Integrating the Healthcare Enterprise

5

IHE Patient Care Coordination (PCC) Technical Framework Supplement

Immunization Content (IC)

10

Trial Implementation

15

20   Date: September 9, 2011

Author: IHE PCC Technical Committee

Email: pcc@ihe.net

Foreword

25 This is a supplement to the IHE Patient Care Coordination Technical Framework V7.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is submitted for Trial Implementation as of September 9, 2011 and will be available for testing at subsequent IHE Connectathons. The supplement may be amended based
30 on the results of testing. Following successful testing it will be incorporated into the PCC Technical Framework. Comments are invited and can be submitted at http://www.ihe.net/pcc/pcccomments.cfm or by email to pcc@ihe.net.

This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as
35 addition of large new sections introduced by editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume:

40 | *Replace Section X.X by the following:* |
| --- |

General information about IHE can be found at: www.ihe.net

Information about the IHE QRPH domain can be found at: http://www.ihe.net/Domains/index.cfm

45 Information about the structure of IHE Technical Frameworks and Supplements can be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current version of the IHE Technical Framework can be found at: http://www.ihe.net/Technical_Framework/index.cfm

50 **CONTENTS**

Introduction

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](#)

This supplement also references other documents[1]. 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.](#)
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.

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?

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

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

---

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

the service call needs to be examined carefully to see if there are any other standard vocabulary items that might need new codes.

120   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 observation needs a code (LOINC?).

125   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.

130 Abstract

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

- **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

135   others wishing to exchange immunization data electronically in a standard format.

- **Immunization Care Plan (ICP) –** The Immunization Care Plan expands upon the Immunization Content profile to supports the exchange of immunization plans and recommendations between HIT systems and immunization decision support systems.

Glossary

140 | *Add the following terms to the Glossary*

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[2].

145 **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.[3]

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 150 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.

155 **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).

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. 160 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[4].

Immunization Recommendation –A set of proposed immunizations to be given to a patient, 165 including the dates to give them. The recommendation may be general, or it may be focused on

---

[2] 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

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

[4] 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

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).

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 170   sponsored by a Public Health Department or Ministry.

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 175   vaccine, and one that is substantially longer than the 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.

180   **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.

Invalid Dose – See Ineffective Dose.

185   **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 weigh them against the benefits of the vaccine before deciding whether or not to proceed with the immunization.

190   **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 1 preceding the Appendices and Glossary*

X The Immunization Content Profile (IC)

195 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 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

200 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 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.

205 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 other information related to the patient's care. For example, it includes medical history, medications, allergies, vital signs, and so forth.

210

X.1 Use Cases

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

215
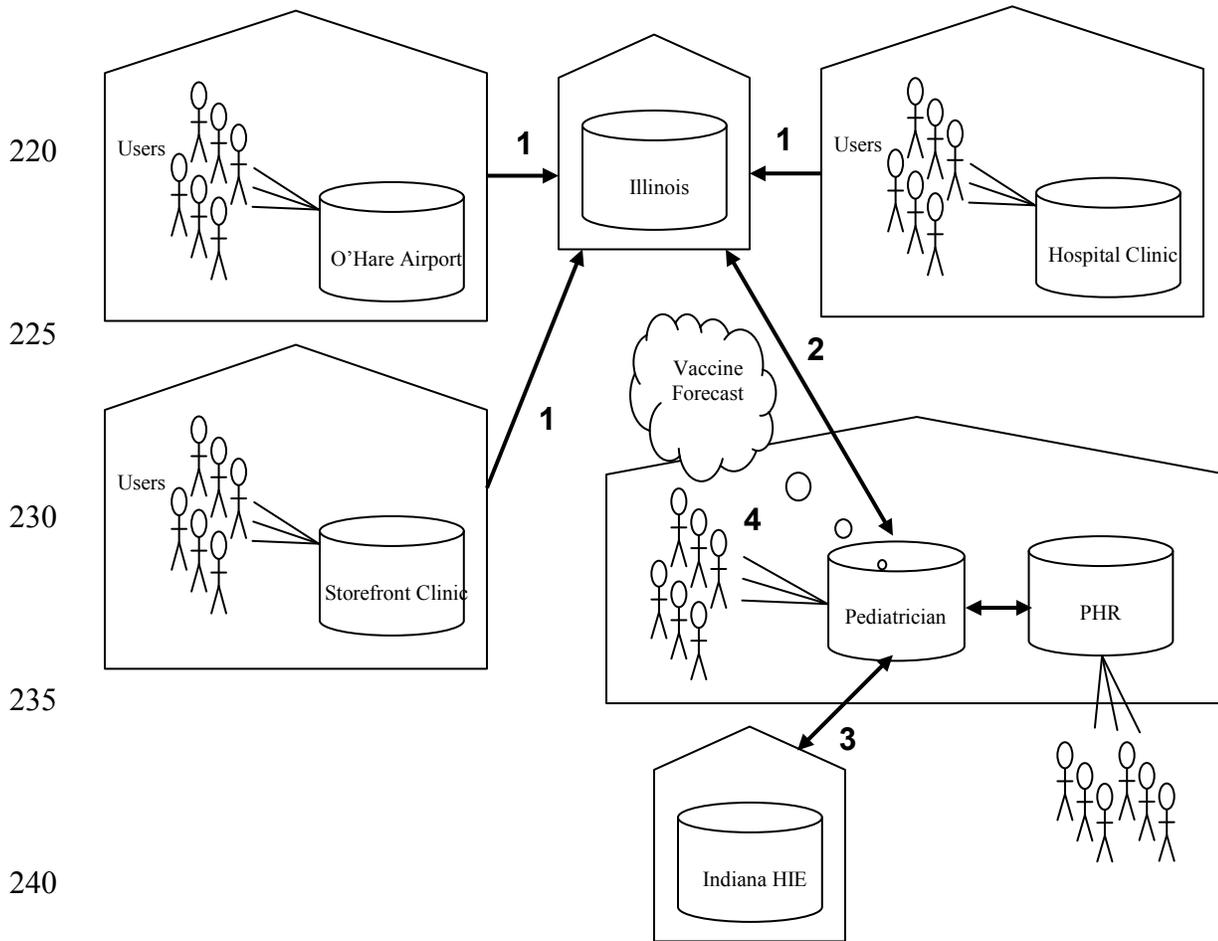
X.1.1 Use Case 1: Immunization Information System Participation

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.

10

X.1.2 Use Case 2: Immunization Yellow Card

250

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 supplement its records with immunizations that the patient may have received from other providers, it queries the

255 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

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

260 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 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

265 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

270 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 payload in Immunization Content format. The pediatrician's EMR system submits the patients Care Provision data that it has previously

275 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

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

280 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 the Content Consumer Actor. The sharing or transmission of content or updates from one actor to the other is addressed by the use of

285 appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR.

11

Figure X.2-1. Immunization Content Actor Diagram

X.3 Options

290

Table X.3-1. Immunization Content Options

Actor	Option	Location in Vol 2
Content Consumer	View Option (Note 1)	PCC TF-2:3.1.1
	Document Import Option (Note 1)	PCC TF-2:3.1.2
	Section Import Option (Note 1)	PCC TF-2:3.1.3
	Discrete Data Import Option (Note 1)	PCC TF-2:3.1.4

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

X.3.1 View Option

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-2:3.1.1 for more details on this option.

295

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.

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

300 X.3.2 Document Import Option

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-2:3.1.2 for more details on this option.

X.3.3 Section Import Option

305 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-2:3.1.3 for more details on this option.

X.3.4 Discrete Data Import Option

310   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-2:3.1.4 for more details on this option.

X.4 Coded Terminologies

315   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.

To facilitate this level of interoperability, the applications that implement actors within this
320   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
325   entry that are supported.

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

330   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
335   Manager and Decision Support Actors of the Request for Clinical Guidance Profile.

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.

340   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.

345
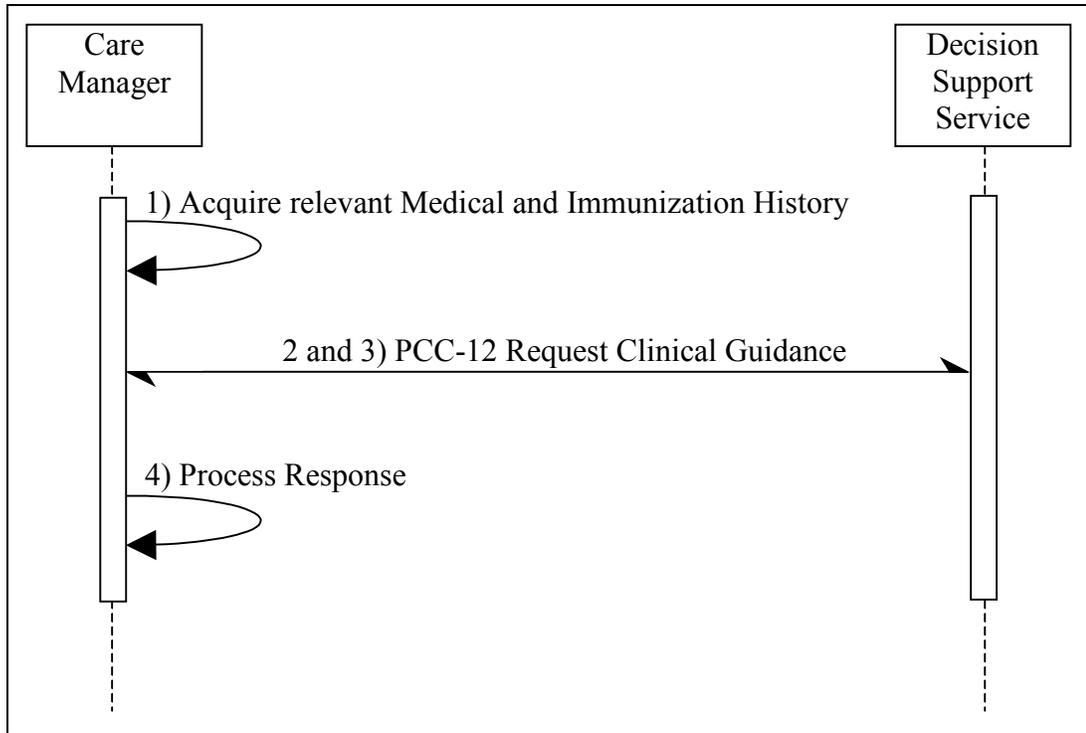
Figure X.5-1. Process Flow for Clinical Decision Support

X.6 Immunization Content Module

350 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-2:6.3.1.Y.

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

14

_____

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.

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 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

_____

15

data elements described in Table X.6-1 above. Note also that some of this information may not be available (or provided) to the generating application.

370 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, when the document is used as immunization record necessary to for enrollment in a school, the content creator actor needs to

375 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 specification of a proposed immunization. This is a proposal for treatment of a patient that can be reviewed by a

380 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 for other uses (e.g., reminder/recall notices). The section template is described in more detail in section 6.1.3.6.Q Immunization Recommendation.

385 The immunization recommendation entry details with the machine readable content and is described further in section 6.1.4.Q   Immunization Recommendation Entry.

The clinical statements about immunizations can be augmented with additional clinical statements to provide more detail on the immunization dosing. Immunization dosing can become complex due to the use of combination vaccines. Combination vaccines provide

390 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. 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

395 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 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

400 medication interactions). Alerts are described in more detail in PCC TF-2:6.1.4.R.

X.7 Grouping

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

Actors from the ITI XDS, XDM and XDR profiles embody the Content Creator and Content

405 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

---

16

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.

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

X.7.2 Request for Clinical Guidance

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).

Appendix F Transforming CDA Documents to Care Record Messages found in the Request for Clinical Guidance 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.

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.

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

440 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.

When immunizations are needed the immunization recommendation in the response should
445 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)

A Document Source may provide the capability to issue a Send Notification Transaction per the
450 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
455 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)

460 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.

465

Volume 2

5.1 IHE Format Codes

Add the following rows the PCC TF-2:5.1 IHE Format Codes

Profile	Format Code	Media Type	Template ID
2009 Profiles			
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

470

Add the following section to the end of PCC TF-2:6.3.1 CDA Document Content Modules

6.3.1.Y Immunization Content Specification1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2

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.

Appendix F Transforming CDA Documents to Care Record Messages found in the Request for Clinical Guide Profile Supplement[5] 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.

6.3.1.Y.1 LOINC Code

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

6.3.1.Y.2 Standards

CDAR2	[HL7 CDA Release 2.0](#)
CCD	[ASTM/HL7 Continuity of Care Document](#)

---

[5] See 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.

6.3.1.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
Authors and Informants	R	NONE	PCC TF-2:6.3.4.1
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
Comments	R2	1.3.6.1.4.1.19376.1.5.3.1.4.2	PCC TF-2:6.3.4.6
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[6]. This observation may appear in any relevant section[7].	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

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.

---

[6] 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".

[7] 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).

6.3.1.Y.5 Conformance

490   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.

```
495  <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=' '/>
500    <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'
505      codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
       <languageCode code='en-US'/>
       <author>
         <!-- Required Authors and Informants Section content -->
       </author>
510       :
       <component><structuredBody>
         <component><section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.23'/>
            <!-- Required History of Immunizations Section content -->
515      </section></component>
       <component><section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2'/>
            <!-- Required if known Comments Section content -->
         </section></component>
520      <component><section>
            <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>
525         <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>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13'/>
530         <!-- Required if known Allergies and Intolerances Section content -->
         </section></component>
         <component><section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
            <!-- Required if known Medications Section content -->
535      </section></component>
         <component><section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
            <!-- Required if known Lab Results Section content -->
         </section></component>
540      <component><section>
            <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>
545         <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>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.35'/>
550         <!-- 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 -->
555      </section></component>
       </strucuredBody>
       </component>
     </ClinicalDocument>
```

Figure 6.3.1.Y.5-1. Sample Immunization Content Document

_____

560 *Update the Immunization Entry in PCC TF-2:6.3.4.17.12 to use the Product Entry directly, instead of through reference to consumable under medications.*

6.3.4.17.12 <consumable typeCode='CSM'>

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

Add the following to after section 6.3.4.17.21

6.3.4.17.22 <entryRelationship inversionInd='false' typeCode='COMP'>

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

_____