited to a selection of vaccine names corresponding to ACTIVE CVX codes only.	Clinical Reminders and CPRS/eHMP
JIC-0695	The system shall provide the ability to permit data input for documentation of historical immunization administrations using any CVX Code, including both ACTIVE and INACTIVE codes.	Clinical Reminders and CPRS/eHMP
JIC-0708	The system shall provide the ability to capture objective readings	CPRS/eHMP

Req ID	Business Requirement	Elaboration/Comments
	following inoculations that require a reading (e.g. smallpox).	
JIC-0709	The system shall provide the ability to capture a clinician's subjective interpretation of inoculations that require reading (e.g. smallpox).	CPRS/eHMP
JIC-0711-1	Provide the ability to filter the display of recent immunizations on the coversheet to the last 'n' occurrences per immunization type Clarification: This is a new requirement based on CAC requests.	CPRS/eHMP
JIC-0711-2	Provide the ability to filter the display of recent immunizations on the coversheet to the last 'x' timeperiod	CPRS/eHMP
JIC-0711-3	Provide the ability to sort the display of recent immunizations on the coversheet by immunization name (alphabetic) or by immunization date (ascending and descending)	CPRS/eHMP
JIC-0720	<p>The Virtual Patient Record (VPR) shall extract following data (fields listed) from the VistA Patient Care Encounter package different files to create an HL7 compliant immunization message.</p> <ul style="list-style-type: none"> - Lot Number (field #1207) from V IMMUNIZATION file <p>Manufacturer (derived as a property of the pointed-to LOT NUMBER file)</p> <ul style="list-style-type: none"> - Expiration Date (also derived as a property of the pointed-to LOT NUMBER), - VIS Given - Date VIS Given (obtained from the multiple field #2 in V IMMUNIZATION, because a single immunization may require more than one vaccine information statement) - Anatomic Body Site (field 1303) - Route of Administration (field 1302), - Dosage (field 1305) 	VPR

Req ID	Business Requirement	Elaboration/Comments
	<ul style="list-style-type: none"> - Event Information Source (field 1301) <p>The three roles that participate are as follows:</p> <ul style="list-style-type: none"> - Ordering provider (field 1202) - Administering provider is 'encounter provider' (field 1204), - Documenting provider is 'immunization documenter' (field 1206). <p>Note: CVX code is already extracted via patch VPR*1*4.</p>	

2.8. Duplicate Requirements

Req ID	Business Requirement	Elaboration/Comments
JIC-0024	<p>The system SHALL auto-populate selected immunization data fields with defaults when an immunization is selected.</p> <p>Clarification: Dose, route, anatomical site, current date/time, name, all available lot numbers.</p>	Duplicate of JIC-0244
JIC-0054	<p>16. The system MAY provide the ability for providers to annotate a result.</p>	Duplicate of JIC-0325 and JIC-0358
JIC-0199	<p>The system SHALL provide the ability to render patient education materials.</p> <p>Clarification: Example – Trifold (MILVAX).</p>	<p>CPRS/eHMP</p> <p>Duplicate of JIC-0200</p>
JIC-0201	<p>The system should provide the ability to render electronically-transmitted patient education materials.</p>	<p>CPRS/eHMP</p> <p>Duplicate of JIC-0200</p>

2.9. Non-Functional Requirements

Req ID	Business Requirement
JIC-0021	The system shall be able to manage immunization data from authoritative sources. Clarification: Federal, state, local (e.g., local public health, IHS).
JIC-0039	1. The system SHALL provide the ability to present numerical and non-numerical current and historical test results to the appropriate provider.

2.10. Out of Scope Requirements

Req ID	Business Requirement
JIC-0027	The system shall provide the ability to capture the delivery status of certified patient letters (e.g., undelivered/delivered). Clarification: Vaccine contamination – Consider under DC.2.5.2 for an Immunizations Functional Profile.
JIC-0028	The system shall provide the ability to update the delivery status of certified patient letters (e.g., undelivered/delivered) Clarification: Vaccine contamination – Consider under DC.2.5.2 for an Immunizations Functional Profile.
JIC-0031	The system shall capture that a user was presented with an immunization interaction / contraindication warning.
JIC-0039	1. The system SHALL provide the ability to present numerical and non-numerical current and historical test results to the appropriate provider.
JIC-0040	2. The system SHALL provide the ability to filter results for a unique patient.
JIC-0041	3. The system SHALL provide the ability to filter results by factors that supports results management, such as type of test and date range.
JIC-0042	4. The system SHOULD indicate normal and abnormal results depending on the data source.
JIC-0043	5. The system SHOULD provide the ability to filter lab results by range, e.g. critical, abnormal or normal.
JIC-0044	6. The system SHOULD display numerical results in flow sheets, graphical form, and allow comparison of results.
JIC-0045	7. The system SHALL provide the ability to group tests done on the same day.
JIC-0047	9. The system SHOULD provide the ability for the user, to whom a result is presented, to acknowledge the result.
JIC-0048	10. The system SHOULD provide the ability to route results to other appropriate care providers, such as nursing home, consulting physicians, etc.

Req ID	Business Requirement
JIC-0049	11. The system MAY route results to patients by methods such as phone, fax, electronically or letter.
JIC-0050	12. The system SHOULD provide the ability for providers to pass on the responsibility to perform follow up actions to other providers.
JIC-0051	13. The system MAY provide the ability for an authorized user to group results into clinically logical sections.
JIC-0055	17. The system MAY display a link to an image associated with results.
JIC-0056	9. The system SHOULD provide the ability to receive, store and present medication details from an external source.
JIC-0076	The system shall provide the ability to identify patient immunization by patient identification number. Clarification: This is an assumption that capability 0 will be in place prior to implementation of JIC.
JIC-0077	The system shall provide the ability to identify a patient record using the following demographic information: reword this statement <ul style="list-style-type: none"> - First Name - Last Name - DOB - Gender - Patient Identification Number - Unit Assignment Clarification: This is an assumption that capability 0 will be in place prior to implementation of JIC.
JIC-0078	The system should have the capability to match patient identification data read from the HSPD12 with patient data found in the iEHR Identity Management service.
JIC-0079	9. The system SHALL provide the ability to retrieve parts of a patient record using a primary identifier, secondary identifiers, or other information which are not identifiers, but could be used to help identify the patient.
JIC-0084	7. The system SHALL present a set of patient identifying information at each interaction with the patient record.
JIC-0095	The system shall provide the ability to capture information related to pregnancy status (e.g. gestational age).
JIC-0119	2. IF the system provides the ability for direct entry by the patient, THEN the system SHALL explicitly label the data as patient entered.
JIC-0120	3. The system SHALL capture and label the source of clinical data provided on behalf of the patient.
JIC-0121	4. The system SHALL present patient-originated data for use by care providers.

Req ID	Business Requirement
JIC-0122	5. The system SHALL provide the ability for a provider to verify the accuracy of patient-originated data for inclusion in the patient record.
JIC-0123	6. The system SHOULD provide the ability to view or comment, but not alter patient-originated data.
JIC-0124	1. The system SHALL provide the ability to capture, present, maintain and make available for clinical decisions patient preferences such as language, religion, spiritual practices and culture.
JIC-0125	2. The system SHALL provide the ability to capture, present, maintain and make available for clinical decisions family preferences such as language, religion, spiritual practices and culture.
JIC-0137	The system shall provide the ability to capture the resolution of a patient's comments related to their immunizations concerns.
JIC-0139	5. The system SHALL provide the ability to capture a report of No Known Allergies (NKA) for the patient.
JIC-0140	6. The system SHOULD provide the ability to capture a report of No Known Drug Allergies (NKDA) for the patient.
JIC-0141	7. The system SHOULD provide the ability to capture the source of allergy, intolerance, and adverse reaction information.
JIC-0142	8. The system SHALL provide the ability to deactivate an item on the list.
JIC-0143	9. The system SHALL provide the ability to capture the reason for deactivation of an item on the list.
JIC-0144	10. The system MAY present allergies, intolerances and adverse reactions that have been deactivated.
JIC-0145	11. The system MAY provide the ability to display user defined sort order of list.
JIC-0146	12. The system SHOULD provide the ability to indicate that the list of medications and other agents has been reviewed.
JIC-0147	13. The system SHALL provide the ability to capture and display the date on which allergy information was entered.
JIC-0148	14. The system SHOULD provide the ability to capture and display the approximate date of the allergy occurrence.
JIC-0178	11. The system MAY provide a list of frequently-ordered medications by diagnosis by provider which could include the full details of the medication, including SIG, quantity, refills, DAW, etc.
JIC-0183	The system shall provide the ability to create order templates (e.g., standing orders). Clarification: Standing order templates, protocol, etc.
JIC-0184	3. The system SHALL provide the ability to use previously developed care plans as a basis for the creation of new plans of care and treatment.

Req ID	Business Requirement
JIC-0189	The system shall provide the ability to capture a standing order or protocol.
JIC-0191	The system SHALL provide the ability to tag changes to a patient-specific immunization schedule. Clarification: With a flag.
JIC-0192	1. The system SHALL provide the ability to capture patient-specific plans of care and treatment.
JIC-0204	"The system shall provide the ability to render immunization after care instructions.
JIC-0209	The system shall provide the ability to capture the consent when required.
JIC-0210	The system shall provide the ability to capture the individual providing consent (e.g., patient, parental, care giver)
JIC-0211	The system shall provide the ability to render documentation of consent when required.
JIC-0212	The system shall provide the ability to store an employee-patient declination statement. Hep B
JIC-0213	The system shall provide the ability for patients to electronically sign employee-patient declination statements.
JIC-0214	The system shall provide the ability to capture signed employee-patient declination statements.
JIC-0215	The system shall provide the ability to render employee-patient declination statements.
JIC-0219	1. The system SHALL provide the ability to indicate that a patient has completed applicable consents and authorizations.
JIC-0220	2. The system SHALL provide the ability to indicate that a patient has withdrawn applicable consents and authorizations.
JIC-0225	7. The system MAY provide the ability to display consents and authorizations chronologically.
JIC-0226	8. The system SHOULD provide the ability to document an assent for patients legally unable to consent.
JIC-0227	9. The system SHALL provide the ability to document the source of each consent, such as the patient or the patient's personal representative if the patient is legally unable to provide it.
JIC-0228	10. The system SHOULD provide the ability to document the patient's personal representative's level of authority to make decisions on behalf of the patient.
JIC-0230	2. The system MAY provide the ability to validate the material prior to update.

Req ID	Business Requirement
JIC-0253	The system shall exchange immunization schedule data with an appointment scheduling system.
JIC-0257	3. The system MAY provide the ability to display patient reminders, manually process, and record associated telephone contacts.
JIC-0264	The system shall provide the ability to maintain a user-defined set of frequently-ordered immunizations by clinic.
JIC-0270	The system SHALL provide the ability to capture the Overseeing Physician for a specified facility.
JIC-0276	2. IF lab results are received through an electronic interface, THEN the system SHALL receive and store the data elements into the patient record.
JIC-0279	2. The system SHOULD provide the ability to create and modify data entry workflows.
JIC-0280	3. The system SHOULD provide the ability to extract appropriate information from the patient record as necessary to document the patient encounter.
JIC-0282	5. The system MAY initiate secondary reporting workflows as a result of information entered into the encounter.
JIC-0295	The system shall provide the ability to annotate an immunization record where the administration data does not meet recommended defaults (e.g., site)
JIC-0305	5. The system SHOULD provide the ability to capture other clinical data pertinent to the immunization administration (e.g. vital signs).
JIC-0312	The system shall provide the ability to capture all adverse reactions to an immunization, including anaphylactic reactions.
JIC-0313	1. The system SHALL provide the ability to capture true allergy, intolerance, and adverse reaction to drug, dietary or environmental triggers as unique, discrete entries.
JIC-0314	2. The system SHOULD provide the ability to capture the reason for entry of the allergy, intolerance or adverse reaction.
JIC-0315	3. The system SHALL provide the ability to capture the reaction type.
JIC-0316	4. The system SHOULD provide the ability to capture the severity of a reaction.
JIC-0322	The system should tag a patient's documented immunization-related allergies. Clarification: For example, component-specific.
JIC-0332	1. The system SHALL present summarized views and reports of the patient's comprehensive EHR.
JIC-0333	2. The system SHOULD include at least the following in the summary: problem list, medication list, allergy and adverse reaction list.

Req ID	Business Requirement
JIC-0339	2. The system SHALL provide the ability to generate instructions pertinent to the patient based on clinical judgment.
JIC-0340	3. The system SHALL provide the ability to include details on further care such as follow up, return visits and appropriate timing of further care.
JIC-0341	4. The system SHALL provide the ability to record that instructions were given to the patient.
JIC-0342	5. The system SHALL provide the ability to record the actual instructions given to the patient or reference the document(s) containing those instructions.
JIC-0345	3. The system SHOULD provide the ability to define outcome measures for specific patient diagnosis.
JIC-0346	4. The system SHOULD provide the ability to define outcome measures to meet various regional requirements.
JIC-0347	5. The system SHOULD provide for the acceptance and retrieval of unique outcome data defined to meet regional requirements.
JIC-0354	The system shall provide the ability to present data related to blood test results.
JIC-0355	3. IF lab results are received through an electronic interface, THEN the system SHALL display them upon request.
JIC-0361	The system shall be able to capture immunization data in disconnected mode.
JIC-0362	The system shall be able to store immunization data in disconnected mode.
JIC-0363	The system shall provide the ability to manually capture patient data, where none exists, in disconnected mode. Clarification: When patient is not in the predefined patient set downloaded prior to entering disconnected mode.
JIC-0364	The system shall provide the ability to annotate immunization records captured in disconnected mode. Clarification: For audit purposes, research, legal, etc.
JIC-0382	The system shall provide the ability to render a patient record when the HSPD12 is scanned or swiped.
JIC-0388	The system shall provide the ability to render ad hoc reports in disconnected mode.
JIC-0392	The system shall provide the ability to link to agency approved staff education materials.
JIC-0393	The system shall provide the ability to render agency approved staff education materials.
JIC-0395	The system shall provide the ability to render ad hoc reports of aggregate

Req ID	Business Requirement
	data from new systems, legacy systems, or both simultaneously.
JIC-0397	The system shall provide the ability to render reports of adverse reactions (e.g., anaphylactic) 0398 to immunization events.
JIC-0402	The system shall provide the ability to exchange ad hoc report templates.
JIC-0414	The system shall render reports scheduled by the user for specific date and time.
JIC-0431	10. The system SHOULD provide the ability to obsolete, inactivate, nullify, destroy and archive a patient's record in accordance with local policies and procedures, as well as applicable laws and regulations.
JIC-0479	1. The system SHALL create a single logical record for each patient.
JIC-0480	2. The system SHALL provide the ability to create a record for a patient when the identity of the patient is unknown.
JIC-0483	1. The system SHALL provide the ability to generate reports consisting of all and part of an individual patient's record.
JIC-0484	2. The system SHOULD provide the ability to define the records or reports that are considered the formal health record for disclosure purposes.
JIC-0486	4. The system SHOULD provide the ability to create hardcopy and electronic report summary information (procedures, medications, labs, immunizations, allergies, vital signs).
JIC-0487	5. The system MAY provide the ability to specify or define reporting groups (i.e. print sets) for specific types of disclosure or information sharing.
JIC-0489	7. The system SHOULD provide the ability to customize reports to match mandated formats.

2.11. Graphical User Interface (GUI) Specifications

GUI improvements will make coded data entry and display for immunizations easier, which will enhance the integrated User Experience. The development effort is inclusive of modifications to CPRS v32, eHMP, ICE and CAT for CDS.

2.12. Multi-divisional Specifications

The modified V IMMUNIZATION, IMMUNIZATION, and SKIN TEST files must continue to support the following:

- Allow multiple VA health care facilities to perform all business and patient care functions
- Allow multi-site operations where VA may be sharing immunization data with a non-VA entity such as Department of Defense (DoD) or the Indian Health Service (IHS)

- Allow multiple VA applications that read/write to these files to perform all business and patient care functions. A partial listing of VA applications identified:
 - Automated Information Collection System (AICS)
 - Computerized Patient Record System (CPRS)
 - Enterprise Health Management Platform (eHMP)
 - Pharmacy: Bar Code Medication Administration (BCMA)
 - Pharmacy: Benefits Management (PBM)
 - Clinical Reminders
 - Ambulatory Care Reporting Project
 - Nationwide Health Information Network Adapter (NHIN)
 - Clinical Case Registries (CCR)
 - Virtual Patient Record (VPR)
 - Data Access Services (DAS)
 - Health Data & Informatics (HDI)
 - Veteran Point of Service (VPS) KIOSK
 - Immunizations Mobile Application
- Allow multiple government, private sector and standards development organizations to perform all business and patient care related functions:
 - Private Sector Pharmacies: Interoperability with VA for Veterans receiving immunizations at the community pharmacy
 - SureScripts (via Walgreens) transmission to state registries
 - Information Exchange (IE)
 - iEHR Data Federation Accelerators
 - V-CAMP

2.13. Performance Specifications

Population size is estimated to be 130,000 VA clinical users. These estimates are based on the Interagency Program Office (IPO) evaluation of Medical Single Sign-On (SSO) and Context Management (CM) Tools, 17 May 2011.

User interactions are expected to undergo “surges” dependent on activities related to immunizations for readiness or other purposes. These include: annual broad immunizations for influenza etc.

2.14. Quality Attributes Specification

VIMM will follow CDC Immunizations Information Systems (IIS) conventions as they relate to the acquisition and management of immunizations data.

<http://www.cdc.gov/vaccines/programs/iis/code-sets.html>

Coding standards to which this development effort shall conform to are found in the following document:

The Department of Veterans Affairs M Programming Standards and Conventions. Revised 04/03/2007.

2.15. Reliability Specifications

- System shall be available 24/7 and fully operational 99.9% of the time, with exceptions for routine maintenance activities during non-peak hours.
- System maintenance shall be scheduled during off peak hours.
- A back-up plan will be provided for when the system is brought off-line for maintenance or technical issues/problems.

2.16. Scope Integration

Following the deployment of VistA Immunization Enhancements (VIMM) 1.0, VistA Immunization Enhancements (VIMM) 2.0 will build on this success, modifying existing Immunization functions and enabling VA to quickly and reliably document and exchange standardized immunization information on Veterans and their dependents with both DoD and external healthcare partners. Modifications will support read/write exchange with decision support for vaccines capability for coded immunizations data, that will be integrated into eHMP and support certification for Meaningful Use (C/MU). Clinicians will have access to a more complete medical history in VistA, resulting in improved health status, as well as public health monitoring.

The VistA Evolution Immunization/Patient Care Encounter System Integration View for FOC is shown below.

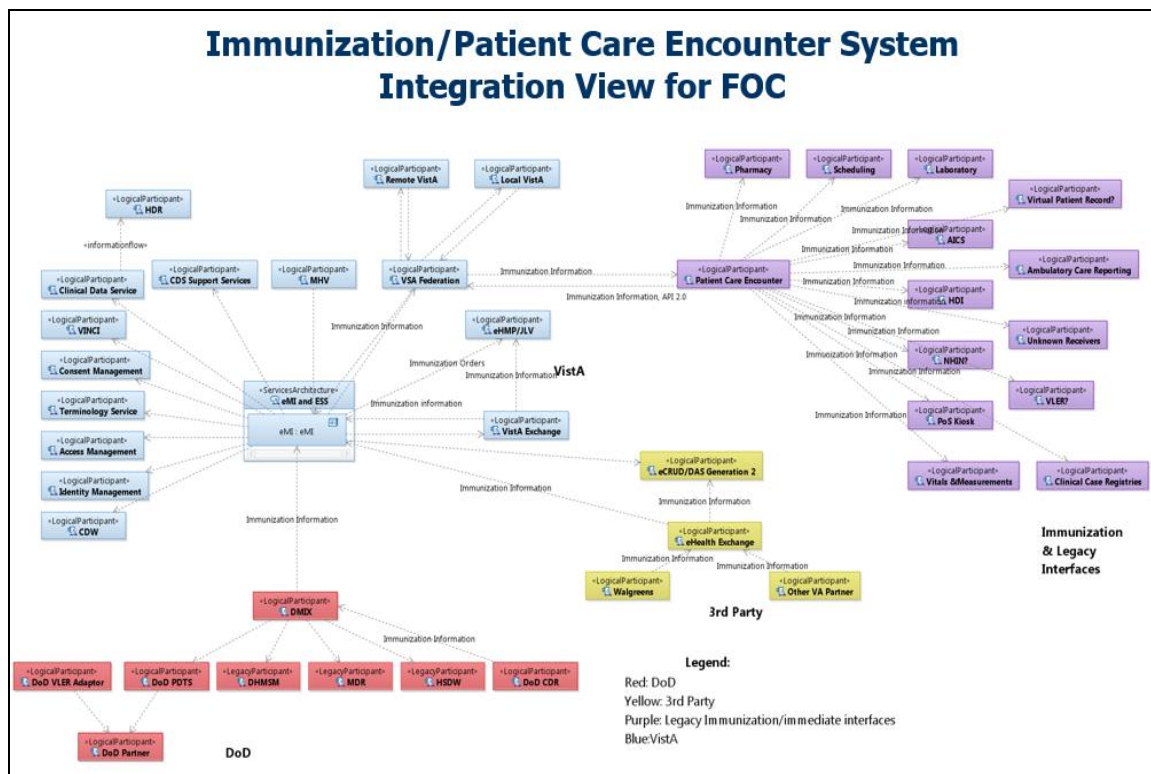


Figure 1. Vista Evolution Immunization/Patient Care Encounter System Integration View for FOC

2.17. Security Specifications

All applicable VA and VHA security requirements will be adhered to. Cross-cutting security requirements are contained in the VA Enterprise Requirements Repository (ERR). Additionally, all applicable VA and VHA Privacy requirements will be adhered to. Efforts that involve the collection and maintenance of individually identifiable information must be covered by a Privacy Act system of records notice.

Federal security specifications are documented in the Federal Information Processing Standard (FIPS) 199 and National Institute of Standards and Technology (NIST) SP 800-60.

Minimum security control requirements are addressed in *NIST SP 800-53* and *VA Handbook 6500, Appendix D*.

2.18. System Features

VIMM 2.0 system features shall include the following:

2.18.1. Inventory Management

VIMM 2.0 shall track immunization/vaccine stock from manufacturer to patient administration including intermediate inventory management at the facility and clinic levels.

2.18.2. Patient Education

VIMM 2.0 shall record Vaccine Information Statement (VIS) data documenting the offer of the VIS to the patient or patient representative, the date of such offer, and the date of the VIS being offered.

2.18.3. Data Interchange

VIMM 2.0 shall share immunization history data to legacy VA/DoD Electronic Health Record (EHR) systems and DoD service readiness systems in order to promote continuity of care.

2.18.4. Computerized Provider Order Entry (CPOE)

VIMM 2.0 shall associate Immunization standing orders and provider's patient-specific orders with a patient record to denote the authorization to administer an immunization.

2.18.5. Clinical Decision Support (CDS)

VIMM 2.0 shall improve patient safety by identifying recommended immunization treatments based on nationally approved immunization schedules.

2.18.6. Alerts and Reminders

VIMM 2.0 shall notify the provider and/or beneficiary of upcoming recommended or required immunizations (see 2.1.8.5 and 2.1.8.8) to ensure all recommended and minimal standards are designated and tracked.

2.18.7. Reporting

VIMM 2.0 shall generate template-driven and ad-hoc reports in order to manage population public health, cohort or panel immunization status

2.18.8. Scheduling

VIMM 2.0 shall interface with legacy VA appointment scheduling systems and the future-state scheduling system in order to facilitate a coordinated effort between an identified immunization that is recommended or required, and the patient/beneficiary's presence to receive that immunization.

2.18.9. Forecasting

VIMM 2.0 shall predict at the population, facility, and cohort levels the required inventory purchases of immunizations for a given time period, utilizing the available clinical decision support tools (2.1.8.5 and immunization histories (2.1.8.3) to define the anticipated need.

2.18.10. Disconnected Mode

VIMM 2.0 shall provide the above services when disconnected from the network, syncing data upon reconnection with the system/network.

The 'Vista Evolution Patient Encounter Logical View for Full Operating Capability (FOC)' system features are shown in the diagram below.

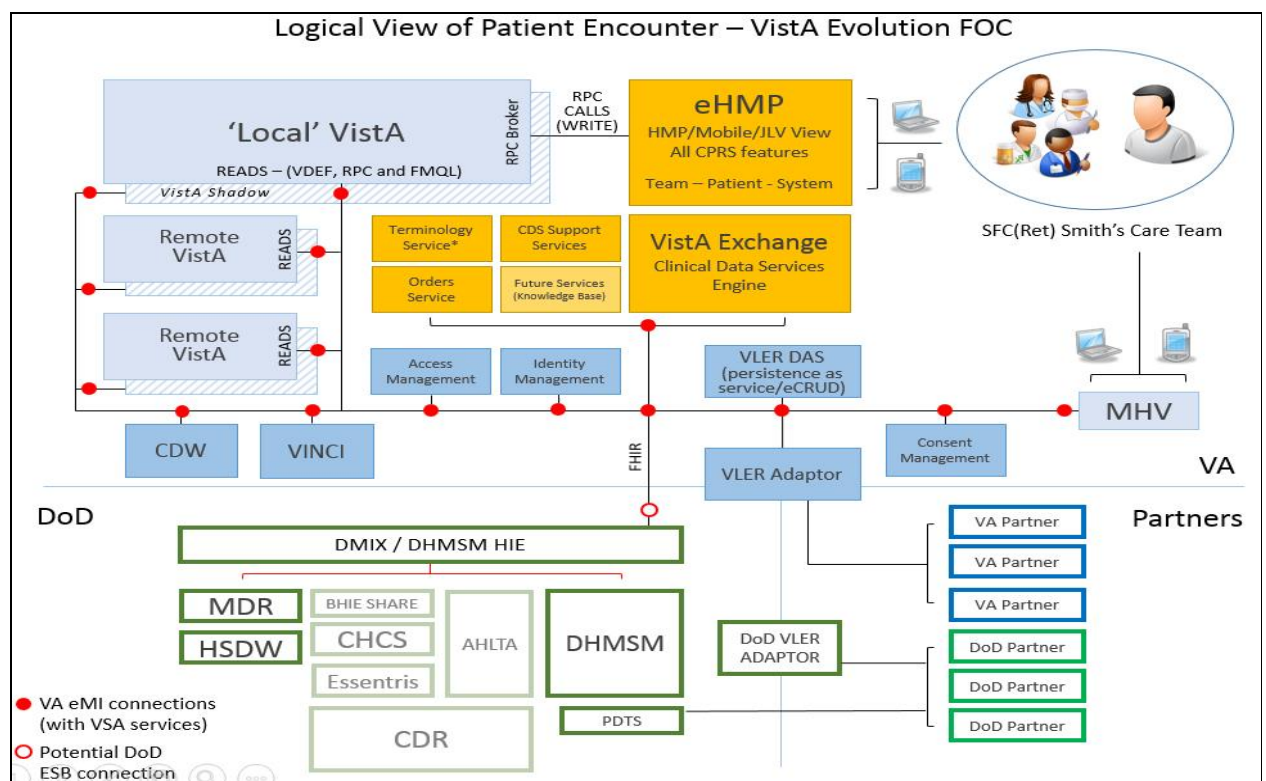


Figure 2. Vista Evolution Patient Encounter Logical View for Full Operating Capability (FOC)

2.19. Usability Specifications

- The system shall ensure that files are organized by a folder / file structure that is easily understood and easy to use.
- The system shall provide convenient document navigation with a Windows-like tree structure and an easy-to-use search engine.

- Training shall be provided to the responsibility areas using a minimum of a user guide and user maintained help information that is accessible through the application.

Training shall target how each responsibility is to use the application in support of their work and communication to other roles and areas.

3. Purchased Components

VistA Immunization will operate using existing infrastructure. There are no purchased components as part of VIMM.

4. Estimation

FP count will be provided.

5. Approval Signatures

REVIEW DATE: 08/18/2015

SCRIBE: Jacquelyn Marian

Heidi Martin, Business Sponsor

Date

Robert Silverman, PharmD, Business Owner Representative

Date

Dan Carroll, IT Program Manager

Date

Keith Magoon, Project Manager, IPT Chair

Date

Appendix A. Non-Functional Requirements

The following non-functional requirements should be reviewed and accessed while developing the requirements for the project.

System Performance Reporting Requirements

Note: Each system developed by the Department of Veterans Affairs (VA) Office of Information and Technology (OI&T) must comply with the following mandatory requirements.

1. Include instrumentation to measure all performance metrics specified in the Non-Functional Requirements section of the Requirements Traceability Matrix (RTM). At a minimum, systems will have the ability to measure reporting requirements for Responsiveness, Capacity, and Availability as defined in the non-functional requirements section of the RTM.
2. Make the performance measurements available to the Information Technology (IT) Performance Dashboard to enable display of “actual” system metrics to customers and IT staff.

Operational Environment Requirements

1. System response times and page load times shall be consistent with _____ standards (for example, My HealtheVet or HealtheVet). (Comment: There may be different expectations for an external display vs. a query. Need to address these different uses. Also indicate if this information is unknown).
2. Maintenance, including maintenance of externally developed software incorporated into the _____ application(s), shall be scheduled during off peak hours or in conjunction with relevant maintenance schedules. The business owner should provide specific requirements for establishing system maintenance windows when planned service disruptions can occur in support of periodic maintenance.
3. Information about response time degradation resulting from unscheduled system outages and other events that degrade system functionality and/or performance shall be disseminated to the user community within 30 minutes of the occurrence. The notification shall include the information described in the current Automated Notification Reporting (ANR) template maintained by the VA Service Desk. The specific business impact must be noted in order for OIT to provide accurate data in the service impact notice of the ANR.
4. Provide a real-time monitoring solution to report agreed/identified critical system performance parameters.
5. Critical business performance parameters shall be identified e.g., transaction speed, response time for screen display/refresh, data retrieval, etc. in a manner that data capture can occur to support metric reporting and support the OI&T performance dashboard display. If no such

performance metrics are required or provided there will be no program specific Service Level Agreements (SLA) created, nor shall there be any active/real time monitoring through OI&T Performance Dashboard to provide the business owners any performance metrics.

6. Notification of scheduled maintenance periods that require the service to be offline or that may degrade system performance shall be disseminated to the business user community a minimum of 48 hours prior to the scheduled event.

Documentation Requirements

1. The training curriculum shall state the expected training time for primary users and secondary users to become proficient at using the _____ application(s).
2. All training curricula, user manuals and other training tools shall be developed/updated by _____ <<insert name of Program Office>> and delivered to all levels of users _____. If known, insert how much time in advance the training tools will be delivered and via what mechanism(s); for example, 2-4 weeks in advance of the release of the enhancement through nationwide conference calls and PowerPoint presentations). The curricula shall include all aspects of the enhanced _____ application(s) and all changes to processes and procedures.
3. The training curriculum developed by the Program Office shall state the expected task completion time for primary and secondary users.
4. User manuals and training tools shall be developed. If they already exist, updates shall be made, as necessary, to them and they shall be delivered to all levels of users.
5. IT will provide the level of documentation required to support the system and maintain operations and continuity. Documentation shall represent minimal programmatic and lifecycle operations support documentation artifacts as defined by VA standards in ProPath and as required by the VA Enterprise System Engineering Lifecycle and Release Management office for sustained operations, maintenance, and support (<http://vawww.eie.va.gov/lifecycle/default.aspx>) prior to approval by any VA change control board and release into production.

Implementation Requirements

1. Technical Help Desk support for the application shall be provided for users to obtain assistance with _____.
2. The IT solution shall be designed to comply with the applicable approved Enterprise SLA.
3. The implementation must be complete by _____. (Enter date – dd-mm-yyyy)

Data Protection/Back-up/Archive Requirements

1. Based upon the criticality of the system, provide a back-up and data recovery process for when the system is brought off-line for maintenance or technical issues/problems.
2. Data protection measures, such as back-up intervals and redundancy shall be consistent with systems categorized as routine (30 day restoration), mission essential (72 hour restoration), or mission critical (12 hour restoration).
3. Business owners are required to state the mission criticality of the IT services required in order to assist the planners and developers in determining best strategies for engineering an IT solution to meet their business objectives/needs. The business owner needs to state the criticality of the data and the impact to the business during a service disruption so appropriate technologies can be considered.

Levels for Disaster Recovery

Classification	Recovery Time Objective	Recovery Point Objective
Routine	30 day restoration	TBD
Mission Essential	72 hour restoration	24 hours
Mission Critical	12 hour restoration	2 hours

Recovery Time Objective (RTO) – RTO defines the maximum amount of time that a system resource can remain unavailable before there is an unacceptable impact on other system resources, supported mission/business processes, and the MTD.

Maximum Tolerable Downtime (MTD) – The MTD represents the total amount of time the system owner/authorizing official is willing to accept for a mission/business process outage or disruption and includes all impact considerations.

Recovery Point Objective (RPO) – The RPO represents the point in time, prior to a disruption or system outage, to which mission/business process data can be recovered (given the most recent backup copy of the data) after an outage.

Data Quality/Assurance Requirements

A monitoring process shall be provided to ensure that data is accurate and up-to-date and provides accurate alerts for malfunctions while minimizing false alarms.

User Access/Security Requirements

Ensure the proposed solution meets all Veterans Health Administration (VHA) Security, Privacy, and Identity Management requirements including VA Handbook 6500 (see the Enterprise Requirements section of the RTM).

Usability/User Interface Requirements

Adhere to good User Interface/User Centered Design (UI/UCD) principles as outlined in the Usability Appendix of the BRD.

Conceptual Integrity

Provide standards based messaging and middleware infrastructure needed to support both Legacy Veterans Health Information Systems Technology Architecture (VistA) and future VistA-4 deployments.

Availability

1. Maintenance window, including maintenance of externally developed software incorporated into the VistA-4 application(s), will be by mutual agreement between OI&T and the VHA Point of Contact (POC) for the affected facility(ies). VHA will provide POCs for each facility.
2. VistA application unavailability due to an unplanned outage or planned outages that exceed the defined maintenance window will not exceed 8.76 hours per year and will not exceed 43.8 minutes per month (99.9% availability).
3. The application shall be available 24 hours a day, seven days a week, with an uptime of 99.9%.
4. All system updates and scheduled maintenance should occur between the hours of 1800 and 0600 (per local time zone), when clinical usage would be lightest.

Interoperability

1. The system shall support all recognized health system standards i.e., Health Level 7 (HL7), Fast Healthcare Interoperability Resources (FHIR).
2. Systems must be heterogeneous and agnostic for operating systems and code bases.
3. Provide the ability to securely transfer large files (of 4-8 gigabyte) from an external source to VA systems.
4. Provide access to the system over a remote access solution.

Manageability

1. Provide Service Desk/Incident and Problem Management tracking related to maintenance events of patient care systems with priority over non-patient care systems.
2. Provide data related to maintenance events, both routine and exceptional, including key metadata:
 - Predicted routine work
 - Occurrences where maintenance is completed, including restart from down time
 - Identity of the organization performing maintenance
 - User performing maintenance (if available)
 - Identity of the system
 - Date/time, physical location

- Systems impacted
 - Does it affect patient care
 - Non-urgent or emergent
3. Provide audit capabilities for system access and usage with settings that are configurable to support internal and external audits based on federal and VHA mandates.
 4. The system must comply with VA Directive 6300 Records and Information Management and with VHA Records Control Schedule (RCS) 10-1, in general and specifically with Electronic Final Version of Health Record: Destroy/Delete 75 years after last episode of patient care, or longer (if specified).

Performance

1. Provide an Infobutton Query Responder on all platforms with a response time of less than .5 seconds.
2. The system shall recognize, report, and retransmit data lost, with less than 0-1% chance of incomplete patient records.
3. Provide patient data (for data within the system) transactions (e.g., capture, search, request for data) within .5 seconds.
4. Mouse or key-based UI controls, e.g., menus, checkboxes shall provide instantaneous responsiveness (<90ms).
5. Part-screen refreshes after user action shall complete within a pro-rated interval between 200 ms and 1200 ms times a percentage of the screen area being refreshed. For example, a component 10% of the screen area would refresh in $(1200 - 200) * 0.10 + 200 = 300$ ms.

Reliability

1. Provide system reliability:
 - Threshold = 99.9%
 - Objective = 99.99% system and application
2. Provide system reliability:
 - Level 1 severity =<1 failure per month
 - Level 2 severity =<2 failures per month
 - Level 3 severity =<3 failures per month

Security

Provide management of electronic attestation of information including the retention of the signature of attestation (or certificate of authenticity) associated with incoming or outgoing information.

Supportability

1. Provide alerts (that extend beyond system messages to external systems like mobile devices) for malfunctions, while preventing false alarms for local, regional, and national evaluations in real time.
2. Provide reports on performance metrics as specified in the VistA-4 Effectiveness and Value / Benefits Framework on a bi-weekly basis.
3. Provide national, regional, and local reports on performance metrics as specified in the VistA-4 Effectiveness and Value / Benefits Framework.
4. Provide performance metrics (from request for information to receipt of information on the screen) monitored by the system and system administrators so they know what the user experience is like without users having to call them and tell them the system is running very slow.
5. Provide the ability for VHA and IT staff to create standard and ad-hoc reports of usage, bandwidth, response time, login time, and other variables with a verification process for measuring the capabilities of the system.
6. Provide end-user training on how to generate the various system performance reports (e.g., in standard file formats such as Comma Separated Values [CSV], Portable Document Format [PDF], or Excel) depending on the user's needs.
7. Provide the ability to view system statistics (e.g., information on the specific network environment) and identify areas that are having issues or are beyond capacity, in near-real-time (to be quantified at a later time).
8. Technical Help Desk support for the application via instant message, on-line, phone, and remote desktop access support, shall be provided for users to obtain assistance 24/7.
9. The IT solution shall be designed to comply with the applicable approved Enterprise SLAs.
10. Data protection measures, such as back-up intervals and redundancy shall be consistent with systems categorized as mission critical (1hr restoration, 2hrs backup recovery). Impact of system failure must be monitored on a near real time basis.
11. Provide the ability to set thresholds and notification type (e.g., email or text alerts) when alerting the user about response time degradation and unscheduled outages.
12. Disaster Recovery Plans (DRP) and Continuity of Operations Plan (COOP) will be updated and tested semi-annually to address the VistA-4 product (see National Security and Homeland Security Presidential Directive: National Continuity Policy. NSPD-51/HSPD-20, May 9, 2007 <http://www.fas.org/irp/offdocs/nspd/nspd-51.htm>).

Usability

1. Provide viewability/usability of VistA-4 applications on mobile devices.

2. User prompts and screen help shall be embedded into the system to guide use of the solution.

Documentation

1. The training curriculum shall be provided in two hours or more of training time for primary users and secondary users to become proficient at using the VistA-4 application(s).
2. All training curricula, user manuals and other training tools shall be developed/updated by the VE Program Office and delivered to all levels of users 4 weeks in advance of the release of the enhancement through mediums that will best support the sharing of information to all affected staff.
3. Provide follow-up training classes tailored to VHA workflow 4 weeks after the users have begun to