



IIS-VAERS Collaboration For Vaccine Adverse Events Reporting

Functional and Process Recommendations
of the American Immunization Registry Association (AIRA)
Vaccine Safety and Registry Community (VASREC) Workgroup

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VASREC Workgroup Roster

Chair, Warren Williams, MPH
CDC – National Immunization Program
Phone: (404) 639-8867
E-mail: wxw4@cdc.gov

AIRA staff, Cindy Sutliff
American Immunization Registry
Association
Phone: 212-676-2325
E-mail: csutliff@health.nyc.gov

Business Analyst, David Lyalin, PhD
CITS - CDC Information Technology
Support
Phone: (678) 530-3583
E-mail: dlyalin@cdc.gov

Participants:

Angel Aponte
NYC Department of Health and Mental
Hygiene
Phone: 212 676-2320
E-mail: aaponte@health.nyc.gov

Mike Berry
HLN Consulting
Phone:
E-mail: berrym@hln.com

Scott Campbell
CDC – National Immunization Program
Phone: 404-639-8579
E-mail: SIC3@cdc.gov

Frank Caniglia, RHIA
Pennsylvania Department of Health
Phone: 717 783-2548 ext 229
E-mail: ccaniglia@state.pa.us

Robert Chen
CDC – National Immunization Program
Phone:
E-mail: Rtc1@cdc.gov

Pete Garner
Florida Department of Health
Phone:
E-mail: Pete.garner@doh.state.fl.us

Harald Heijbel
Swedish Institute
Phone: +46 46 188035
E-mail: harald.heijbel@swipnet.se

Philip LaRussa
NY-Columbia
Phone: 212 305 0898
E-mail: Psl1@columbi.edu

Marlene Lugg, DrPH
Southern California Kaiser Permanente
Phone:
E-mail: Marlene.M.Lugg@kp.org

Amy Metroka
NYC Department of Health and Mental
Hygiene
Phone: 212 676-2319
E-mail: AMETROKA@health.nyc.gov

Dennis Michaud, M.Ed.
Massachusetts Department of Public Health
Phone: 617-983-6838
E-mail: Dennis.Michaud@state.ma.us

Vicky Papadouka
NYC Department of Health and Mental
Hygiene
Phone: 212 676 2331
E-mail: VPAPADOU@health.nyc.gov

Susanne Pickering, MS
CDC – National Immunization Program
Phone: 404-639-6038
E-mail: SHP9@cdc.gov

Ali Rashidee
 AHRQ – Agency for Healthcare Research and Quality
 Phone: 404 498-1103
 E-mail: AIR9@cdc.gov

Lise Stevens
 FDA – U.S. Food and Drug Administration
 Phone: 301-827-3974
 E-mail: stevensl@cber.fda.gov

Beth Rowe-West
 NC Registry
 Phone:
 E-mail: beth.rowe-west@ncmail.net

Michael Suralik
 HLN Consulting
 Phone: 215-568-3004
 E-mail: suralik@hln.com

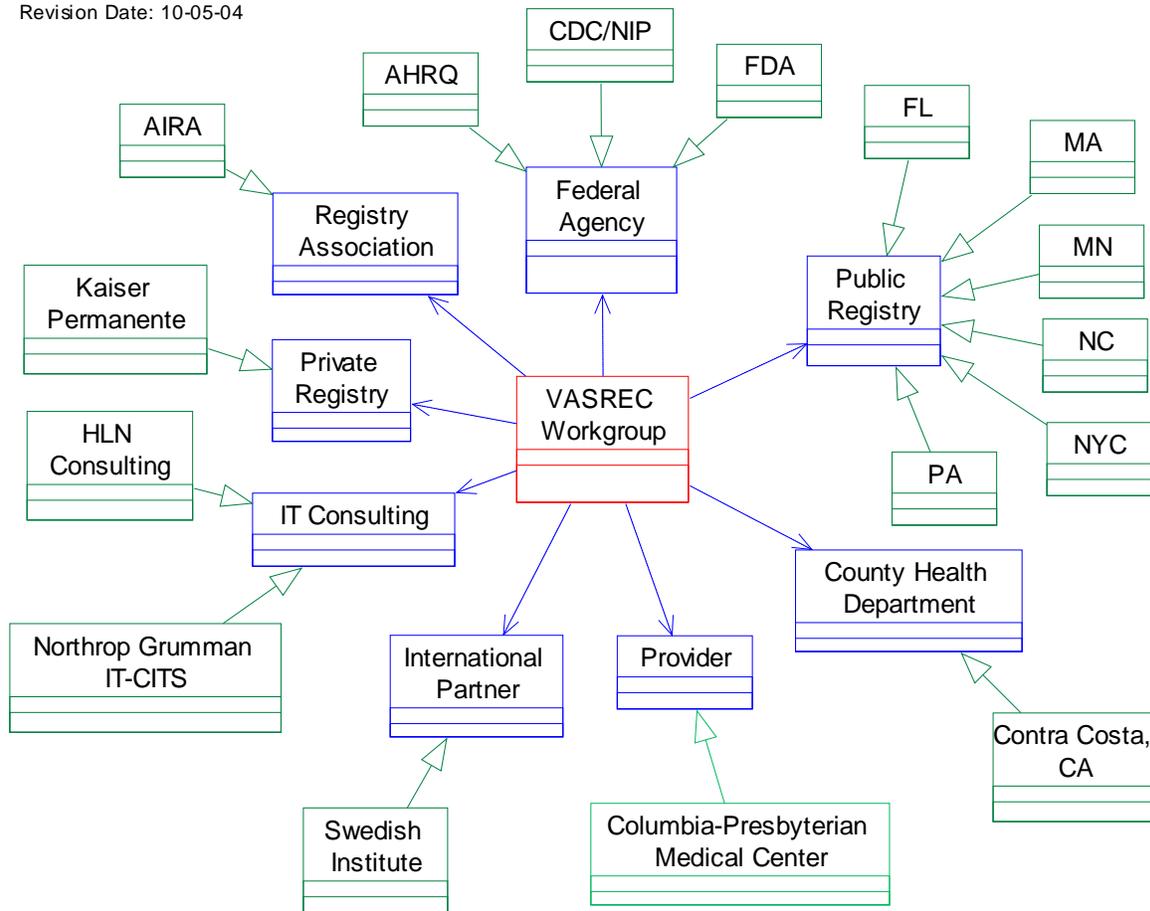
Linda Stevens
 Minnesota Department of Health
 Phone: 612-676-5673
 E-mail: linda.stevens@health.state.mn.us

Siu Wing Tong
 Contra Costa Health Services
 Phone: 925- 313 6327
 E-mail: swtong@hsd.co.contra-costa.ca.us

Ron Van Duyne
 CDC – National Immunization Program
 Phone: 404 639-8867
 E-mail: Rsv0@cdc.gov

VASREC workgroup at a glance: structure and diversity visualization

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Introduction

This document is intended to serve as an operational best practices guide supporting various stakeholders involved in reporting vaccine adverse events to the Vaccine Adverse Events Reporting System (VAERS) through Immunization Information Systems (IIS).

This document is prepared by the American Immunization Registries Association (AIRA) Vaccine Safety and Registry Community (VASREC) Workgroup. It contains workgroup's recommendations in a form of functional requirements and a conceptual level consensus-based description of the vaccine adverse events reporting process. Recommendations identify activities and flow of information for the reporting to the VAERS that utilize IIS data and services. This document seeks to integrate generic scenarios for the VAERS reporting through the IIS with IIS functional capabilities and Vaccine Adverse Event Reporting requirements, as stipulated by the National Childhood Vaccine Injury Act of 1986. Developed recommendations are technology neutral and written at the business / functional level. This document may evolve over time to include other specific areas such as reporting structure, additional business rules, and more detailed functional requirements.

1. Vaccine adverse events domain

This section presents a description of the Vaccine Adverse Events Domain. The Domain Diagram presents a graphic illustration of domains and the entities within them. It can serve as an introductory point for learning about the IIS-VAERS relationships.

A *Domain* is an area of knowledge or activity characterized by a set of concepts and terminology. Practitioners in that area typically understand the knowledge and activity. The Domain diagram shows major business entities, their responsibilities, and relationships. The domain diagram also captures a business vocabulary. Business vocabularies are the names given to entities within a domain. A name can be a static thing, like a report, an entity or organization like immunization registry, a person or actor like a provider or an activity like “reports to.”

Domain modeling is used to ensure that all terminology and concepts that will appear in the workflow are known and understood by the domain practitioners (agreed upon definitions and meaning). A Domain Diagram provides a foundation from which other diagrams, including a workflow diagram can evolve.

It is important to know that a Domain diagram is not:

- Data model.
- Workflow model.

Domain diagram is a static representation of the main “things” involved into the IIS-VAERS collaboration, including a description of how these “things” are related.

Explanation Of The Domain Diagram For IIS-VAERS

Following brief description provides an interpretation of the domain diagram for IIS-VAERS collaboration (see the diagram below). There are three groups of entities (classes) presented on this diagram.

Green color is designated for entities that comprise basic immunization activities from the IIS perspective.

Activities and Entities in the Green Zone

Provider conducts *Immunization Event* by administering *Vaccine Dose* to *Patient*.

A link between *Vaccine Dose* and *Immunization Event* is characterized by a multiplicity 1 to 1; other words, every Immunization Event relates to one and only one administered Vaccine Dose.

- The fact that several vaccine doses can be administered during one visit is reflected with the entity *Immunization Encounter*. Each Immunization Encounter includes many (one or more, or 1 to n) Immunization Events.
- Immunization Event is recorded in *Patient Immunization History*. The IIS collects and stores Patient Immunization History entities from *Providers* who are enrolled in the IIS.

Pink color is for entities related to adverse events of vaccination

Activities and Entities in the **Pink Zone**

- **Immunization Event** may or may not result in **Vaccine Adverse Event**. Multiplicity between *Immunization Event* and *Vaccine Adverse Event* is 1..n to 0...n, one or more *Immunization Events* can be associated with zero, or one, or more (many) *Vaccine Adverse Events*.
- Vaccine Adverse Event is identified during **Diagnostic Encounter** and recorded in **Patient Adverse Events History**, which is a part of *Patient Immunization History*.

Blue color is designated for entities associated with the reporting of vaccine adverse events.

Activities and Entities in the **Blue Zone**

- **Vaccine Adverse Event** may or may not be reportable. **Reportable Events** Table (add citation or footnote) is a reference source that lists standard *Reportable Events* (line items).
- Vaccine Adverse Event corresponds to zero or one line items (Reportable Events) in Reportable Events Table.
- Reportable Event (line item in the table) corresponds to zero, or one, or more (many) real life *Vaccine Adverse Events* (multiplicity between *Vaccine Adverse Event* and *Reportable Event* is 0...n to 0...1).
- Reportable Vaccine Adverse Event has to be reflected in **VAERS Report**.
- **VAER System**, operated by **VAERS Contractor**, accumulates VAERS reports.
- **Provider** populates VAERS Report.
- *IIS (Registry)* populates VAE Report with additional information, stores a copy of the report, and submits it to VAER System. Designated **State Authority** uses *IIS (Registry)* to get VAE information to act upon.

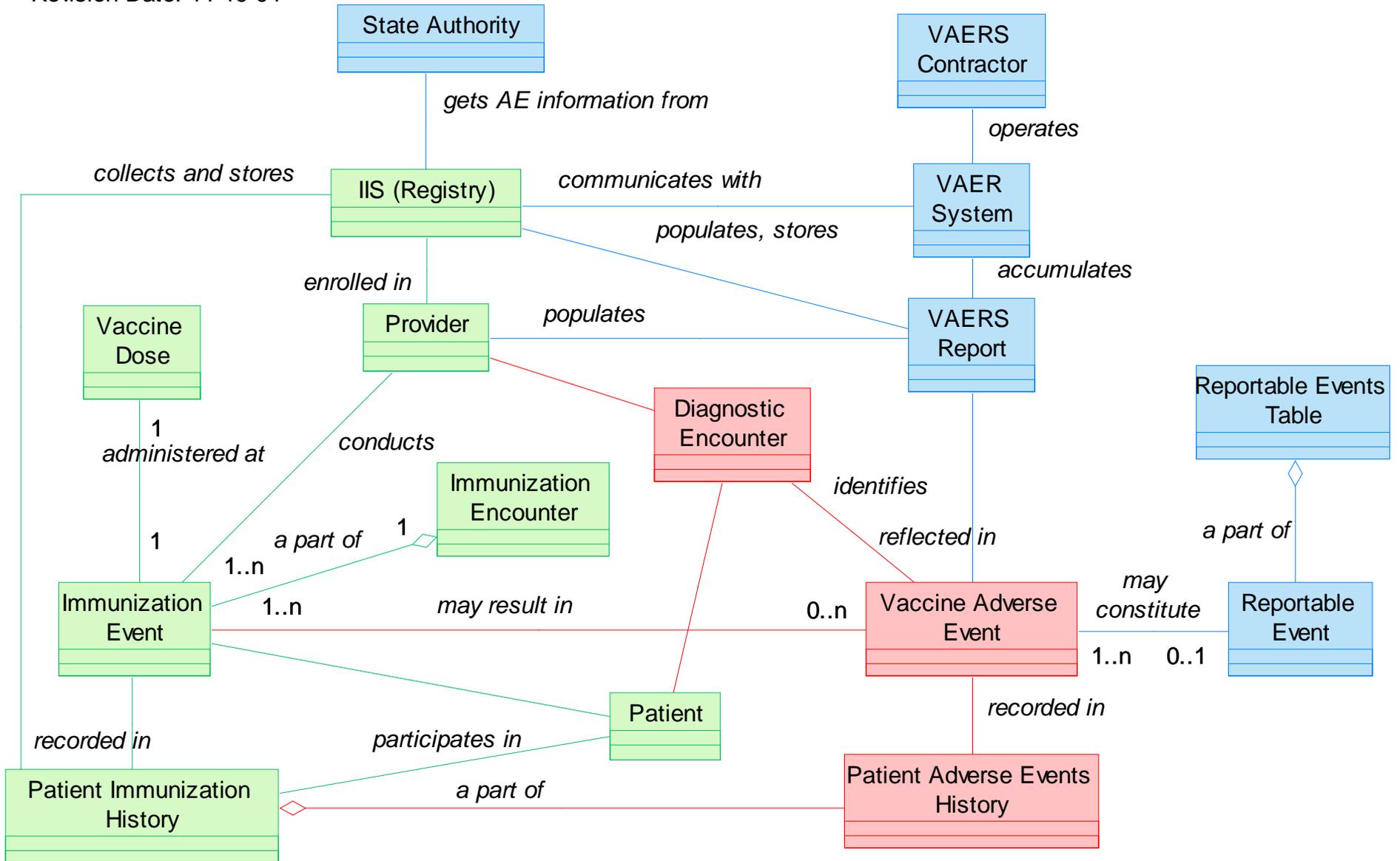
How to Read and Interpret the Domain Diagram

- Relationships between Entities are visualized by connecting lines.
 - Names associated with these lines describe the type of the relationships between entities.
Example, a relationship between VAERS Contractor and VAER System is shown as a connecting line with the name “**operates**”. Such a relationship should be read as “VAERS Contractor operates VAER system”.
1. The general convention for interpretation of relationships between entities is to construct such a description by reading clockwise, starting from the first entity name (VAERS Contractor), then relationship name (operates – note, that the name is shown on the right side of the line, supporting a clockwise reading), then second entity name (VAER System).
 2. If we need to read the same description in the opposite direction, from VAER system to VAERS Contractor, we would have to place a second name - “operated by” – on the left side of the line. In this case, using the clockwise reading rule, a description would be “VAER

System operated by VAERS Contractor”. In most cases just one name for a relationship is employed – like “operates” in the case that was just considered – assuming that it should be sufficient for a proper interpretation of a relationship in both directions.

Domain diagram: Vaccine Adverse Events Reporting from IIS to VAERS

Revision Date: 11-19-04



2. Functional Standards.

This section describes the core functional standards that are encouraged as functions to promote the use of immunization information systems in support of vaccine adverse event reporting. Currently there are ten (10) functional standards for VAERS and IIS reporting.

The purpose of this section is to describe what the desired functional standards should be at the business/programmatic level view, not the technological solution designed to implement them.

The functional standards depicted with an Importance of Feature Designation (IFD):

R = Required, is an indication that the function is necessary to meet existing clinical or VAERS reporting requirements.

S = Significant, is an indication that the function supports a significant provider based or state programmatic optimum practice.

O = Optional, is an indication that the function is a “nice to have” option and shows a value-added benefit.

1. (R) Electronically report the adverse event directly to the VAERS contractor utilizing the immunization registry (immunization information system).
2. (R) Store data about an adverse event.
3. (S) Notify the appropriate state authority, such as the immunization program manager or state epidemiologist, that an adverse event has been reported in their jurisdiction.
4. (S) Provide an indication that a previous adverse event has been recorded for patient.
5. (R) Supply denominator data for adverse event investigations. This may include certain data items for number of does of X over time period y.
6. (S) Provide clinical protocol information for adverse event inquiry.
7. (R) Ensure reports are of appropriate quality and completeness.
8. (O) Provide the ability for Provider to recall and correct/edit a VAERS report.
9. (S) Provide the ability for Provider to report a VAE for every patient, not just IIS core constituents.
10. (R) Provide the ability for Provider to print out the VAERS report.

3. Process description: IIS-VAERS Collaboration

3.1 Key Actors/Participants

Provider (Health Care Provider), Immunization information system (IIS), VAERS Contractor, State Immunization Program Manager/Health Department Authority

3.2 Business Preconditions

1. The Provider is enrolled in an Immunization information system (IIS).
2. The Provider reports immunizations to an Immunization information system (may be a state, local, regional or private registry). Reporting may be via electronic exchange between a provider system and an IIS (EMRs, large provider systems).
3. The Provider accesses the Immunization information system (IIS) to report vaccine adverse events to VAERS.
4. An electronic communication has been established between the Immunization information system (IIS) and the VAERS e-submission site.

3.3 Operational scenarios

Following are some highlights regarding usage of “Main” and “Alternative” scenarios in the process description:

- The Main scenario describes "sunny day" sequence of events, when everything goes as planned.
- Alternative scenarios describe situations when something is going wrong or differently.
- As a result, the Main scenario is significantly simplified and easier to read.
- All complexity and nuances moved to the Alternative scenarios section.
- This approach better addresses needs of the different readers: person who is not very familiar with the VAERS domain can read the Main scenario and quickly grasp what this process is about; at the same time an expert can study the details, focusing on alternative scenarios.
- It provides better structure for our future work, allowing us to address one scenario at a time, instead of working with the single big, complex description.

3.3.1 Main scenario.

(when everything is going as planned – most conventional version of the process).

Phase 1: Pre-Adverse Event Phase. This phase starts when the patient is in attendance for immunization.

- 1) The Provider reviews the patient’s immunization history and adverse events history [1]. Such a review may be conducted by accessing the Immunization information system (IIS), but that IIS access is not required to perform this task (given applicable legal requirements).
- 2) The Provider decides to administer vaccine(s) and proceeds with vaccine(s) administration.
- 3) The Provider enters/reports the immunization event to the IIS.
- 4) The IIS stores information about the immunization event [2] .

Phase 1 of the process ends.

Phase 2: Post-Adverse Event Phase. This phase starts when a person (patient, doctor) presents or reports a possible adverse event [4].

- 1) The Provider, referencing [3, 4], decides to report the adverse event.
Related business rules: BR01 and BR02.
- 2) The Provider accesses the immunization information system (IIS) to query for information:
 - 2.1) The Provider selects a specific patient's record using a demographic query.
 - 2.2) The Provider selects the specific encounter within the patient's record to be linked with the adverse event using an encounter/date query.
- 3) The Provider initiates the VAERS Reporting.
Related business rules: BR05.
- 4) The IIS automatically populates the VAERS report [1, 5] with some or all the required demographic information [5] and with required immunization history or encounter information [5].
Related business rules: BR03, BR04, BR06, BR07, BR08.
- 5) The Provider enters additional information as required to complete the VAERS report.
Related business rules: BR06 and BR07.
- 6) The IIS stores the VAERS report.
- 7) The Provider, using the IIS, electronically submits the VAERS report to the VAERS Contractor.
- 8) The VAERS Contractor assigns e-tracking number to the report. Report is locked from future editing.
- 9) The VAERS Contractor provides the IIS with the unique e-tracking number.
- 10) The VAERS Contractor processes the completed report.
- 11) The IIS notifies state programmatic or other designated authorities about the adverse event and its e-tracking number.
- 12) State programmatic or other designated authorities retrieve the individual VAERS report from the IIS and use this information to address the adverse event.
The process ends.

Note:

Regarding the issue of linking all reports for the same Patient together. Each report submitted to the VAERS gets unique e-tracking number. The VAERS links all reports for a Patient together via the internal process that is based on the demographic information, such as name, birth date, vaccination date, etc. However, currently the IIS does not receive results of the reports linkage process from the VAERS. At the same time the VAERS periodically (every 1-3 months) sends a listing of all submitted reports with assigned e-tracking numbers back to the State Health Department Authority, indicating linkages found between the reports for the same Patient. In the future it would be desirable to find a way of providing the IIS with such information that allows to link reports for the same Patient together.

Also, the IIS might play a role in helping the VAERS in the linkage process by putting e-tracking number for all subsequent reports for the Patient (see issues for discussion on page 27).

3.3.2 Alternative scenarios

(when something is going wrong or differently compare to the Main scenario above).

Phase 1.

- 2a) The Provider decides not to administer vaccine(s)
The process ends.

Phase 2.

- 1a) The Provider decides not to report the adverse event
The process ends.

- 2a) IIS accommodating patient not in the system.

The Provider creates a record for the Patient in IIS.

Process continues from step 3.

Additionally, the Provider places a hard copy of the VAERS Report into the Patient's Medical Record.

- 2b) IIS down, communications problem, or provider's computer problem

Provider fills out Vaccine Adverse Event Form and stores it in the patient record.

Provider marks patient visit notes for adverse event and any other relevant clinical information.

Provider enters both immunization event information and VAERS information into IIS when it returns.

Process continues from step 3.

- 5a) Insufficient VAERS information (e.g. patient leaves)

After the vaccination Patient leaves. Primary physician does not have all necessary information, but, for example, secondary physician does.

Provider reports available information based on minimum requirements defined by VAERS.

Provider submits additional reports as new information becomes available.

Process continues from step 6.

- 7a) VAERS report is partially completed

- 7a1) The Provider submits the VAERS report anyway.

If a partially completed VAERS report has been sent, the Provider can add additional information in a new report later and submit it to the VAERS Contractor (repeat steps 2-7). Also, as the medical condition of the patient develops further, additional reports can be completed by the Provider and submitted to the VAERS Contractor (This is an iterative process - repeat steps 2-7).

Process continues from step 8.

- 7a2) Another Alternative scenario: The Provider waits until additional information is obtained to complete the report (repeat steps 5-6), and then submits.

Process continues from step 8.

7b) The Provider submits the VAERS report to the IIS for screening and subsequent reporting to the VAERS Contractor.

Note: The IIS is motivated to screen VAERS Reports and to conduct quality control activities for the reporting due to the expected recurring follow-up requests from the VAERS (see step 10a below).

7b1) The IIS facilitates the reporting process (for example, consults with PM or other clinical experts, conducts Quality Assurance activities, de-duplicates VAERS reports, etc).

If a decision is made to report, then the process continues (step 7b2).

If a decision is made not to report, then the process ends.

7b2) The Immunization information system (IIS) electronically submits the VAERS report to the VAERS Contractor.

Process continues from step 8.

7c) The vaccine adverse events related to a potential or actual bioterrorism (BT) agent exposure.

IIS submits report to VAERS contractor (step 7b2).

Process continues with steps 8, 9, and 10.

Also, IIS notifies appropriate state authority about possible BT-related adverse event. State authority communicates with federal authority (CDC) to request a release of the Vaccinia Immune Globulin (VIG) or Cidofovir to be administered to a patient.

7d) VAERS report is submitted for the wrong patient.

7d1) Provider flags the report as “submitted for the wrong patient” in the IIS.

7d2) Provider submits report for the right patient.

Both reports are stored in the IIS. Process continues from the step 8.

7e) VAERS is down or communications problem.

7e1) IIS resubmits VAERS report when VAERS system is available.

Process continues from step 8.

Note: IIS takes a responsibility to complete VAERS reporting for the Provider, who initiated it (see step 7 in the Main scenario).

10a) The VAERS Contractor needs additional information.

10a1) VAERS Contractor contacts the Provider– follow-up.

The Provider submits additional information to the VAERS. Such information can be submitted via the additional VAERS Report (via the IIS), or such information can be submitted without producing additional VAERS report - directly to VAERS (then IIS does not receive this information).

Note: Due to the privacy considerations, the IIS may not receive certain clinical information regarding the Patient. That is one of the reasons why Provider might submit requested information directly to VAERS, bypassing the IIS.

10a2) VAERS Contractor contacts the State Health Department Authority – follow-up.
Note: The listing of all submitted reports provided by VAERS to State Health Department Authority is accompanied by follow-up requests for cases with missing information (see the note on page 13).
Such follow-ups are involve medical personnel and are conducted by the State Health Department Authority and not by the IIS.



5. Business Rules: IIS-VAERS Collaboration.

Business rules represent requirements of how the business must operate based on the laws, policies, regulations, and chosen business style. Often business rules are buried in the IT systems’ code. Business rule modeling techniques allow the capture of essential business knowledge in a technology-neutral format, like a plain text.

Business rules are referenced within the textual process description and are shown as boxes (objects) on the workflow process diagram. Each business rule is related to one or more associated process steps / activities. Each business rule within the textual process description and on the workflow diagram is labeled with a business rule number (ID) that can be used for referencing a business rule description within a business rules table.

Table 1. Business Rules.

BR #	Theme / Area	Business Rule statement	High-level business motivation aimed for by the Business Rule	Remarks / Links
BR01	Scope	Vaccine Adverse Events listed in the Reportable Events Table (RET) have to be reported.	Satisfy legal requirements	Mandated by law – 42 USC 300aa-25
BR02	Scope	Vaccine Adverse Events not listed in the Reportable Events Table (RET) may be reported as per Provider’s discretion.	Expand amount of data available for analysis	Helps overall goal of VAERS - Increase understanding of adverse events following vaccination.
BR03	VAERS Report	A separate adverse event report has to be used for each patient.	Patient level reporting is the unit of analysis for VAERS	The VAERS Contractor links all reports for a vaccine adverse event for a patient together.
BR04	VAERS Report	A separate report has to be used for each adverse event.	Patient level reporting is the unit of analysis for VAERS	The VAERS Contractor links all reports for a vaccine adverse event for a patient together.

BR #	Theme / Area	Business Rule statement	High-level business motivation aimed for by the Business Rule	Remarks / Links
BR05	VAE Reporter	Anyone with authorized access to the IIS, not necessarily the VA, may submit a VAERS report.	To encourage reporting	Form VAERS-1 (FDA) - Providers other than the Vaccine Administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the report to meet the VA's legal responsibility.
BR06	VAERS Report	The VAERS Report must contain the following minimum set of data elements: 7 and 13.	Maintain minimum data uniformity. Allow provider to report with minimum available data.	Form VAERS-1 (FDA)
BR07	VAERS Report	The VAERS Report should contain the following recommended additional set of data elements: 3, 4, 8, 10 and 11.	Maintain quality of report	Form VAERS-1 (FDA)

BR #	Theme / Area	Business Rule statement	High-level business motivation aimed for by the Business Rule	Remarks / Links
BR08	VAERS Report	The IIS should populate the VAERS report with available core data elements subject to local policy and regulation and is subject to change by the provider.	Leverage Registry/IIS data to benefit the provider (by reducing time burden due to double data entry). Enhance the quality, timeliness and accuracy of the provider report.	Form VAERS-1 (FDA)

6. VAERS Reporting: Legal Guidelines and Information.

The following links and documents detail the legal guidelines, based on the HIPAA Privacy Rule, which apply to Vaccine Adverse Event Reporting. Local, regional and state IIS systems and programmatic staff should consult state or other local regulations or statutes to understand requirements for specific localities.

- Guidance from CDC and the U.S. Department of Health and Human Services on the HIPAA Privacy Rule and public health, available at www.cdc.gov/mmwr/PDF/wk/su5201.pdf
- Information on VAERS and HIPAA at <http://www.vaers.org/hipaa.htm>

7. References

- [1] 2003 Report of the Committee on Infectious Diseases, American Academy of Pediatrics, Redbook, page 40
- [2] Recommended Core Data Set for Immunization Registries
- [3] 2003 Report of the Committee on Infectious Diseases, American Academy of Pediatrics, Redbook, page 40
- [4] Reportable Events Table, <http://www.vaers.org/reportable.htm>
- [5] Form VAERS-1 (FDA)
- [6] Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol. Implementation Guide Version 2.1. Centers for Disease Control and Prevention, Atlanta, Georgia, September 2002.
- [7] American Immunization Registry Association Web Page (Special Interest Groups): http://www.immregistries.org/docs/IIS-VAERS_Coll_Desc_06-25-2004_v2.doc
- [8] Presentation at the 2004 Immunization Registry Conference: http://cdc.confex.com/cdc/irc2004/techprogram/paper_6172.htm

Appendix A: VASREC workgroup Charter

Initial draft of the Workgroup Charter – developed by workgroup’s organizers:

Purpose of the AIRA workgroup: To serve as a forum for consensus development, problem solving, and feedback on issues, topics, concerns relating to closer integration of Vaccine safety information into immunization registries. Specifically electronic reporting Vaccine Adverse Event Reporting (VAERS) that specifically relate to immunization registries.

Participants: Open to members of the immunization registry community who have expressed an interest in bridging activities of VAERS and Immunization Registries. Members should have knowledge about the issues affecting immunization registries, standards, computer systems, general adverse event reporting and knowledge of strategies to capture registry denominators to calculate rates.

Meeting Schedule: Typically the group would meet once a month, probably for a year. Participation will be virtual (email, etc) and conference calls. As necessary the group may determine a need for a permanent workgroup i.e. a standing group or committee to address these issues. Perhaps meet in person at other conferences or venues. Routine meetings will be the 3rd Friday of the month at 2:00 pm Eastern time.

Expectations: Much of the group may be able to rely on other knowledge, consensus and development activities from other group efforts. The recommendations and suggestions from the group will assist in program planning, and direction efforts for vaccine safety and immunization registry joint efforts. The group will initially focus on VAERS reporting and IIS. Technology neutral, vendor independent and open solutions will be encouraged.

Products and Deliverables: The group will strive to produce documents that describe a consensus perspective on the specific issue being addressed. Many of the issues will be functional descriptions and descriptions of options. The first deliverable will be a conceptual framework for laying out VAERS reporting with Immunization Information Systems, it will be comprised of visual conceptual models and text descriptions. We hope to have the first product completed by the IRC conference and on the AIRA web page for further vetting and discussion.

Expanded Workgroup Charter - developed by workgroup's members:

Focus Statement

The focus statement is a statement of the solution domain; the portion of the world (e.g., organization) that can be examined and potentially included in the development of the solution. The focus statement is our attempt to come to a more complete understanding of the parts of the business this project is expected to address in some way. The focus statement is intended to help us focus our energies to the desired areas of the business. The focus statement includes five different dimensions or elements: Breadth, Emphasized Perspectives, Universality, Depth, and Scope of Integration; each element is described below.

Focus Statement - Breadth (Scope)

The portion of the business processes, activities, functions, and/or organizational units covered by the effort. The following statements clarify our understanding of the events thought to be in our focus “from” some event, “until” some event; everything between these events is considered to be within our focus. The scenarios presented are in the sequence identified.

The VASREC workgroup scope is activities of vaccine adverse events reporting by health care providers and/or state programmatic entities through the IIS to the VAERS. The process begins when a possible adverse event is presented in a clinical setting and ends when the VAERS provides IIS with the final notification (e-tracking number) for the adverse event(s). Everything between these events is considered to be within the VASREC workgroup's focus.

The scope explicitly includes following activities:

- Determination of VAE reportability at Provider and IIS levels
- Population of the VAERS form in collaboration between Provider and IIS
- Submitting VAE report to VAERS and/or state or local programmatic entities.
- Providing additional information to VAERS (consecutive reports)
- VAERS notification of IIS with the e-tracking number for VAE report.

Additionally, following activities are included into the focus/scope:

- Support of denominator data for VAERS investigations
- Notification of and providing AE information to state authorities

The scope explicitly excludes following activities:

- Internal VAERS operations and business processes
- Exact technical specification of interfacing or communications technology components

Focus Statement - Emphasized Perspectives

Emphasized perspectives include the individuals or classes of individuals whose points of view should be reflected in the solution. Normally these would be a subset of the stakeholders. This is not to say that we would not consider other stakeholders' perspectives, but that we will take extra precaution to assure that the emphasized perspectives are included. The identified perspectives to be emphasized are presented in no particular sequence (they are not considered to be ranked)

Because the Working Group is focused on the bridging of VAERS and Immunization Registries, perspectives of stakeholders in these two areas are critical to the group. In the immunization registry community, points of view that are particularly relevant include those of registry staff with knowledge about the issues affecting immunization registries, standards, computer systems, and general adverse event reporting. In the VAERS community, stakeholders within the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) present a point of view that should be reflected in the solution. The perspectives of healthcare providers, vaccine manufacturers, and state vaccine programs should also be part of the solution..

Focus Statement - Depth

Depth indicates how much detail of the business must be explored to produce the appropriate deliverables. Depth helps put into context how our work will be used, and therefore provides guidance on how much detail to include in our work products.

The VASREC conceptual framework is a high-level document describing players (Healthcare Providers, IIS, and VAERS and programmatic entities), roles, relationships, and the fundamental data communication needs between existing sources of information. A set of business requirements, business rules, and use cases that will need to be implemented by the stakeholders will be documented in this phase. These documents include high-level diagrams, descriptions, and core needs for reporting Vaccine Adverse Events through IIS, written for a non-technical audience.

Once the framework, requirements, business rules, and use cases are complete, they will need to be followed by a lower-level technical design specification, describing how the requirements will be implemented. The technical design specification must include a secure and reliable messaging solution for the communication of Vaccine Adverse Events between the IIS and VAERS.

Note: part of the standard messaging solution is described in [6].

After technical design is completed, each IIS will need to flesh out fully detailed technical design documents, as it applies to the individual information system. Subsequently, items described in the requirements and design documents will need to be implemented, tested, deployed into production use, and maintained by each IIS and VAERS. Technical design, software implementation, testing, deployment, and maintenance depend on the availability of resources for the required enhancements to the IIS and VAERS.

Focus Statement - Universality

Universality describes how generic of a solution is required. The more generic the solution needs to be, the more rigorous we need to be in gathering requirements (for example). We address problem set, geopolitical and time frame universality, and each is described below.

Solutions required and designed by the VASREC workgroup must be generalize to all IIS that are expected to communicate with VAERS. Since IIS employ different Web, database, systems, and programming language technologies, the message transport solution selected must be portable enough to run in all of these environments. The message format will contain data

elements that are required for successful communication and will not contain ancillary fields that are not needed by the IIS and VAERS systems.

Solutions required and designed by the VASREC workgroup must also consider and optimize programmatic VAERS reporting requirements. The IIS VAERS reporting solutions must incorporate a common standard, process and data validation that addresses immunization program reporting requirements. Roles and relationships between IIS users, VAERS reporting at the Federal level and programmatic requirements are considered within the conceptual framework, business rules and business needs and the development of use cases.

Focus Statement – Scope of Integration

The scope of integration describes what other business initiatives or systems this effort should investigate interfacing with, being compatible with, or coordinating with. These efforts are outside our focus but we do anticipate interaction and therefore need to plan ahead to assure smooth interaction.

The scope of this integration is limited to all private and public IIS in the United States and VAERS.

Project Values

The set of beliefs, trade-offs, and judgment-guidelines that govern the results of the project as well the obtainment of those results.

Technology neutral, vendor independent and open solutions will be encouraged.

Context - Risks and Opportunities

Risks are unfavorable potential occurrences or circumstances (i.e., things that could go wrong). Opportunities are favorable potential occurrences or circumstances (i.e., things that could go better than expected.)

There is a risk that the IISs and VAERS may not have the resources needed to implement the requirements and business processes described in this document. The IISs that are staffed and funded for this work will need to closely collaborate with the VAERS team to ensure successful capture and communication of information. There is also a risk that the steps detailed in this document may be too challenging for IISs that do not have enough technical resources for this work.

There is an opportunity for dramatic increases in VAERS data quality and reporting volume through the use of hands on the ground at state, local, and private IISs. There is also an opportunity for increased research, dissemination of knowledge, and education on vaccine adverse events at the state, local, and private level through the analysis of adverse event information captured, as detailed in this document. Through the bi-directional sharing of information between IISs and VAERS, there is also an increased opportunity to reduce adverse events and potentially save lives.

The enhancement of VAERS reporting capacity technically, however, presents a real opportunity for guidance and support from the National Immunization Program and VAERS branches to state and local programmatic offices to transition and integrate current reporting processes with ISS upgrades to support that capacity. A granting process that supported a Programmatic planning process integrated with a functional design and implementation steps for the ISS would be necessary to integrate both objectives.

Appendix B: Issues needing discussion

These are the tracked items to follow up:

- List of terms and definitions – as a minimum, based on the terms presented on the domain diagram.
- Add a recommendation to put e-tracking number into all subsequent reports (as either a business rule or an addition to the main scenario).
- Get a professional Technical Writer involved to edit and format the final version of this document (workgroup's recommendations). Produce a PDF version of the document.
- Further investigation on measures for IIS-VAERS collaboration should be conducted see appendix C for a partial list.

Appendix C: Evaluation and measures

The following is a list of possible evaluation techniques to examine the relevance of this document to the functions of an IIS.

Q1: On scale 0 to 10, with 10 being the "most far", and 0 being "most close", how close are your registry's capabilities to perform the functions described in this document now?

Q2: On scale 0 to 10, with 10 being the "most far", and 0 being "most close", how close are your registry's capabilities to perform the functions described in this document within next three (3) years?

Other measures should be examined and assessed to measure the performance of the IIS and VAERS contribution: