

# Integrating the Healthcare Enterprise



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## **IHE Patient Care Coordination (PCC) Technical Framework Supplement 2009-2010**

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### **Immunization Content (IC)**

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**Trial Implementation Supplement  
August 10, 2009**

20 **Foreward**

This page is standard language for all IHE supplements. The Introduction section following will list all other IHE documents that are modified by this supplement. This document is a supplement to the IHE Patient Care Coordination Technical Framework 4.0. The technical framework can be found at

25 [http://www.ihe.net/Technical\\_Framework/index.cfm#pcc](http://www.ihe.net/Technical_Framework/index.cfm#pcc).

This and all IHE supplements are written as changes to a base document. The base document is normally one or more IHE Final Text documents. Supplements tell a technical editor and the reader how to modify the final text (additions, deletions, changes in wording). In order to understand this supplement, the reader needs to read and understand all of the base documents that are modified by this supplement.

30

In this supplement you will see “boxed” instructions similar to the following:

<i>Replace Section X.X by the following:</i>
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These “boxed” instructions are for the author to indicate to the Volume Editor how to integrate the relevant section(s) into the overall Technical Framework.

35 This format means the reader has to integrate the base documents and the supplement. When the material in the supplement is considered ready for incorporation into the final text of the Technical Framework, the IHE committees will update the technical framework documents with the final text. Supplements are written in this format to avoid duplication material. This means that two IHE documents (one possibly final text, and the other a supplement) should not contain contradictory material.

40

Text in this document is not considered final for the Technical Framework. It becomes Final Text only after the IHE PCC Technical Committee ballots the supplement (after testing) and agrees that the material is ready for integration with the existing Technical Framework documents.

45 **It is submitted for Trial Implementation starting August 10, 2009.**

**Comments on this supplement may be submitted <http://forums.rsna.org>:**

1. Select the “IHE” forum
2. Select Patient Care Coordination Technical Framework
3. Select 2009-2010 Supplements for Public Comment
4. Select Immunization Care Plan

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Please use the Public Comment Template provided there when starting your New Thread.

**Details about IHE may be found at: [www.ihe.net](http://www.ihe.net)**

**Details about the IHE Patient Care Coordination may be found at: <http://www.ihe.net/Domains/index.cfm>**

55 **Details about the structure of IHE Technical Frameworks and Supplements may be found at: <http://www.ihe.net/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>**

## Introduction

60 This supplement is written for Trial Implementation. It is written as changes to the documents listed below. The reader should have already read and understood these documents:

1. [PCC Technical Framework Volume 1, Revision 5.0](#)
2. [PCC Technical Framework Volume 2, Revision 5.0](#)

65 This supplement also references other documents<sup>1</sup>. The reader should have already read and understood these documents:

1. [IT Infrastructure Technical Framework Volume 1, Revision 6.0](#)
2. [IT Infrastructure Technical Framework Volume 2, Revision 6.0](#)
3. [The Patient Identifier Cross-Reference \(PIX\) and Patient Demographic Query \(PDQ\) HL7 v3 Supplement to the IT Infrastructure Technical Framework.](#)
- 70 4. HL7 and other standards documents referenced in Volume 1 and Volume 2
5. Dilbert 2.0: 20 Years of Dilbert by Scott Adams, ISBN-10: 0740777351, ISBN-13: 978-0740777356

This supplement defines the Immunization Content (IC) profile provided for trial implementation.

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<sup>1</sup> The first three documents can be located on the IHE Website at [http://www.ihe.net/Technical\\_Framework/index.cfm#IT](http://www.ihe.net/Technical_Framework/index.cfm#IT). The remaining documents can be obtained from their respective publishers.

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### Open Issues for Immunization Content

1. Immunization Content needs to be able to specify one or more immunization guidelines to be used. For example, the request may indicate that the patient is to be immunized using Standard CDC / ACIP population guidelines, or travel guidelines for travel to SE Asia. How should these guidelines be referenced?

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2. Value and extent of a “selection of rank-ordered immunization care plans” that might be returned to support various combinations of vaccine availability and / or limitations on the number of shots to be given in any single visit?

### **Closed issues for Immunization Content**

- 120 1. Need specific codes to use for “Intent” of IC Domain Content in the RCG-IC response for both “Validated” history content, and for “Proposed” immunization care plan. The use of IC for both “validated history” and “immunization care plan” in the response to the service call needs to be examined carefully to see if there are any other standard vocabulary items that might need new codes.  
125 These were established by the Immunization Recommendation entry, and for “validated history”, in the alert entry.
2. We agreed that invalid doses would not have the dose number flagged to indicate that they are invalid, but would instead have an observation indicating the administrative status of “invalid” with the relevant reasons. This  
130 observation needs a code (LOINC?).  
See the alert entry.
3. The PCC Immunization Content Profile Supplement needs to be changed to specify additional ActCode values or MoodCode values to support “validated” history, and “proposed” vaccine forecast / immunization Care Plan.

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## Abstract

*Add the following bullet to PCC TF-1:2.7 History of Annual Changes*

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- **Immunization Content Profile (IC)** – The Immunization Content Profile defines standard immunization data content for Immunization Information Systems (IISs), other public health systems, electronic medical records (EMR) systems, Health Information Exchanges, and others wishing to exchange immunization data electronically in a standard format.

## Glossary

*Add the following terms to the Glossary*

- 145 **Adverse Event** – An Adverse Event (AE) is any unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease which either occurs during the study, having been absent at baseline, or if present at baseline, appears to worsen<sup>2</sup>.
- 150 **Antigen** – A component of a disease-causing agent that stimulates an immune response. More commonly, the disease which a vaccine is supposed to protect against. In the context of immunization, the latter is the meaning of interest.<sup>3</sup>
- 155 **Combination Vaccine** – A vaccine product containing antigens to more than one disease. Combination vaccines are commonly used to reduce the number of “needle sticks” required to give multiple vaccines at the same time. A combination vaccine is effectively the same thing as a Multiple Antigen Vaccine or a Poly-valent Vaccine.
- Contraindication** – Any medical, environmental, genetic, or other condition that makes a treatment inadvisable. Contraindications include increased likelihoods of a serious Adverse Events, reduced effectiveness of treatment, or duplicative therapies.
- 160 **Dose of Antigen / Vaccine Component** – Immunization CDS will analyze an existing immunization history by vaccine component, or doses of antigen, in order to build a proposed immunization care plan (ICP).
- 165 **Dose of Vaccine / Administered Dose** – This is a quantity of medication or vaccine substance that is administered as a single shot. It will contain one *or more* doses of antigens. Immunization histories are typically recorded in terms of administered doses of vaccine, rather than doses of antigens.
- Guidelines** – Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances<sup>4</sup>.
- 170 **Immunization Recommendation** – A set of proposed immunizations to be given to a patient, including the dates to give them. The recommendation may be general, or it may be focused on a particular disease (such as an influenza pandemic) or a particular risk situation (such as travel to places with high risk factors for certain diseases).

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<sup>2</sup> Adapted from the NINDS Glossary of Clinical Research Terms, Last updated November 24, 2008, retrieved from [http://www.ninds.nih.gov/research/clinical\\_research/basics/glossary.htm](http://www.ninds.nih.gov/research/clinical_research/basics/glossary.htm)

<sup>3</sup> From the HL7 Glossary, retrieved from <http://www.hl7.org/v3ballot2009may/html/help/glossary/glossary.htm>

<sup>4</sup> Field MJ, Lohr KN. Guidelines for Clinical Practice: from development to use. Washington DC: National Academic Press, 1992. Retrieved from [http://www.nap.edu/openbook.php?record\\_id=1863&page=27#p200063cf8960027001](http://www.nap.edu/openbook.php?record_id=1863&page=27#p200063cf8960027001)

**Immunization Information System (IIS)** – A software system designed to collect all information about immunizations given to a certain population. An IIS is typically funded or sponsored by a Public Health Department or Ministry.

- 175 **Immunization Interval** – A measure of the interval between doses of antigens. For maximum effectiveness against the targeted disease, many vaccines must have booster shots given after the initial dose. The recommended interval varies by vaccine. In most cases, administration of a vaccine with less than the minimum immunization interval reduces the effectiveness of the vaccine, and one that is substantially longer than the
- 180 recommended interval exposes a person to a higher risk of contracting the disease during the period of delay.

**Immunization Recommendation** – A collection of proposed immunizations and encounters which a provider may use to develop an immunization care plan. Also known as an Immunization or Vaccine Forecast.

- 185 **Immunization Registry** – See Immunization Information System

**Ineffective Dose** – This is a dose of administered vaccine or vaccine component which may be predictably less effective than desired, due to inadequate immunization interval, expired vaccine, concurrent administration of antibiotics, vaccine recall, improper vaccine storage, or other issues.

- 190 **Invalid Dose** – See Ineffective Dose

**Multiple Antigen Vaccine** see Combination Vaccine.

- Precaution** – A statement indicating any medical, environmental, genetic, or other condition that may increase the likelihood of an Adverse Event, or reduce the effectiveness of the medication or immunization. A clinician should review the risks and
- 195 weigh them against the benefits of the vaccine before deciding whether or not to proceed with the immunization.

**Vaccine** – This is a substance designed to be administered to a person in order provide protection against future disease. See also Combination Vaccine.

*Add Section X below to the end of Volume I preceding the Appendixes and Glossary*

200 **X The Immunization Content Profile (IC)**

The Immunization Content Profile (IC) provides a standard document to exchange immunization data. It is intended to facilitate the exchange of immunization data among multiple systems belonging to a single or to multiple organizations. Data exchange with and among the installed base of U.S. Immunization Information System (IIS) base was a  
205 critical consideration in formulating this profile. However, its intention is to go beyond data exchange among IISs, and facilitate immunization data exchange on a healthcare information network that includes electronic medical record (EMR) systems, Health Information Exchanges, other public health systems, Personal Health Record (PHR) systems, and other stakeholder systems. Thus, the profile specifies common data formats  
210 for exchanging immunization data only, or for exchanging immunization data along with medical summary data needed for the overall care of a patient related to immunizations.

To accomplish this, IC includes a history of administered vaccines with such details as lot number, who administered the shot, and so forth, and handles immunization as well as  
215 other information related to the patient's care. For example, it includes medical history, medications, allergies, vital signs, and so forth.

## X.1 Use Cases

The following progression of use cases is illustrated in the drawing below

220

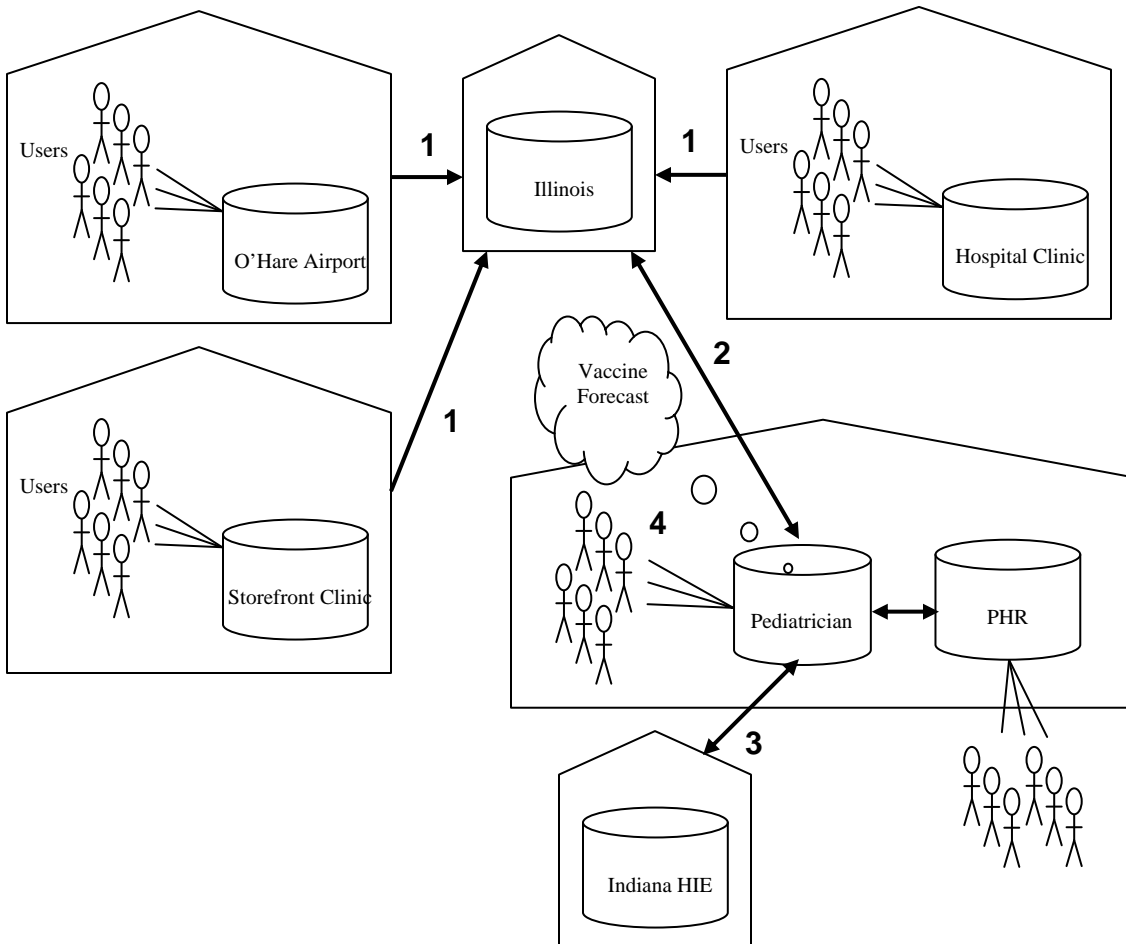
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### X.1.1 Use Case 1: Immunization Information System Participation

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Various provider organizations - airport flu shot clinics, storefront vaccine clinics, and hospital vaccine clinics - wish to submit immunization histories for patients to a regional Immunization Information System (IIS) with appropriate patient consent. The provider IT departments configure HL7 Version 2.3.1 connections with the IIS. Each time immunizations are recorded, records of the administered vaccines are automatically sent to the IIS using an HL7 version 2.3.1 standard format. This is representative of the present-state use case in the U.S.

### **X.1.2 Use Case 2: Immunization Yellow Card**

260 A pediatrician's office produces official immunization records (sometimes called "Yellow  
Card") for patients. The provider electronic medical record (EMR) system retrieves  
demographic information and records of immunization its immunization repository. To  
265 supplement its records with immunizations that the patient may have received from other  
providers, it queries the regional Immunization Information System (IIS). It passes the  
immunization content to a software module or service that prints the information in the  
official Yellow Card format.

### **X.1.3 Use Case 3: Personal Health Record**

270 The provider wishes to make the assembled immunization information available in the  
patient's Personal Health Record (PHR). The pediatrician's office EMR system includes  
the retrieved immunization information in its complete care provision information about  
the patient. The standard Care Provision information contains current conditions,  
allergies and past adverse events, medications, vital signs, past medical history such as  
275 disease history, and so forth, in addition to immunizations. Knowing that the patient also  
has visited providers in a neighboring state, the EMR system queries the neighboring  
state's Health Information Exchange (HIE) to retrieve additional care provision  
information in a standard format. Since the neighboring state IIS is also part of the HIE,  
the retrieved information also includes immunizations. The pediatrician's office EMR  
system combines the retrieved and local information and sends it to the provider's PHR  
system in a standard format.

### **X.1.4 Use Case 4: Vaccine Forecast**

280 The pediatrician's office wishes to run an automated Clinical Decision Support Service to  
calculate which immunizations are due on the next visit, and to assist with  
reminder/recall. The service may be integrated within the EMR or may be accessed  
externally using a web service interface. The service accepts a standard XML-based  
285 payload in Immunization Content format. The pediatrician's EMR system submits the  
patients Care Provision data that it has previously assembled to the Clinical Decision  
Support Service and receives immunization recommendations in return. It records the  
care plan and uses it in reminder/recall.

## **X.2 Actors/Transaction**

290 There are two actors in the IC profile, the Content Creator and the Content Consumer.  
Content is created by a Content Creator and is to be consumed by a Content Consumer.  
The sharing or transmission of content from one actor to the other is addressed by the  
appropriate use of IHE profiles described below, and is out of scope of this profile. A  
Document Source or a Portable Media Creator may embody the Content Creator Actor. A  
Document Consumer, a Document Recipient or a Portable Media Importer may embody  
295 the Content Consumer Actor. The sharing or transmission of content or updates from one  
actor to the other is addressed by the use of appropriate IHE profiles described in the  
section on Content Bindings with XDS, XDM and XDR.



Figure X.2-1 IC Actor Diagram

300 **X.3 Options**

Table X.3-1 IC Options

Actor	Option	Location in Vol 2
Content Consumer	<a href="#">View Option (1)</a>	PCC TF-2:3.0.1
	<a href="#">Document Import Option (1)</a>	PCC TF-2:3.0.2
	<a href="#">Section Import Option (1)</a>	PCC TF-2:3.0.3
	<a href="#">Discrete Data Import Option (1)</a>	PCC TF-2:3.0.4

Note 1: The Actor shall support at least one of these options.

**X.3.1 View Option**

305 This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the medical document. See the View Option in PCC TF-2:3.01 for more details on this option.

A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was displayed by the Content Consumer Actor.

310 The Content Consumer Actor shall be able to present a view of the document using this style sheet if present.

**X.3.2 Document Import Option**

315 This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire medical document and managing it as part of the patient record. See the Document Import Option in PCC TF-2:3.02 for more details on this option.

**X.3.3 Section Import Option**

320 This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the medical document and managing them as part of the patient record. See the Section Import Option in PCC TF-2:3.03 for more details on this option.

### **X.3.4 Discrete Data Import Option**

325 This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the medical document and managing them as part of the patient record. See the Discrete Data Import Option in PCC TF-2:3.04 for more details on this option.

### **X.4 Coded Terminologies**

330 This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Actors from this profile may choose to utilize coded data, but interoperability at this level requires an agreement between the communicating parties that is beyond the scope of this Profile.

335 To facilitate this level of interoperability, the applications that implement actors within this profile shall provide a link to their HL7 conformance profile within their IHE Integration statement. The conformance profile describes the structure of the information that they are capable of creating or consuming. The conformance profile shall state which templates are supported by the application implementing the profile Actors, and which vocabularies and/or data types are used within those templates. It should also indicate the optional components of the entry that are supported.

340 An Example HL7 Conformance Profile is available to show how to construct such a statement. See the [HL7 Refinement Constraint and Localization](#) for more details on HL7 conformance profiles.

### **X.5 Process Flow**

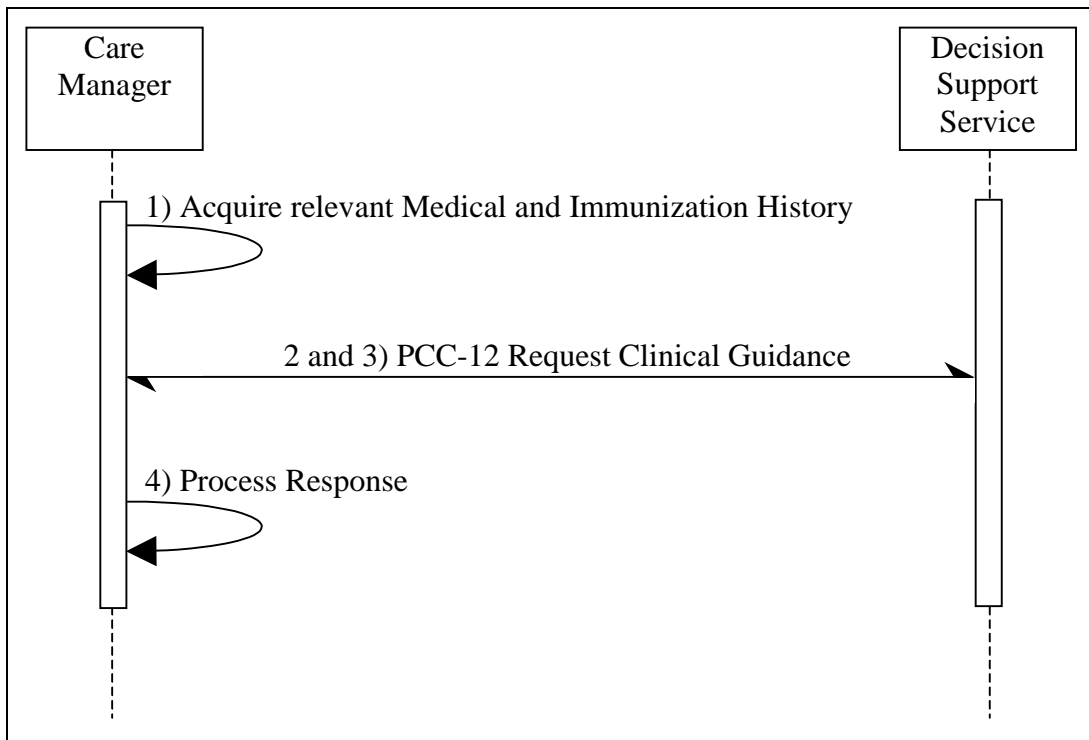
345 There are several process flows for use of this content profile. The document oriented process flows are described in PCC TF-1:2.6 PCC Profiles Overview, where the content being exchanged is are documents conforming to the Immunization Content module.

Another process flow uses this same content in a message used for clinical decision support. In this process flow, the content creator and content consumer actors are grouped with the Care Manager and Decision Support Actors of the Request for Clinical Guidance Profile.

- 350 1. A Care Manager Actor acquires the medical and immunization history of a patient.
2. The Care Manager Actor submits the relevant portions of this medical history along with the complete immunization history to the Decision Support Service using PCC-12 Request for Clinical Guidance Transaction.
- 355 3. The Decision Support Service processes the result and returns a response to the Care Manager actor in that same transaction.
4. The Care manager then applies the return information. How this information is used by the care manager is out of scope of this profile.

This process flow is shown below in figure X.5-1.

360



**Figure X.5-1 Process Flow for Clinical Decision Support**

## X.6 Immunization Content Module

365 The Immunization Content Module is designed to provide a record of a patient's immunizations, document planned immunizations, provide details about the effectiveness of past immunizations, and to propose immunizations to be given as part of the overall care plan for the patient. This content module is fully defined in PCC TF-2:6.1.1.Y.

370 The collection of information making up this content module is described in Table X.6-1 below and discussed in more detail following it.

**Table X.6-1 Immunization Care Plan Data Elements**

Data Element / Section	Description	Opt
History of Immunizations	This section lists of immunizations previously given to a patient. For each immunization given this list should include the date it was given, the name of the vaccine, a coded value for the vaccine, the lot number of the vaccine, the manufacturer of the vaccine, the provider giving the immunization, and any reactions or adverse events caused by the immunization, and the severity of those reactions, and if refused, the reason for the refusal.	R
Authors and Informants	The source of the information may be the patient, parent or guardian, another provider, immunization registry, et cetera. The IHE PCC technical framework supports recording of the author or informant that provided the information being recorded in all coded entries.	R
History of Past Illness	The history of past illnesses section includes clinical diagnoses relevant to immunizations. This may include prior illnesses that convey immunity or otherwise influence an immunization recommendation.	R2
Problem List	The problem list includes those relevant to immunization recommendations, including current illnesses, conditions or risks (e.g., immunosuppression) that might be contraindications for providing an immunization.	R2
Allergies and Intolerances	This section includes those allergies or intolerances to substances commonly used in vaccinations, e.g. egg albumin, et cetera, as well as allergies or intolerances to other medications or immunizations	R2
Medications	This is the list of relevant medications for the patient.	R2
Lab Results	The laboratory results section may include information about antibody tests or titers that show that immunization has or has not been already conferred to a patient. This section may also include information about the results of point of care tests, such as a TB test.	R2
Coded Vital Signs	This section supports the recording of Vital signs such as height and weight. These enable dosing calculations to be performed. Other vital signs (e.g., temperature) may be included to enable the identification potential contraindications for immunization (e.g., fever).	R2
Gestational Age at Birth	In the case of premature birth, immunizations are determined based upon the adjusted age of the infant. The gestational age at birth can be used to determine the adjusted age.	R2
Pregnancy History	This section may be present to include information about current pregnancy status for the patient, as this can also influence the type of vaccinations that may be proposed.	R2
Advance Directives	This section includes advance directives that would influence the immunizations proposed for a patient.	R2
Comments	This allows providers to add comments to the content.	O
Immunization Recommendation	Immunization recommendations indicate the immunizations that are proposed or intended for the patient and their schedule. It may reference specific guidelines to activate certain protocols (e.g., travel to a foreign country).	C (See note 1)

Note 1: This data element is required when this content is used with the Request for Clinical Guidance (RCG) profile, and is required if known (R2) otherwise.

375 The material necessary to generate an immunization record is required of all instances of  
this content module. This record may be used to electronically exchange the  
immunization record of a patient as a clinical document.

This content module includes information relevant to a clinical decision support service  
that reviews the immunization history and care plan present within it to make  
380 immunization recommendations. The immunization recommendations include those  
immunizations and encounters that are proposed and should identify the guidelines from  
which the recommendations are derived. Material needed for generating these  
recommendations is required if known in the data elements described in Table X.6-1  
above. Note also that some of this information may not be available (or provided) to the  
385 generating application.

A content creator actor that implements this content profile shall be able to demonstrate  
that it can create a document that is sufficient for both uses. We note that not all uses of  
this content profile will require that level of output. There are cases where the data  
produced must be limited to a smaller set due to policy considerations. For example,  
390 when the document is used as immunization record necessary to for enrollment in a  
school, the content creator actor needs to be able to conform to local law, regulation, and  
policy regarding the information permitted in the exchange.

Thus, content creators must be also configurable to generate the appropriate result.

The immunization recommendations found in this content module support the  
395 specification of a proposed immunization. This is a proposal for treatment of a patient  
that can be reviewed by a decision support service, or could be output from a decision  
support service. This can also be described as being part of the intended plan of care for  
the patient. In this case, the intended treatments can be reviewed and potentially updated  
by a decision support service, or can serve as persistent documentation of the current plan  
400 for other uses (e.g., reminder/recall notices). The section template is described in more  
detail in section **Error! Reference source not found..** The immunization  
recommendation entry details with the machine readable content and is described further  
in section **Error! Reference source not found..**

The clinical statements about immunizations can be augmented with additional clinical  
405 statements to provide more detail on the immunization dosing. Immunization dosing can  
become complex due to the use of combination vaccines. Combination vaccines provide  
multiple antigens protecting against multiple disease conditions. A single immunization  
dose given to a patient can result in multiple antigens being used. It is the antigen doses  
that matter when trying to determine what immunizations are necessary for the patient.  
410 Guidelines vary by antigen with respect to the appropriate immunization interval and  
dose. One antigen within a combination vaccine may not be considered effective, while  
others could be. The Antigen Dose entry described in PCC TF-2:6.1.4.S to provide these  
details

The information exchanged can include alerts used to inform clinicians about exceptional  
415 conditions. Alerts can be applied to existing immunization events to provide an  
evaluation of the effectiveness of those events. Alerts can identify other relevant clinical  
data that could impact the immunization care plan (e.g., pregnancy) or subsequent

medical treatment (e.g., potential medication interactions). Alerts are described in more detail in PCC TF-2:6.1.4.R.

420 **X.7 Grouping**

**X.7.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messages**

425 Actors from the ITI XDS, XDM and XDR profiles embody the Content Creator and Content Consumer actors of this profile when it is used to share immunization histories and plans as clinical documents. A Content Creator or Content Consumer may be grouped with appropriate actors from the XDS, XDM or XDR profiles to exchange the content described therein. The metadata sent in the document sharing or interchange messages has specific relationships or dependencies (which we call bindings) to the content of the clinical document described in the content profile.

430 The Patient Care Coordination Technical Framework defines the bindings to use when grouping the Content Creator of this Profile with actors from the IHE ITI XDS, XDM or XDR Integration Profiles.

**Table X.7-1 Bindings to XDS, XDR and XDM Profiles**

Content	Binding	Actor	Optionality
Immunization Content	Medical Document Binding to XDS, XDM and XDR	Content Creator	R
		Content Consumer	R

435 **X.7.2 Request for Clinical Guidance**

440 To support the generation of immunization recommendations through a clinical decision support service, the Care Manager and Decision Support Service actors of the RCG profile shall each be grouped with the Content Creator and Content Consumer actors of this profile. This supports the exchange of Immunization Content containing the patient’s immunization history and care plan (from the Care Manager to the Decision Support Service Actor) and the updated immunization history and plan with immunization recommendations (from the Decision Support Service Actor to the Care Manager).

445 Appendix F Transforming CDA Documents to Care Record Messages found in the Request for Clinical Guide Profile Supplement describes the model by which the Immunization Content document found in this profile can be transformed to the Care Record message used in the Request for Clinical Guidance transaction.

450 This profile places specific requirements upon the Care Manager and Decision Support Service actors that are over and above those specified within the Immunization Content Module itself. These are detailed below.

### **X.7.2.1 Care Manager Requirements**

The Care Manager as the Content Creator shall create at least one proposed Immunization Recommendation Entry specifying the type of immunization being requested and may include a reference to the guidelines to apply.

455 This module shall contain a required immunization recommendation. The proposed immunization shall contain a required proposal for immunization entry. The effective time of the proposal shall be present to indicate the time range of the request for immunizations to be given. The proposal may include a reference to one or more specific guidelines to indicate that this proposal is intended to comply with those guidelines.

### **X.7.2.2 Decision Support Service Requirements**

The Decision Support Service Actor shall duplicate the content provided to it in the original request, annotating or augmenting that content as needed. It shall create immunization recommendations proposing the vaccinations that should be given for the proposed immunization, or record why no recommendation can be made.

465 When immunizations are needed the immunization recommendation in the response should include at least one suggested list of encounters in which immunizations will be provided. Each encounter will contain one or more proposed immunization activities describing the vaccine to be given.

### **X.7.3 Notification of Document Availability (NAV)**

470 A Document Source may provide the capability to issue a Send Notification Transaction per the ITI Notification of Document Availability (NAV) Integration Profile in order to notify one or more Document Consumer(s) of the availability of one or more documents for retrieval. One of the Acknowledgement Request options may be used to request from a Document Consumer that an acknowledgement should be returned when it has received and processed the notification. A Document Consumer should provide the capability to receive a Receive Notification Transaction per the NAV Integration Profile in order to be notified by Document Sources of the availability of one or more documents for retrieval. The Send Acknowledgement option may be used to issue a Send Acknowledgement to a Document Source that the notification was received and processed.

### **X.7.4 Document Digital Signature (DSG)**

480 When a Content Creator Actor needs to digitally sign a document in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source. When a Content Consumer Actor needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

# Volume II

## 3.1 IHE Format Codes

490 *Add the following rows the PCC TF-2:3.1 IHE Format Codes*

Profile	Format Code	Media Type	Template ID
<b>2009 Profiles</b>			
Immunization Content (IC)	urn:ihe:pcc:ic:2009	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2

*Add the following section to the end of PCC TF-2:4.3 CDA Document Content Modules*

### 6.1.1.Y Immunization Content Specification 1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2

495 The immunization content module specifies the information that can appear within a clinical document or message to convey information about immunizations. When used within a clinical document, this specification has the usual requirements. When used within a message, the encoded clinical data must be present, but the sections need not be. Systems accessing this content through a message must be able to process these messages regardless of whether the sections are present.

500 Appendix F Transforming CDA Documents to Care Record Messages found in the Request for Clinical Guide Profile Supplement<sup>5</sup> describes the model by which the document created using this content module can be transformed to the Care Record message used in the Request for Clinical Guidance transaction.

#### 505 6.1.1.Y.1 LOINC Code

The LOINC code for this document is **11369-6 HISTORY OF IMMUNIZATIONS**

#### 6.1.1.Y.2 Standards



[HL7 CDA Release 2.0](#)



[ASTM/HL7 Continuity of Care Document](#)

<sup>5</sup> See [http://www.ihe.net/Technical\\_Framework/index.cfm#pcc](http://www.ihe.net/Technical_Framework/index.cfm#pcc) for the material contained within the Request for Clinical Guidance Supplement to the PCC Technical Framework.

**6.1.1.Y.4 Specification**

Data Element Name	Opt	Template ID	Vol 2
Immunizations	R	1.3.6.1.4.1.19376.1.5.3.1.3.23	PCC TF-2:6.3.3.3.5
Active Problems	R2	1.3.6.1.4.1.19376.1.5.3.1.3.6	PCC TF-2:6.3.3.2.3
History of Past Illness	R2	1.3.6.1.4.1.19376.1.5.3.1.3.8	PCC TF-2:6.3.3.2.5
Allergies and Other Adverse Reactions	R2	1.3.6.1.4.1.19376.1.5.3.1.3.13	PCC TF-2:6.3.3.2.11
Medications	R2	1.3.6.1.4.1.19376.1.5.3.1.3.19	PCC TF-2:6.3.3.3.1
Coded Results	R2	1.3.6.1.4.1.19376.1.5.3.1.3.28	PCC TF-2:6.3.3.5.2
Coded Vital Signs	R2	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2	PCC TF-2:6.3.3.4.5
Pregnancy History When present, the pregnancy history section shall contain a Pregnancy Observation using the 11449-6 PREGNANCY STATUS code from LOINC to indicate whether the patient is pregnant.	R2	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4	PCC TF-2:6.3.3.2.18
Coded Advance Directives	R2	1.3.6.1.4.1.19376.1.5.3.1.3.35	PCC TF-2:6.3.3.6.6
Simple Observation The gestational age at birth of the patient may be recorded using the IHE Simple Observation template with a code identifying this observation as the gestational age of the patient at birth. One such code supporting that interpretation from SNOMED CT is 268477000 fetal gestation at delivery <sup>6</sup> . This observation may appear in any relevant section <sup>7</sup> .	R2	1.3.6.1.4.1.19376.1.5.3.1.4.13	PCC TF-2:6.3.4.20
Immunization Recommendations The section may be present to document the schedule of vaccinations that are intended or proposed for the patient. When present the section shall include Immunization entries in intent or proposal mood describing the immunization plan. The section may include a reference to one or more specific guidelines in definition mood to indicate the guidelines being used.	C (see note 1)	1.3.6.1.4.1.19376.1.5.3.1.1.18.3.1	PCC CDA Supplement 2:6.3.3.6.13

510

Note 1: This section is conditionally required based upon the use of the content. When the content module appears within a clinical document is required if known. When used in a clinical decision support message it is required.

<sup>6</sup> This code used the preferred term “fetal gestation at delivery” and is a “neonate observable” which makes it more appropriate for a newborn than the “length of gestation at birth” which is a “measure of fetus”.

<sup>7</sup> For infants born prematurely that this may appear within the problem list section, but after a certain age, it might be considered history and so appear elsewhere (e.g. history of past illness).

#### **6.1.1.Y.5 Conformance**

515 CDA Release 2.0 documents that conform to the requirements of this content module shall indicate their conformance by the inclusion of the appropriate **<templateId>** elements in the header of the document. Please note that when instantiated as a document this content module must also conform to the IHE Medical Document specification found in PCC TF-2:6.1.1.1.

This is shown in the sample document below.

```

520 <ClinicalDocument xmlns='urn:hl7-org:v3'>
    <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1' />
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2' />
    <id root=' ' extension=' ' />
525 <code code='11369-6' displayName='HISTORY OF IMMUNIZATIONS'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
    <title>Immunization Detail</title>
    <effectiveTime value='20080724012005' />
    <confidentialityCode code='N' displayName='Normal'
530     codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
    <languageCode code='en-US' />
    :
    <component><structuredBody>
        <component><section>
535         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.23' />
         <!-- Required History of Immunizations Section content -->
        </section></component>
        <component><section>
540         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.6' />
         <!-- Required if known Problem List Section content -->
        </section></component>
        <component><section>
545         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.8' />
         <!-- Required if known History of Past Illness Section content -->
        </section></component>
        <component><section>
550         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13' />
         <!-- Required if known Allergies and Intolerances Section content -->
        </section></component>
        <component><section>
555         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19' />
         <!-- Required if known Medications Section content -->
        </section></component>
        <component><section>
560         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />
         <!-- Required if known Lab Results Section content -->
        </section></component>
        <component><section>
565         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2' />
         <!-- Required if known Coded Vital Signs Section content -->
        </section></component>
        <component><section>
570         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4' />
         <!-- Required if known Pregnancy History Section content -->
        </section></component>
        <component><section>
575         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.35' />
         <!-- Required if known Coded Advance Directives Section content -->
        </section></component>
        <component><section>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.18.3.1' />
         <!-- Conditional Immunization Recommendations Section content -->
        </section></component>
    </structuredBody>
    </component>
</ClinicalDocument>

```

**Figure 6.1.1.Y-1 Sample Immunization Content Document**

*Update the Immunization Entry in PCC TF-2:6.1.4.17.12 to use the Product Entry directly, instead of through reference to consumable under medications.*

**6.1.4.17.12 <consumable typeCode='CSM'>**

- 580 The <consumable> element shall be present, and shall contain a <manufacturedProduct> entry conforming to the Product Entry template found in PCC TF-2:6.14.19.

*Add the following to after section 6.4.4.17.21*

585 **6.4.4.17.22 <entryRelationship inversionInd='false' typeCode='COMP'>**

This repeatable element shall be used if needed to record the antigen doses applicable to an immunization. It shall contain an Antigen Dose entry (templateId 1.3.6.1.4.1.19376.1.5.3.1.4.12.1).