CCDR
Canada Communicable Disease Report
ISSN 1188-4169
Volume : 28S6 December 2002

Functional Standards and Minimum (Core) Data Sets for a National Immunization Registry Network and Vaccine Associated Adverse Events Surveillance System

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This publication was produced by the Scientific Publication and Multimedia Services Section of the Business Integration and Information Services Directorate, Health Canada.

This publication can also be accessed electronically via Internet using a Web browser at http://www.hc-sc.gc.ca/pphb-dgspsp

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Division of Immunization and Respiratory Diseases
Centre for Infectious Disease Prevention and Control

Health Canada
March 2002

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Background

In 1996, at the Canadian Immunization Conference, it was recommended that

- An immunization tracking system is urgently needed in Canada to identify children due or overdue for immunization, to notify parents, to make appointments, to provide a database for health care providers to monitor the immunization of patients at each encounter regardless of where the vaccine was administered, to assist in planning and identifying populations at risk for delayed immunization, to target interventions appropriately, and to evaluate the success of the program. In provinces where physicians deliver the bulk of immunization, tracking systems adapted for practice, as well as for public health needs, must be developed. The positive exchange of ideas between conference participants suggests that the time has arrived for a national program to be administered provincially, thus ensuring compatibility between provinces so that this health care information can be accessed when needed.

As a follow-up to these recommendations, Health Canada convened the Canadian Consensus Conference on a National Immunization Records System, held in March 1998. It was at this conference that the goal for a National Immunization Records Network* was developed:

- Immunization registries will facilitate the control and elimination of vaccine preventable diseases in Canada by ensuring the provision of information and knowledge necessary to achieve the best possible immunization coverage for Canadians[1].

In 1998, Health Canada created the National Working Group for an Immunization Records Network (NWGIRN) and charged the group with the responsibility of overseeing the implementation of the recommendations from the 1998 Consensus Conference. The working group has representation from key stakeholders, including governments, health care providers, and non-governmental organizations with an interest in immunization. The terms of reference are as follows:

- To monitor the implementation of immunization registries in Canada;
- To provide advice to Health Canada, provincial and territorial governments, and providers of health services to other groups to assist them with the establishment and operation of immunization registries;
- To recommend standards and guidelines, and describe best practices for immunization registries in Canada;

* Since renamed National Immunization Registry Network

- To provide a forum for exchange of ideas and information about immunization registries;
- To create sub-committees as necessary to address issues requiring special expertise; and
- To provide regular updates to stakeholders regarding progress towards a national immunization registry in Canada.

Sub-committees on Data and Technical Standards

In order to meet the timeframe of development of a National Immunization Registry Network by the year 2003, the NWGIRN created sub-committees to focus on the implementation of the Consensus Conference recommendations. A work plan was developed to ensure that necessary tasks were completed in an orderly and timely fashion. One of the tasks identified in the work plan was the development of national standards, to include the following:

1. A minimum (core) data set for immunization registries;
2. Common data definitions for the elements identified in the minimum data set;
3. System compatibility standards (to ensure that computerized registries in different jurisdictions are capable of sharing data with each other);
4. An individual immunization message (the standard electronic record to be shared between provinces/territories).

Development of data and technical standards was not limited to immunization. As the link to the Vaccine Associated Adverse Events Surveillance System (VAAESS) would benefit both providers of immunization and those in population health who require the information for surveillance, the decision to combine efforts was inevitable.

Vaccine Safety

In 1965, the VAAESS was developed to maintain public confidence in vaccines and immunization programs.

The cornerstone of the VAAESS is a voluntary system in which health care professionals (mainly public health nurses and physicians) report to local, provincial and/or territorial public health authorities events that they feel were temporally associated with administration of a vaccine. These authorities, as well as vaccine manufacturers and occasionally other agencies that receive information, forward all such reports for aggregation at a national level to the Division of Immunization and Respiratory Diseases of the Centre for Infectious Disease Prevention and Control, Health Canada. About 95% of the reports come from health care professionals and 5% from industry.

The reports are collected in a computerized database. The data collected include epidemiologic and medical information on the reported events. To calculate adverse event rates, the Division of Immunization and Respiratory Diseases obtains lot-specific data from vaccine manufacturers on the number of doses of their products distributed across the country. These "vaccine distribution" data are used as an approximation of the actual number of doses of vaccine administered. However, because of varying reporting practices, differences in lot-specific adverse event rates require cautious interpretation. Although these denominator data are limited in reliability, they are very useful in risk assessment. Further estimates of denominator data are obtained from vaccine coverage studies.

The following are the proceedings from NWGIRN sub-committee meetings held to establish the functional standards and minimum (core) data sets for immunization registries and the VAAESS. These meetings fulfilled the first three recommended tasks of the work plan and established the foundation for a National Immunization Registry Network.

Functional Standards, Minimum (Core) Data Set, and Data Definitions for a National Immunization Registry Network

A Sub-committee on Data and Technical Standards of the NWGIRN was struck and convened in July 2000. There were three primary objectives of the 2-day meeting:

1. To review and propose functional standards to be recommended for a National Immunization Registry Network;

2. To develop an agreed upon list of core data elements on immunization, including their definitions and characteristics, to be collected by every province and territory; and

3. To identify next steps and a relevant action plan.

In order to achieve the objectives in the limited time available, participants were asked to review a comprehensive list of immunization data currently collected by the provinces and territories as well as the elements selected by the United States and Australia for their core data set[2-6]. Also provided was a list of standards being used by the U.S. and Australian National Immunization Registry projects in addition to those mentioned in the Canadian Consensus Conference of March 1998. Participants were asked to provide some preliminary feedback regarding their recommendations, for both data elements and standards, by submitting their completed worksheets upon arrival at the meeting. Spreadsheets were then populated with the information provided and reviewed during the following 2 days. The results demonstrated a reasonable level of consensus and provided a solid basis for further discussions.

To set the stage for their deliberations and to provide participants with additional information for their consideration, the meeting began with presentations from the National Immunization Program, Centers for Disease Control and Prevention, in the United States; the Australian Childhood Immunization Registry, Health Insurance Commission, Australia; and the National Immunization Record Network initiative, Health Canada.

The following day, breakout groups were formed to review, discuss and achieve consensus on the core data elements for immunization that, at a minimum, would be collected by every province and territory. Once these core groups of concepts were identified, participants were then asked to develop the associated definitions and field characteristics relative to each element. By the end of the second day, participants had achieved 100% consensus on 21 core data elements.

A report was generated from the proceedings of the meeting and disseminated for comment in August 2000 to all provincial/territorial jurisdictions

and key stakeholders in immunization in Canada. After consultation, recommended changes to the functional standards and core data elements were tabled for discussion and resolution at the meeting of the Public Health Working Group Subcommittee on Immunization in November 2000.

The functional standards and minimum (core) data concepts were then presented to and approved by the Health Surveillance Working Group and the Public Health Working Group as well as the Advisory Committee on Public Health in January 2001.

Results

Functional Standards for a National Immunization Registry Network

It was agreed at the Canadian Consensus Conference in March 1998 that Canada would have a "records network" with each province and territory developing an electronic immunization registry through which information could flow within and between jurisdictions. These data will

- enable immunization providers and parents to check on the immunization status of an individual child, regardless of where the child was immunized (in Canada);
- form the basis of an optional recall/reminder scheme that informs parents when their child's next vaccination is due or past due;
- provide a measure of immunization coverage at a national, provincial/territorial and local level; and
- provide an effective management tool for monitoring immunization coverage and service delivery.

It was further agreed that Health Canada would provide leadership in

- development of standards and processes for immunization registries in Canada, in consultation with key stakeholders;
- development of provincial/territorial registries through pilot projects; and
- maintenance of the standards for immunization registries.

Provinces and territories will be responsible for the maintenance of immunization registries in their jurisdictions, including the provision of the required technological and human resources.

Initially, every immunization registry in Canada will contain electronic records of children < 7 years of age residing in its jurisdiction. This will include all Canadian citizens with or without provincial/ territorial health card numbers and landed immigrants who have lived in Canada for ≥ 3 months.

Only authorized practitioners will have access to registries. An authorized practitioner is a regulated health professional who is authorized within the provincial or territorial jurisdiction to provide immunizations or administer immunization programs. Authorized

practitioners are obliged to practise in accordance with guidelines established by their regulatory body and the provincial/territorial legislation where they practise and/or reside.

The following standards are essential to the functionality of a National Immunization Registry Network in Canada.

Standard #1

Electronically store data on all core data elements approved by the Advisory Committee on Population Health (ACPH) and Advisory Committee on Health Infostructure (ACHI)

Every immunization registry computer database must contain fields for ACPH and ACHI approved core data elements. Registries will be a provincial/territorial responsibility and will be maintained centrally in their jurisdictions.

Standard #2

Establish a registry record within 7 days of birth for each newborn child

Identifying information (demographic and locating information, and vaccine given at birth) is regularly sent to or retrieved by the registry in a computer file format that requires little, if any, manipulation by registry staff for the data to be entered into the immunization registry. Such information is available in the registry within 7 days of birth.

Standard #3

Access information from the registry of immunization records at the time of the patient's visit

Every registry provides a means by which authorized practitioners can access immunization records before and at the time of the patient's visit.

Standard #4

Submit core data on immunization at the time of encounter or within 7 days of vaccine administration

Every registry provides a means by which authorized practitioners can submit immunization information within 7 days of vaccine administration.

Standard #5

Protect medical information (confidentiality measures)

Every registry has written confidentiality policies and procedures in place, including administrative and technical practices to protect medical information.

Standard #6

Protect medical information (security measures)

Every registry has written security policies and procedures in place. The procedures include administrative and technical practices and physical safeguards to protect medical information in accordance with the Canadian Organization for the Advancement of Computers in Health (COACH: http://www.coachorg.com).

Standard #7

Recover lost data (disaster recovery)

The provincial and territorial immunization registry database is backed up incrementally on a daily basis and fully on a weekly basis. At least one copy of backup media is stored securely in a separate location and tested. In addition, the registry has a regularly tested (at least annually) disaster recovery plan for providing basic system functions and ensuring access to registry data in an emergency (e.g. natural disaster or computer failure).

Standard #8

Exchange information records using data transferring standards

Every registry has a function, at the provincial/territorial central level, that creates, receives, and properly processes the electronic immunization message.

Standard #9

When an individual presents for a vaccination, determine the immunization(s) needed based on either the existing provincial/territorial schedules or the National Advisory Committee on Immunization (NACI) recommendations

Every registry has a function, accessible at the provider level, that determines needed immunizations based on provincial/territorial schedules and/or NACI recommendations, given an individual's immunization history to date.

Standard #10

Identify individuals who are due or late for immunizations to enable the production of reminder/recall notifications

Every registry has a function that produces a list of individuals who, as of a given date, are due or late for immunizations according to the registry's algorithm. The output from this function gives the ability to produce reminder or recall notices.

Standard #11

Produce immunization coverage reports

Every registry has a function to measure immunization coverage (proportion of children "up-to-date" for their age). "Up-to-date" should be defined according to vaccine recommendations implemented in the registry's algorithm.

Standard #12

Produce authorized immunization records

Every registry has a function that allows authorized users to print an individual's immunization record, which serves as an "official immunization record."

Standard #13

Consolidate all immunization records from multiple providers, using de-duplication and edit checking procedures to optimize accuracy and completeness

The registry has a method in place to combine all available information relating to a particular individual into one, complete immunization record that contains the individual's demographic and locating information, and history of immunizations received. The registry

employs special procedures/ programming to eliminate duplicate entries and minimize data entry errors.

Standard #14

Record immunization services in the registry through a variety of alternatives

Every registry has options for practitioners to record immunization data. These may include, but are not limited to, web-based, electronic data interchange, computer diskette, or manually completed encounter forms that are scanned or inputted into the central registry.

Standard #15

Allow parents or guardian of a child to opt out of the recall/ reminder scheme or to prevent any details from being released from the registry

In these circumstances, information relating to the child will be maintained in the registry and will be used only for the purpose of statistical analysis or in emergency situations, e.g. a serious disease outbreak.

Minimum (Core) Data Concepts

The following is the comprehensive list of the minimum (core) data concepts to be collected by immunization registries in Canada. Registries at the provincial, territorial and local/regional level may require the collection of more information in order to manage immunization programs for their jurisdiction or community. The concepts listed here are required, at a minimum, in order to fulfil the needs of practitioners in making immunization decisions.

Name
Unique identifier
Geolocator
Date of birth
Gender
Vaccine
Trade name
Vaccine dose number
Vaccine lot number
Date of vaccination
Anatomical site of vaccination
Not immunized (flag)
Adverse vaccine event (flag)

Data Definitions

A standard definition for each data concept is necessary to ensure that the information collected on immunization is consistent in every jurisdiction. As well, standards for field name, size and type are necessary for transfer of data electronically.

Minimum data sets and standards for communicable disease reporting and vaccine associated adverse events have been developed through a similar process. The data standards from different systems have been incorporated into a comprehensive data model, and a data dictionary listing each element's characteristics is in production. The harmonization of the data elements will ensure that surveillance data are coordinated and that standard data elements can be used in complementary program areas. The data definitions will be made available on the Internet by the Centre for Surveillance Coordination, Health Canada, in the near future.

Functional Standards, Minimum (Core) Data Set, and Data Definitions for a Vaccine Associated Adverse Events Surveillance System (VAAESS)

In October 2000, the Sub-Committee on Minimum Data Set, Technical and Functional Standards for Vaccine Associated Adverse Events Surveillance, reporting to the NWGIRN, called a meeting of representatives from the provinces/territories and national organizations. The objectives of the meeting were to reach agreement on the following:

- federal/provincial/territorial (F/P/T) functional standards on the collection and transfer of data and the dissemination of reports on VAAEs;
- a minimum core data set for VAAEs that will be collected electronically by all provinces and territories; and
- the levels of government (F/P/T) that will collect information on each component of the data set.

International and national information on vaccine associated adverse event reporting and existing data standards and functional standards were provided to all participants to review before the meeting. It was expected that participants would use the information on best practices as a basis for their decisions. Similar to the process used for the development of standards for immunization registries, the participants were asked to complete a review of data elements and standards before the meeting.

The meeting began with presentations from the Vaccine Adverse Event Reporting System (USA), the Swedish Institute for Infectious Disease Control, and the Division of Immunization and Respiratory Diseases, Health Canada, to augment the information provided for the meeting.

Breakout groups reviewed the data currently being collected for the VAAESS and considered some preliminary functional standards. Possible changes were discussed within the groups, and these were then brought back to a plenary session as a basis for further discussion. A reasonable level of consensus was achieved, but not all of the objectives were met. Accordingly, a follow-up meeting was held in March 2001, at which time participants finalized the core data set and the definitions of their concepts, and proposed some changes to the functional standards. A third meeting was held in July 2001 with the objectives of

- developing rules for abbreviations of vaccines and manufacturers,

- applying these to the vaccines' and manufacturers' names, and
- reviewing the CCI (Canadian Classification of Health Interventions) codes for the vaccines.

The rules and data standards are presented in this report. The CCI codes will be published by the Canadian Institute for Health Information (CIHI).

Results

Functional Standards for a Vaccine Associated Adverse Events Surveillance System

Standard #1

VAAE database as module of the Registry

Each provincial/territorial immunization registry computer database will have a vaccine associated adverse events (VAAE) database as a module. The VAAE database will be a provincial/territorial responsibility.

Standard #2

Electronically store data on all core data concepts approved by the Advisory Committee on Population Health (ACPH) and Advisory Committee on Health Infostructure (ACHI)

Every VAAE computer database must contain, as a minimum, fields for ACPH and ACHI approved core data concepts.

Standard #3

Consolidate all VAAE records from multiple providers or follow-up reports using de-duplication and edit checking procedures to optimize accuracy and completeness

The VAAE database has a method in place to combine all available information relating to a particular episode into one, complete VAAE record. The database employs special procedures/programming to eliminate duplicate entries and minimize data entry errors in adverse event reports.

Standard #4

Submit VAAE reports electronically to the Division of Immunization and Respiratory Diseases, Health Canada

Every F/P/T VAAE database provides a means for provinces/territories to submit electronic records of VAAE data concepts in their jurisdiction to the Division of Immunization and Respiratory Diseases, Centre for Infectious Disease Prevention and Control, Health Canada.

Standard #5

Timely VAAE reports provided by the Division of Immunization and Respiratory Diseases, Health Canada

The Division of Immunization and Respiratory Diseases will summarize the status of adverse events submitted by provinces/territories and provide reports on a quarterly basis, with notifications as required. Periodically, the Division will also export files to the World Health Organization. As well, summary reports will be sent to the Advisory Committee on Causality Assessment (ACCA) and NACI. Line

listings will be sent regularly to each manufacturer on its products, to Canadians making requests under Access to Information legislation, and to other programs.

Standard #6

Authorized use of / access to the VAAE database

Only authorized users will have access to the central VAAE database.

Standard #7

Protect information (confidentiality and privacy measures)

Every F/P/T VAAE database has written confidentiality policies and procedures in place, including administrative and technical practices to protect the confidentiality of the information.

Standard #8

Protect medical information (security measures)

Every VAAE database has written security policies and procedures in place. The procedures include administrative and technical practices and physical safeguards to protect information in accordance with the Canadian Organization for the Advancement of Computers in Health (COACH).

Standard #9

Recover lost data (disaster recovery)

Every VAAE database is backed up incrementally on a daily basis and fully on a weekly basis. At least one copy of backup media is stored securely in a separate location and tested. In addition, the database has a regularly tested (at least annually) disaster recovery plan for providing basic system functions and ensuring access to data in an emergency (e.g. natural disaster or computer failure).

Standard #10

Exchange information records using HL7 data transferring standards

Every registry has a function, at the provincial/territorial central level, that creates, receives, and properly processes the electronic immunization message using HL7 message type.

Standard #11

Record VAAE reports in the database through a variety of mechanisms

Every VAAE database has options for practitioners to record VAAE data, ideally electronically. These may include, but are not limited to, web-based, electronic data interchange, computer diskette, or manually completed encounter forms that are scanned or inputted into the central database.

Minimum (Core) Data Concepts

The minimum (core) data concepts that have been described for the registry core data set will be used as the basis for vaccine associated adverse event reporting. The "Vaccine Associated Adverse Event" flag in immunization registries will open a VAAES module or form for the completion of information pertaining to the adverse event. Not all information contained in the immunization registry would be used for provincial/territorial or federal reporting; however, a recorded adverse event for an individual will assist the immunization provider in making immunization decisions.

The following are the minimum (core) data concepts for vaccine associated adverse event reporting.

Adverse event – VAC-ART
Adverse event – WHO-ART
Reporter identification
Reporter's professional status
Date reported
Date received
Province reported
MOH assessment and date
Outcome of event
Medical assistance sought
Concomitant medication
Medical history
Expert review
Supplementary information
Seriousness of report

VAC-ART

Those adverse events to be collected for the VAAESS for which strict definitions have been developed are known as VAC-ART data. When the definition is not met, the symptoms are described in the text field or narrative, from which the text will be coded using the WHO-ART thesaurus. The VAC-ART data are as follows:

1. local reaction at injection site
2. parotitis
3. anaphylaxis
4. other allergic reactions
5. rashes
6. arthralgia
7. arthritis
8. severe vomiting
9. hypotonic-hyporesponsive episode
10. severe diarrhea
11. seizure
12. encephalopathy
13. meningitis
14. thrombocytopenia
15. events of interest
16. other severe or unusual events

For a more detailed description of VAC-ART data, please see Appendix 1.

Data Definitions

A standard definition for each data concept is necessary to ensure that the information collected on vaccine associated adverse events is consistent in every jurisdiction. As well, standards for field name, size and type are necessary for transfer of data electronically.

Minimum data sets and standards for communicable disease reporting and immunizations have been developed through a similar process. The data standards from different systems have been incorporated into a comprehensive data model, and a data dictionary listing each element's characteristics is in production. The harmonization of the data elements will ensure that surveillance data are coordinated and that standard data elements can be used in complementary program areas. The data definitions will be made available on the Internet by the Centre for Surveillance Coordination, Health Canada, in the near future.

Vaccine Abbreviations – Naming Principles

In deriving an abbreviation for a vaccine, as many as possible of the following criteria need to be considered[7]:

1. Onomatopoeia. The abbreviations should use up to six letters: either (a) the first letters, (b) key consonants, or (c) initial letters of key words of the name of the disease or its pathogenic agent.

2. Intuitiveness. The abbreviation should represent as intuitively as possible to a general audience the name of the disease or its pathogenic agent.

3. Specificity. The abbreviation should be unique to avoid confusion with other vaccines – obsolete, current, or anticipated – with similar names.

4. Simplicity. The abbreviation should be simple, non-offensive, and clear.

5. Consistency. The abbreviations should anticipate similarity with future vaccines that have parallel disease or etiologic agent names.

6. Extensions. Limited use is to be made of lowercase format, since databases frequently cannot cope with these. For historical reasons lowercase "d" will be used for "adult diphtheria".

7. Suffixes. There should be consistency in suffixes, i.e. antitoxin - Atox; toxin - Tox; antibody - Ab; antivenom - Aven.

8. Historical consistency. Well-known and accepted abbreviations will be maintained.

9. Ordered. Order of letters will be that of the historical development of the combination vaccines.

10. Monovalent vaccines may have more letters than combination vaccines.

11. Complexity. The abbreviation should not be too complex, particularly for combination vaccines.

List of Vaccines, Single or Combination, and their Abbreviations (mixture of upper and lower case is preferred)

Acellular Pertussis		aP
Anthrax		ANTH
Bacillus Calmette Guérin		BCG
Botulism Antitoxin		BAtox
Cholera		CHOL
Diptheria Antitoxin		DAtox
Diphtheria, Tetanus - adult		Td
Diphtheria, Tetanus - paediatric		DT
Diphtheria, Tetanus, Polio - adults		TdP
Diphtheria, Tetanus, Polio - paed		DTP
Diphtheria, Tetanus, Acellular Pertussis - adults		TdaP
Haemophilus influenzae type b		*Hib*
Hepatitis A		HA
Hepatitis A and B		HAHB
Hepatitis B		HB
Hepatitis B - Thimerosal free		HB-Tmf
Immune Globulin		Ig
Hepatitis B Immune Globulin		HBIG
Influenza		FLU
Japanese Encephalitis		E
Lyme		LYM
Measles		M
Measles, Rubella		MR
Measles, Mumps, Rubella		MMR
Measles, Mumps, Rubella, Varicella		MMRV
Meningococcal		MEN
Meningococcal-Polysacharide-alpha		MEN-P-alpha
Meningococcal-Conjugate-#		MEN-C-#
	e.g	MEN-P-AC
		MEN-P-ACWY
Mumps		Mu
Pentacel Da		PTPHib
Plague		PLAG
Pneumococcal		PNEU
Pneumococcal-Polysaccharide-#		PNEU-P-#
Pneumococcal-Conjugate-#		PNEU-C-#
	e.g.	PNEU-P-23

Polio	PV or OPV
	P
Quadracel	DaPTP
Rabies	RAB
Rabies Immune Globulin	RIG
Respiratory Syncytial Virus Immune Globulin	RSVIg
Respiratory Syncytial Virus Monoclonal Antibody	RSVAb
Rubella	R
Snake Antivenom	SnakAven
Spider Antivenom	SpidAven
Tetanus	T
Tetanus Immune Globulin	TIG
Tickborne Encephalitis	TBE
Typhoid Intramuscular	TYPH-IM
Typhoid Oral	TYPH-0
Varicella Zoster	VZ
	V
Varicella Zoster Immune Globulin	VZIG
Yellow Fever	YF
Archival	
Diphtheria	D
Diphtheria, Tetanus, Acellular Pertussis - paed	DPT
Quad - Diphtheria, Tetanus, Pertussis, activated Polio	DPTP
Penta - Diphtheria, Tetanus, Pertussis, inactivated Polio, Hib	DPTPH

Rules and Abbreviations for Manufacturers

The following criteria were developed for consideration:

1. Code distributor rather than manufacturer.
2. Update to new names as companies change, amalgamate, or split.
3. If single name, use first 3-4 letters.
4. If names of different companies put together, use first letters.
5. Be sensitive to abbreviation or previous use.
6. Avoid confusion.

Manufacturers' Abbreviations

Aventis Pasteur (Pasteur Merieux Serums et Vaccins; Connaught Labs, Biken - Research foundation for microbiological diseases Osaka University)	AP
Baxter	BAX
Bayer	BAY
Berna Biotech (Berna Products, Swiss Serum and Vaccine Institute Berne)	BERN
GlaxoSmithKline (SmithKline Beecham Pharma)	GSK
Merck Frosst (Merck Manufacturing, Merck Sharp and Dohme)	MF
Shire Biologics (IAF Biovac, Biochem Pharma, Biochem Vaccines)	SHIR
Wyeth-Ayerst (Lederle labs, Div American Cyanamid Co; Wyeth, Praxis Biologics)	WA
Chiron	CHIR

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Appendix 1: Definitions of VAC-ART Codes

Data Concept: Local Reaction at Injection Site

Definition

Sterile Nodule: A nodule occurring at the vaccination site without evidence of bacterial infection. Persists ≥ 1 month, is ≥ 2.5 cm in diameter and/or drainage is evident.

Severe Inflammation, Not Infected: Redness and swelling at the injection site that is at least 5 cm in diameter and begins within 48 hours of immunization. Less severe reactions are also reported if they are painful and persist for at least 4 days or the swelling involves a joint, or if the reactions are felt to be clinically significant by the reporter.

Bacterial Infection: Existence of swelling and redness at the vaccination site with one or both of the following: signs of purulence and inflammation, usually well demarcated, and positive gram stain or culture obtained from site of infection or regional lymph node.

Rationale

Collection of data related to local reaction at injection site will assist in differentiating between reactions that are related to injection technique and those truly related to the immunizing agent or its constituents.

Bacterial Infection with prompt to:

Cellulitis with prompt to

- lymphangitis (painful subcutaneous red streaks along vessels)
- positive gram stain, or
- existence of purulent discharge with inflammatory signs

Abscess with prompt to

- positive gram stain or culture
- existence of purulent discharge with inflammatory signs

Impetigo

Recommended Names on Drop Down List

Sterile nodule
Severe inflammation, not infected
Bacterial infection
Bacterial infection - abscess
Bacterial infection - cellulitis
Bacterial infection - impetigo

Data Concept: Parotitis

Definition

Swelling with pain and/or tenderness of parotid gland(s)

Rationale

Parotitis is a common manifestation of mumps infection. Since the mumps vaccine is a live virus vaccine, low-grade infection following immunization can occasionally produce the same manifestation. It is transient and self-limiting.

Recommended Names on Drop Down List

Parotitis

Data Concept: Anaphylaxis

Definition

A severe allergic reaction in a previously sensitized individual to a specific antigen or hapten, having a sudden onset after immunization, occurring within 15-30 minutes of immunization, and involving at least two body systems with multiple symptoms such as hives, flushing, angioedema, stridor, wheezing, shortness of breath, nausea/vomiting, diarrhea, pallor, dizziness and syncope.

Explosive, occurring within 15 to 30 minutes after immunization and evolving rapidly towards cardiovascular collapse AND requiring resuscitative therapy.

Rationale

Anaphylaxis is caused by immediate hypersensitivity to IgE-mediated antibodies, which induce histamine release from tissue mast cells. It cannot occur on first exposure to an antigen, but can occur on the second or any subsequent exposure in sensitized individuals.

Anaphylaxis has been known to occur up to 24 hours after immunization. However, for the purpose of the VAAESS database VAC-ART coding, anaphylaxis should have occurred within 15 to 30 minutes of immunization in order to be consistent with the recommendations from NACI.

An overwhelming and potentially life-threatening allergic reaction to a foreign substance, anaphylaxis refers to a collection of symptoms affecting multiple systems in the body. The most dangerous are breathing difficulties or a drop in blood pressure, which are potentially fatal.

Confirmed/diagnosed by a physician.

Recommended Names on Drop Down List

Anaphylaxis

Data Concept: Other Allergic Reactions

Definition

An immune complex-mediated reaction characterized by respiratory manifestations and/or skin manifestations. Must occur within 72 hours of immunization. Most instances begin within 12 hours of immunization.

Rationale

An allergic reaction is an acquired hypersensitivity to an antigen that does not normally produce such a reaction. It is essentially a disorder of the immune system, whereby antigen-antibody complexes stimulate the release of chemicals, such as histamine, which produce overt signs and symptoms of hypersensitivity. It can occur in response to a component of a vaccine in a person previously sensitized, i.e. antibodies must be present from a previous exposure to the antigen. Therefore, allergic reactions are rarely seen after the first dose in a vaccine series, but may be seen with the second or any subsequent dose.

Prompts (via a drop down list) should be established for each of the three concepts on the drop down list, to include:

Respiratory manifestations

- Wheezing
- Shortness of breath
- Bronchospasm
- Prompt to Past Medical History

Swelling

- Localized
- Generalized

Prompt to text field to indicate body part (e.g. eyes, intra-oral, face, etc)

Skin manifestations

- Hives
- Pruritus

Recommended Names on Drop Down List

Allergic reaction:
Allergic reaction - respiratory manifestations
Allergic reaction - swelling - local
Allergic reaction - swelling - general
Allergic reaction - skin manifestation

Data Concept: Rashes

Definition

An eruption on the skin, typically with little or no elevation above the surface. Must last 4 or more days and/or require hospitalization.

Rationale

Most rashes occurring in children are caused by an inter-current viral illness, even those temporally related to immunization. The exception is a rash related to MMR vaccine, which produces a mild, non-transmissible measles-like illness that can be manifest as a generalized rash with fever. It occurs in 5% to 10% of individuals following the first dose of MMR, usually 7 to 10 days after vaccination. It is much less common after the second dose of MMR. Similarly, varicella rash occurs in 5.5% of those immunized with the first dose, usually between 7 and 21 days, and 0.9% after the second dose, usually within 23 days of immunization.

Petechial rashes are rare and warrant investigation for thrombocytopenia, a rare complication of MMR vaccination.

Urticaria should be reported as an allergic reaction, not as a rash.

Prompt to Supplementary Information to describe type of rash such as measles-like or varicella-like.

Recommended Names on Drop Down List

Rashes, generalized
Rashes, injection site

Data Concept: Arthralgia

Definition

Joint pain lasting at least 24 hours. If the condition is an acute exacerbation of a pre-existing condition or is difficult to distinguish from myalgia, provide details under Supplementary Information.

Rationale

Arthralgia can be a manifestation of natural rubella infection in adults.

Fever, with or without rash, may be seen in about 5% to 10% of individuals 7 to 10 days after administration of MMR vaccine (*Canadian Immunization Guide*, 6th ed, p. 147).

Prompt to Supplementary Information.

Recommended Names on Drop Down List

Arthralgia

Data Concept: Arthritis

Definition

Inflammation of joints due to infectious, metabolic, or constitutional causes, as manifested by joint swelling, pain, redness and/or sensation of warmth.

Must last at least 24 hours and/or require hospitalization.

If the condition is an acute exacerbation of a pre-existing condition, give details under Supplementary Information.

Rationale

Arthritis is usually associated with arthralgia, but arthralgia may occur without obvious arthritis (see arthralgia). Rubella vaccine-associated arthritis involves, in order of decreasing frequency, the joints of the fingers, knees, wrists, elbows, ankles, hips and toes. The arthritis must last at least 24 hours.

Confirmed/diagnosed by a physician.

Prompt to Supplementary Information.

Recommended Names on Drop Down List

Arthritis

Data Concept: Severe Vomiting

Definition

Must be severe enough to interfere with daily routine or consist of at least three episodes in 24 hours.

Rationale

Not specifically related to a particular vaccine. It could be a manifestation of low-grade infection after immunization with live vaccines or a physiologic response to a foreign substance.

Nausea and vomiting have been particularly associated with oral typhoid vaccine, human diploid cell rabies vaccine (HDCV), and Japanese B encephalitis vaccine. Following administration of oral typhoid vaccine, nausea and vomiting are the most commonly reported adverse events.

Recommended Names on Drop Down List

Severe vomiting

Data Concept: Severe Diarrhea

Definition

Must be severe enough to interfere with daily routine or consist of at least three episodes in 24 hours.

Rationale

Not specifically related to a particular vaccine. It could be a manifestation of low-grade infection after immunization with live vaccines or a physiologic response to a foreign substance.

Recommended Names on Drop Down List

Severe diarrhea

Data Concept: Hypotonic-Hyporesponsive Episode

Definition

A hypotonic-hyporesponsive episode (HHE) is an unusual reaction occurring within 48 hours of vaccine administration and consisting of an acute diminution in sensory awareness or loss of consciousness accompanied by pallor, cyanosis, and muscle hypotonicity. Most reported episodes occur between 1 and 12 hours after immunization. Children are initially irritable and may be febrile. They become pale, limp, and unresponsive or hyporesponsive. Respirations are shallow, and cyanosis is frequently noted. As a result, parents may report that the child was not breathing. These episodes are usually transient (lasting a few minutes) and self-limiting, although 36 hours may elapse before the child returns to normal.

The HHE episode (at least two of the four symptoms) must occur within 72 hours after immunization in infants ≤ 2 years of age.

Confirmed/diagnosed by a physician.

Rationale

Most often seen in infants receiving pertussis-containing vaccines. The cause of these episodes is unknown, but the episodes are most consistent with infant fainting spells. Some HHE episodes may represent atonic seizures, consisting of sudden loss of postural tone and consciousness, perhaps triggered by fever. Other cases have been confused with anaphylaxis or hypoglycemia. They are not associated with any lasting sequelae.

Recommended Names on Drop Down List

Hypotonic-hyporesponsive episode

Data Concept: Seizure

Definition

Paroxysms of generalized, tonic, skeletal muscle contractions and generalized clonic jerking, usually associated with decreased level of consciousness. They must be distinguished from vasovagal or fainting episodes, in which isolated muscle contractions may occur. Seizures may last for several minutes or more.

Seizures must have onset > 30 minutes after immunization and must not occur in conjunction with any other conditions being reported, such as fainting.

Rationale

Febrile seizures, which may include prolonged and atypical types, are not uncommon in children. Collection of data on afebrile seizures is of importance to ACCA.

Prompt to Past Medical History if field completed.

Recommended Names on Drop Down List

Seizure
Seizure afebrile
Seizure febrile

Data Concept: Encephalopathy

Definition

Encephalopathy: Acute onset of major neurological illness characterized by two or more of the following:

1. seizures
2. distinct change in level of consciousness or mental status (behaviour and/or personality) lasting ≥ 24 hours
3. focal neuropathy signs that persist for > 24 hours

Encephalitis: Acute onset of major neurological illness characterized by any two or more of the above symptoms AND with infectious cause.

Encephalitis is a form of encephalopathy, therefore only one term can be used in reporting. The term "encephalitis" is used when there is evidence of an inflammatory response within the brain (e.g. pleocytosis in the cerebrospinal fluid).

"Encephalopathy" is used when an illness clinically appears like an encephalitis but no inflammatory response is evident[8].

Rationale

Encephalopathy is sometimes discussed in relation to whole-cell pertussis-containing vaccine, although there is no biologically plausible explanation for pertussis vaccine to cause encephalopathy. Recent epidemiologic studies have indicated that

DPT (whole cell pertussis) vaccine may be associated, albeit rarely, with acute encephalopathy.

Cerebrospinal fluid (CSF) findings should accompany encephalitis diagnosis.

Confirmed/diagnosed by a physician.

Recommended Names on Drop Down List

Encephalopathy
Encephalitis

Data Concept: Meningitis

Definition

1. Inflammation of the meninges of the brain or spinal cord and especially of the pia mater and the arachnoid

2. A disease that may be either a mild illness caused by a virus (as the coxsackievirus) or a more severe, usually life-threatening, illness caused by a bacterium (especially the meningococcus or the serotype designated B of *Haemophilus influenzae*), possibly associated with fever, headache, vomiting, malaise, and stiff neck, which, if untreated, may progress (in bacterial forms) to confusion, stupor, convulsions, coma, and death.

Rationale

For mumps vaccine and other live virus vaccines, an association with meningitis has been postulated because such an association has been seen with natural mumps infection. The postulated mechanism is infection of the meninges with the vaccine virus. Such a causal relation has been established with the Urabe strain of mumps virus (1 case reported per 62,000 vaccinations), which is no longer used in vaccines in Canada. There is no evidence of a causal association with the Jeryl Lynn strain of mumps used in MMR or with any of the other routinely used live virus vaccines.

There is no causal relation between non-live vaccines and meningitis. Studies that have included cases of acute encephalitis and acute encephalopathy have identified a causal relation with whole-cell DPT.

CSF findings should accompany a meningitis diagnosis.

Confirmed/diagnosed by a physician.

Recommended Names on Drop Down List

Meningitis

Data Concept: Thrombocytopenia

Definition

Persistent decrease in the number of blood platelets, which is often associated with hemorrhagic conditions. The number of platelets is reduced to < 150,000/mm^3.

Under Supplementary Information provide laboratory report with the lowest recorded value and/or clinical evidence, including duration of illness.

Rationale

The cause of vaccine associated thrombocytopenia is unknown. It is postulated that live virus vaccine suppresses the bone marrow and hence the production of platelets.

Thrombocytopenia is a known complication of both rubella and measles vaccination, occurring in 1 per 30,000-40,000 children following vaccination with the first dose of measles vaccine. It may also occur after the second dose, even in someone who did not have a reaction after the first. However, thrombocytopenia after the first dose may increase the risk of recurrence with the second dose[9].

Confirmed/diagnosed by a physician.

Recommended Names on Drop Down List

Thrombocytopenia

Data Concept: Events Of Interest

Definition

These events are known or suspected to be vaccine related and are of temporary public health interest.

This field will be updated to include or delete conditions, symptoms or syndromes as needed.

Rationale

Events of interest will assist in enhanced surveillance of certain conditions or syndromes of interest. These can be reviewed regularly and removed, or new items added for a given period of time.

Recommended Names on Drop Down List

Examples

Guillain-Barré Syndrome
Paralysis
Oculo-Respiratory Syndrome
Zoster

Data Concept: Other Severe Or Unusual Event

Definition

Other severe or unusual conditions not otherwise captured in the VAAE reporting system. These must be clinically intriguing or epidemiologically interesting, and they usually require medical intervention for reporting.

This data concept may be replaced by a new concept "Event of Interest" or could become a text box for further information, or be combined with the general text box.

Rationale

Reporting of severe or unusual events is important not only to identify a possible causal relation with vaccination but also to rule out the vaccine as the cause.

To capture new events or those previously unknown to be related to vaccines.

Important aspect of health surveillance.

Recommended Names On Drop Down List

Other severe or unusual

Appendix 2: Lists of Participants

Minimum (Core) Data Set for a National Immunization Records Network Retreat
July 12-14, 2000

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Minimum Core Data Set for Vaccine Associated Adverse Events Retreat
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Vaccine Associated Adverse Events Surveillance (VAAES) Sub-Committee Meeting Minimum Data Set for VAAE Reporting March 12-13, 2001

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Meeting on Abbreviations for Vaccines and Manufacturers and CCI Codes
July 17-18, 2001

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