Integrating the Healthcare Enterprise

IHE Quality, Research, and Public Health Technical Framework Supplement

Family Planning Version 2 (FPv2)

Rev. 1.1 – Trial Implementation

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Quality, Research and Public Health (QRPH) Technical Framework. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on August 18, 2017 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the QRPH Technical Framework. Comments are invited and may be submitted at http://www.ihe.net/QRPH_Public_Comments.

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

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

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/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://www.ihe.net/IHE_Process and http://www.ihe.net/Profiles.

The current version of the IHE QRPH Technical Framework can be found at http://www.ihe.net/Technical_Frameworks.

CONTENTS

Introduction to this Supplement

This supplement is written for trial implementation. It is written as an addition to the Quality, Research and Public Health Technical Framework.

This supplement also references and draws upon the following documents. The reader should review these documents as needed:

1. IT Infrastructure Technical Framework, especially in reference to Retrieve Form for Data Capture (RFD).
2. Gavin L, Moskosky S, Carter M, Curtis K, Glass E, Godfrey E, Marcell A, Mautone-Smith N, Pazol K, Tepper N, Zapata L. Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR Recomm Rep. 2014 Apr 25;63(RR-04):1-54. PMID: 24759690.
3. American College of Obstetricians and Gynecologists. Guidelines for Women's Health Care: A Resource Manual. Washington, DC: American College of Obstetricians and Gynecologists; 2007.
4. Bellanca HK, Hunter MS. ONE KEY QUESTION®: preventive reproductive health is part of high quality primary care. Contraception. 2013 Jul;88(1):3-6. PubMed PMID: 23773527.
5. Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC). U.S. Selected Practice Recommendations for Contraceptive Use, 2013: adapted from the World Health Organization selected practice recommendations for contraceptive use, 2nd edition. MMWR Recomm Rep. 2013 Jun 21;62(RR-05):1–60. PMID: 23784109
6. Institute of Medicine (U.S.). Clinical preventive services for women: closing the gaps. Washington, D.C.: National Academies Press; 2011.
7. Johnson K, Posner SF, Biermann J, Cordero JF, Atrash HK, Parker CS, Boulet S, Curtis MG, CDC/ATSDR Preconception Care Work Group, Select Panel on Preconception Care. Recommendations to improve preconception health and health care--United States. A report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. MMWR Recomm Rep. 2006 Apr 21;55(RR-6):1–23. PMID: 16617292.
8. World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health Center for Communication Programs (CCP), Knowledge for Health Project. Family Planning: A Global Handbook for Providers (2011 update). Baltimore and Geneva: CCP and WHO, 2011.

Contraception is a major preventive health service that is not fully integrated nor consistently captured within many electronic medical record (EMR) systems. Pregnancy intention and contraceptive method are essential health indicators for women and men and for primary and specialty care clinicians, healthcare administrators, academic researchers, non-profit advocacy organizations, and local, jurisdictional, and federal public health authorities. A variety of gaps currently exist in the healthcare setting if pregnancy intention and contraceptive method fields do not exist in the EMR system and are not explicitly addressed in the clinical setting or captured for practice- and clinician-level performance metrics. The absence of standardized data capture, reporting, monitoring, and evaluation of family planning services to public health authorities is often a burden to already stretched practices with multiple, diverse reporting obligations. This lack of integration requires substantial backend work to extract and export meaningful data. Additionally, many data elements important to family planning providers are critical to other clinical domains (e.g., blood pressure) while others are currently used primarily in family planning settings (e.g., client's pregnancy intention), and need to be better captured in primary care to improve preconception health screenings. Standardized capture and recording of these variables across multiple clinical settings and diverse medical record documentation would facilitate more efficient reporting and adherence to clinical guidelines.

Clear specification on data elements, aligned with industry, clinical, US and international standards, is an important goal for advancement of high-quality health information technology. Contraceptive prevalence, chlamydia screening, unmet need for family planning rates are examples of measures used for national statistics that would contribute to health service delivery assessment at local or institutional levels if data were available in electronic health records. The usefulness of these kinds of measures is dependent on the existence of quality data. Pregnancy intention and contraceptive use data are currently sporadically collected, if at all, especially among male clients. It is not possible to collect this data adequately through the use of billing or diagnostic codes because not all methods are dispensed or prescribed (e.g., abstinence or withdrawal). Further, it is not possible to collect visit-level data with these codes because a method may be dispensed at one visit and still be in use at a subsequent visit but would not require entry of such codes at the later visit. The only way to address these challenges in data collection is through standardized clinical decision support and data capture.

The Family Planning (FP) Profile describes the content and format to be used within the pre-population data part of the Retrieve Form Request transaction from the RFD Profile (see ITI TF-1: 17). It is expected that the Form Filler and Form Manager will implement transactions as specified in the RFD Profile, and this profile does not include any additional constraints or extensions.

Open Issues and Questions

1. Is the “Unavailable/Unknown” payer in the PHIN VADS PHSDC Source of Payment Typology used to indicate a lack of insurance or to indicate that insurance status is unknown? How are Medicaid SPA and waivers categorized in this typology?

2. Do the 5 lab results listed adequately reflect the most important results that should be captured? Should some of these be optional?
3. There are many codes and OIDS in the profile that are currently being obtained from LOINC and SNOMED-CT, with placeholders used in the meantime. CPs will be required to update these placeholders with real values when they become available.

Closed Issues

None

General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A – Actor Summary Definitions

No new actors.

Appendix B – Transaction Summary Definitions

No new transactions.

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

Glossary Term	Definition
Pregnancy Intention	A client's plan or desire to either become pregnant or have a child in the near future or to prevent a future pregnancy. It is also important to know if a woman intends to conceive in the near future so that she can be counseled about improving her health before pregnancy, taking folic acid and avoiding toxic exposures such as alcohol, tobacco and certain medications. This variable is important because a client's desire for a future pregnancy has bearing on which contraceptive method a provider should be providing counseling on, given that some methods are long-acting or permanent. Sample questions and response options might include: - Would you like to become pregnant in the next year? Yes/No/Unsure/Okay either way. (One Key Question Initiative®) - Which best describes your plans or desire to have a child? 1. I do not want to have a child, 2. I do want to have a child in the next year, 3. I do want to have a child in 1-2 years, 4. I do want to have a child in 3 or more years, 5. I am unsure about whether I want to have a child. - Which of the following best describe your current situation? 1. Trying to get pregnant, 2. Wouldn't mind getting pregnant, 3. Wouldn't mind avoiding pregnancy, 4. Trying to avoid pregnancy, 5. Don't know (Prospective London Measurement of Unplanned Pregnancy (pLMUP))
Language Proficiency	Family planning users who do not speak the national dominant language as their primary language and who have a limited ability to read, write, speak or understand the dominant language and therefore require language assistance services (interpretation or translation) in order to optimize their use of health services. Include users who receive services from multilingual staff in the user's preferred language, are assisted by a competent agency or contracted interpreter, or who opt to use a family member or friend as an interpreter after refusing the provider's offer of free language assistance services. Do not include users who are visually or hearing impaired or have other disabilities unless they also have a need for language assistance service.

Glossary Term	Definition
Tiers of effective contraception	Three tiers of effectiveness for available contraceptive methods have been established based upon efficacy of use and typical failure rates, per USAID and WHO recommendations. The tier 1 methods (such as the intrauterine device, implants, and sterilization) are rated the most highly effective because they are long-acting and independent from coitus, user motivation, or adherence and therefore have failure of rates of <1%. The lower tier methods are more highly dependent upon correct and consistent usage at every coital episode and thus susceptible to user failure with rates greater than 9%. Data elements that present contraceptive options should be ordered by these tiers. See: Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. Contraceptive Technology: Twentieth Revised Edition. New York NY: Ardent Media, 2011.

Volume 1 – Profiles

Copyright Licenses

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

There are no new copyright additions.

Add Section X.

X Family Planning version 2 (FPv2) Profile

The Family Planning version 2 (FPv2) Profile provides a means to capture information needed for mandated reporting, monitoring and evaluation, and quality improvement initiatives related to family planning service delivery. This profile builds on the earlier Family Planning Profile and uses several different mechanisms for capturing and communicating that information, including CDA®[1] documents and the actors and transactions defined in the ITI Retrieve Form for Data Capture (RFD) Profile to capture structured data using digital forms.

FPv2 defines a specialized Family Planning version 2 (FPv2) CDA document, which can be submitted directly to a Content Consumer, or used to prepopulate an electronic form for submission. FPv2 also supports prepopulation of the form using a more general Continuity of Care document (CCD®[2]). Use of the FPv2 CDA document will optimize the prepopulation of the form and minimize the need for manual data entry.

X.1 FPv2 Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://ihe.net/Technical_Frameworks.

The FPv2 Profile defines two ways to exchange the data required for a Family Planning encounter report. First, creation of an FPv2 CDA document is supported, either directly from a Content Creator, or through transformation of forms data into CDA format. The other method is through the forms based collection of data supported through the RFD transactions and pre-population mechanisms to supplement human data entry. Using the FPv2 document for pre-population maximizes the number of data elements that can be pre-populated (ideally, all) to minimize the amount of human data entry required.

[1] CDA is the registered trademark of Health Level Seven International.

[2] CCD is the registered trademark of Health Level Seven International.

Figure X.1-1 shows the actors directly involved and their relevant transactions between them.

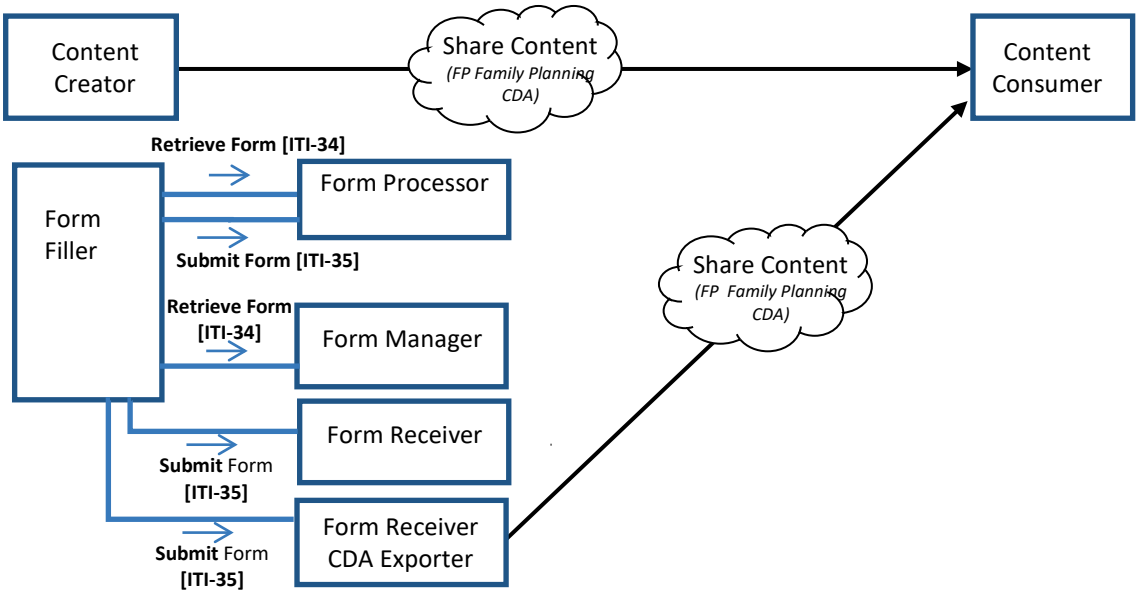


Figure X.1-1: FPv2 Actor Diagram

Note: Examples of a Form Filler include an EMR system into which clinical site staff enters information. The Form Manager would include an information system that provides displayable forms. The Form Receiver may be an information system that accepts and re-packages the FP form data for subsequent distribution to an integrated health system or an intermediary information system entity that provides aggregate reports to Public Health authorities. A Form Processor would be capable of performing the actions of the Form Manager and the Form Receiver.

Table X.1-1 lists the transactions for each actor directly involved in the FPv2 Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table X.1-1: FPv2 Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Form Filler	Retrieve Form [ITI-34]	R	ITI TF-2b: 3.34
	Submit Form [ITI-35]	R	ITI TF-2b: 3.35
Form Manager	Retrieve Form [ITI-34]	R	ITI TF-2b: 3.34
Form Receiver	Submit Form [ITI-35]	R	ITI TF-2b: 3.35
Form Processor	Retrieve Form [ITI-34]	R	ITI TF-2b: 3.34
	Submit Form [ITI-35]	R	ITI TF-2b: 3.35
Form Receiver CDA Exporter	Submit Form [ITI-35]	R	ITI TF-2b: 3:35
Content Creator	N/A	N/A	N/A

Actors	Transactions	Optionality	Reference
Content Consumer	N/A	N/A	N/A

Table X.1-2 lists the content module(s) defined in the FP Profile. To claim support with this profile, an actor shall support all required content modules (labeled "R") and may support optional content modules (labeled "O").

Table X.1-2: FPv2 - Actors and Content Modules

Actors	Content Modules	Optionality	Reference
Form Receiver CDA Exporter	Family Planning version 2 Document (1.3.6.1.4.1.19376.1.7.3.1.1.27.1)	R	QRPH TF-3:6.3.1.D1
Form Processor	Family Planning version 2 Document (1.3.6.1.4.1.19376.1.7.3.1.1.27.1)	R	QRPH TF-3: 6.3.1.D1
Content Creator	Family Planning version 2 Document (1.3.6.1.4.1.19376.1.7.3.1.1.27.1)	R	QRPH TF-3: 6.3.1.D1
Content Consumer	Family Planning version 2 Document (1.3.6.1.4.1.19376.1.7.3.1.1.27.1)	R	QRPH TF-3: 6.3.1.D1

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

X.1.1.1 Form Filler

The Form Filler is defined in the ITI RFD Profile and SHALL support the requirements defined in that profile, with the following qualifications:

The Form Filler SHALL support the XHTML Option for the Retrieve Form transaction [ITI-34] and the Submit Form transaction [ITI-35].

The Form Filler MAY support the Pre-pop Option with the Retrieve Form [ITI-34] transaction by supplying any of the following summary documents:

- IHE PCC MS Referral Summary (1.3.6.1.4.1.19376.1.5.3.1.1.3),
- IHE PCC Discharge Summary (1.3.6.1.4.1.19376.1.5.3.1.1.4),
- IHE PCC XPHR (1.3.6.1.4.1.19376.1.5.3.1.1.5),
- HL7®[3] Continuity of Care Document (CCD) (2.16.840.1.113883.10.20.1.22)

[3] HL7 is the registered trademark of Health Level Seven International.

In order to support the need to save a form for editing at a later time, the Form Filler SHALL be able to submit a form for the same patient multiple times, using a form instance id provided by the Form Manager to identify the appropriate form.

X.1.1.2 Form Manager

The Form Manager is defined in the ITI RFD Profile and SHALL support the requirements defined in that profile, with the following qualifications:

The Form Manager SHALL support the XHTML Option for the Retrieve Form transaction [ITI-34].

The system fulfilling this role SHALL accept pre-pop data in the form of content defined by any of the following summary documents:

- IHE PCC MS Referral Summary (1.3.6.1.4.1.19376.1.5.3.1.1.3),
- IHE PCC Discharge Summary (1.3.6.1.4.1.19376.1.5.3.1.1.4),
- IHE PCC XPHR (1.3.6.1.4.1.19376.1.5.3.1.1.5),
- HL7 Continuity of Care Document (CCD) (2.16.840.1.113883.10.20.1.22)

and return a form that has been appropriately pre-populated based on the mapping rules specified in this document in QRPH TF-3: 3 6.3.1.D1.4 Data Element Requirement Mappings for Form Pre-Population. The Form Manager shall support ALL of these pre-pop documents.

The Form Manager SHALL supply a form instance id along with the form in response to a request. If the Form Filler retrieves a previously populated form using this instance id, the Form Manager shall supply the previously populated content.

X.1.1.3 Form Receiver

The Form Receiver is defined in the ITI RFD Profile and SHALL support the requirements defined in that profile with the following qualifications:

The Form Manger SHALL support XHTML Option for the Submit Form transaction [ITI-35].

No further requirements are placed on the Form Receiver within the scope of this profile.

X.1.1.4 Form Processor

The Form Processor is defined in the ITI RFD Profile and SHALL support the requirements defined in that profile with the following qualifications:

The Form Filler SHALL support the XHTML Option for the Retrieve Form transaction [ITI-34] and the Submit Form transaction [ITI-35].

The system fulfilling this role SHALL accept pre-pop data in the form of content defined by any of the following summary documents:

- IHE PCC XDS-MS Referral Summary (1.3.6.1.4.1.19376.1.5.3.1.1.3),
- IHE PCC Discharge Summary (1.3.6.1.4.1.19376.1.5.3.1.1.4),
- IHE PCC XPHR (1.3.6.1.4.1.19376.1.5.3.1.1.5),
- HL7 Continuity of Care Document (CCD) (2.16.840.1.113883.10.20.1.22)
- and return a form that has been appropriately pre-populated based on the mapping rules specified in this document (QRPH TF-3: 6.3.1.D1.4 Data Element Requirement Mappings for Form Pre-Population).

To facilitate completion of partially saved form data, the Form Processor SHALL support the ability to return previously submitted form data and metadata using a provided form instance id, and return the form containing previously submitted data.

X.1.1.5 Content Creator

The Content Creator SHALL be able to create a valid CDA document which conforms to the Family Planning version 2 Document template (1.3.6.1.4.1.19376.1.7.3.1.1.27.1). This document is defined in QRPH TF-3:6.3.1.D1.

X.1.1.6 Content Consumer

The Content Consumer SHALL implement the Discrete Data Import Option when consuming the Family Planning Document.

X.1.1.7 Form Receiver CDA Exporter

The Form Receiver CDA Exporter receives data submitted through the Submit Form [ITI-35] transaction, transforms that data to create a CDA document, and shares that CDA document with a Content Consumer. For FP, this transform produces a Family Planning version 2 Document (1.3.6.1.4.1.19376.1.7.3.1.1.27.1) as defined in QRPH TF-3: 6.3.1.D1. Specification of the transformation rules from the FP Form elements to the CDA content is defined in QRPH TF-3:6.3.1.D1.4.

X.2 FPv2 Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1.

Table X.2-1: FP - Actors and Options

Actor	Option Name	Reference
Form Filler	Summary Document Pre-pop	Section X.2.1
Form Manager	None	--
Form Receiver	None	--
Form Processor	None	--

Actor	Option Name	Reference
Form Receiver CDA Exporter		
Content Creator		
Content Consumer	Discrete Data Import	

X.2.1 Summary Document Pre-Pop Option

This option enables Form Fillers to provide medical summary pre-pop data to the Form Manager. Use of the pre-pop option is strongly encouraged. A Form Filler that supports the Summary Document Pre-Pop Option SHALL populate the value of the pre-pop Data parameter in the Retrieve Form Request (see ITI TF-2b: 3.34.4.1) with a well-formed xml document. The document SHALL be one of:

- IHE PCC XDS-MS Referral Summary (1.3.6.1.4.1.19376.1.5.3.1.1.3)
- IHE PCC XDS-MS Discharge Summary (1.3.6.1.4.1.19376.1.5.3.1.1.4)
- IHE PCC XPHR (1.3.6.1.4.1.19376.1.5.3.1.1.5)
- HL7 Continuity of Care Document (CCD) (2.16.840.1.113883.10.20.1.22)

If the Form Filler supports the Summary Document Pre-pop Option, the value of the pre-pop parameter SHALL be a well formed xml document as defined for the above document types.

X.3 FPv2 Required Actor Groupings

There are no required groupings with actors.

X.4 FPv2 Overview

Family Planning services provide individuals and couples with the information and means to exercise personal choice in determining the number, spacing, and timing of births, when desired, and access to means of pregnancy prevention when children are not desired. These services include contraceptive counseling and contraceptive methods to prevent pregnancy, pregnancy testing and counseling, preconception health counseling and services, basic infertility services to achieve pregnancy, sexually transmitted infection screening, diagnosis, and treatment, and related preventive health services. These services are designed to provide women and men with the highest standards of reproductive health care over the entire life course and, for women and couples who desire pregnancy, with the opportunity to have safe pregnancies, births, and healthy infants. *(World Health Organization, US DHHS Title X)*

Pregnancy intention and contraceptive method are also essential health indicators for health care providers and administrators, academic researchers, non-profit advocacy organizations, and governmental entities. Standardized capture and recording of these methods across multiple clinical settings and diverse medical record documentation would facilitate more efficient reporting and adherence to clinical guidelines. If a woman is not asked whether she wants to become pregnant in the next year, and her contraceptive needs are not addressed, she may leave

the visit with no method or one that does not fit her individual needs or circumstance. The clinician has missed an important clinical assessment of other health factors, and the client may return a short time later with an unintended pregnancy. Unintended pregnancies are at higher risk for poor health outcomes for both the mother and child. A different woman who desires pregnancy, but whose pregnancy intentions are not addressed, may not receive vital preconception information on smoking cessation, folic acid use, or STI (Sexually Transmitted Infection) screening. Men also may report to clinics seeking STI screening. This is an opportunity to conduct STI education, such as the risks *chlamydia trachomatis* (CT) poses to women to ensure future healthy pregnancies. Alternatively, men in whose reproductive intention is unaddressed, may have undiagnosed low fertility and counseling would raise the possibility of diagnostic assessment and intervention options.

Health centers are currently challenged to accurately capture and record family planning data. Costs of the current inefficiencies are difficult to estimate due to the range of systems in use and variability within clinic settings. The vast majority of healthcare facilities would incur a range of costs associated with designing and implementing documentation of family planning services in their EMR systems. Adding custom fields may cause problems whenever the health center upgrades to a new version of the software; these problems include additional time-consuming testing, functionality issues, the need to update reports, and the need to recreate the field and corresponding difficulties using historical data. Another solution deployed has been to create dummy codes for contraception that are not standard across a network of health care providers, requires additional staff training and time, and prevents this vital data from being stored in the EMR alongside relevant clinical information.

EMR systems may not provide a method to capture pregnancy intention as structured data, thus a clinician may not discuss or record the client's pregnancy plans or consider whether the contraceptive method aligns with the client's desires. Non-discrete data capture alsogenerates confusion and interrupts workflow for clinical providers, resulting in a time-consuming attempt to enter information or simply skipping the assessment or documentation of contraceptive needs of a client. Creating a standardized Family Planning Profile ensures that these important data are collected among reproductive-age clients in a systematic, structured, and more easily-extractable way. The ability to use EMR data to more accurately measure these variables enables better estimates of the benefits of family planning services, the cost of unplanned pregnancies, and assurance that compliant, high-quality services are delivered with accountability. Improving the quality of standard data capture in this content domain helps accomplish the goal of using health information technology infrastructure to accomplish quality improvement.

Transactions and content for aggregate reports are out of scope for this profile, but are illustrative of the potential uses and data requirements needed for reporting. Future developments of this specification will describe Form Receiver Options to transmit messages and medical summaries to an Information Recipient.

X.4.1 Concepts

The Family Planning version 2 (FPv2) Profile will define structured data capture in forms to facilitate interoperable exchange of information important for program reporting requirements, measurement of clinical quality, and monitoring and evaluation of family planning services.

Similar Public Health interoperability challenges have been addressed using the IHE IT Infrastructure (ITI) Retrieve Form for Data Capture (RFD) Profile when the solution to information needs of myriad stakeholders with diverse information systems infrastructure is a standards-based, content-specific mechanism for structured data capture. The RFD Profile can be used with a wide variety of EMRs currently in use. The form data would be gathered for every clinical encounter and thus unique to the patient–date event. Lab results, except for those that can be conducted in the clinic and HIV supplemental tests, are excluded. This form data can eventually contribute to important social, behavioral, and medication information to Medical Summaries and Continuity of Care Documents, using CDA constructs, delivered to patients and other providers. This IHE profile will support better alignment between EMRs and Public Health monitoring and evaluation programs by specifying the content and transactions to be used to capture and communicate Family Planning service and care data.

X.4.2 Use Cases

A client presents for a family planning visit. The clinician documents in the EMR the family planning services provided and basic screening tests required to deliver high-quality care. The EMR also manages the relevant client demographics supporting monitoring and evaluation (e.g., sex, age, ethnicity, race, payer). The clinic can also proactively triage and evaluate clinical performance metrics related to family planning services, (e.g., percentage of women of childbearing age in the patient panel receiving family planning services) if these data elements are incorporated into a reporting and performance measurement system that interoperates with clinics' EMRs. At the conclusion of the visit, the Family Planning information is filed electronically with the population affairs office.

X.4.2.1 Use Case #1: FP Manual Data Entry

X.4.2.1.1 Use Case Description

A client presents to a health center and receives services consistent with a family planning encounter but the health center has an EMR system that cannot create a Summary Document for pre-pop. Staff would select the FP form, it would display as if the form were native to the EMR system, and staff would manually enter all data elements.

X.4.2.1.2 Processing Steps

X.4.2.1.2.1 Pre-conditions

The Form Filler has no access to family planning data elements and other clinical and demographic data needed to populate and construct a Summary Document.

X.4.2.1.2.2 Main Flow

The Form Filler requests the family planning form.

The Form Manager provides the form, along with a form instance id.

The Form Filler presents the form for manual completion of the form.

The Form Filler submits the form.

The Form Receiver receives the submitted data.

X.4.2.1.2.3 Post-conditions

The data are made available to monitor data and clinical quality, and for evaluation purposes.

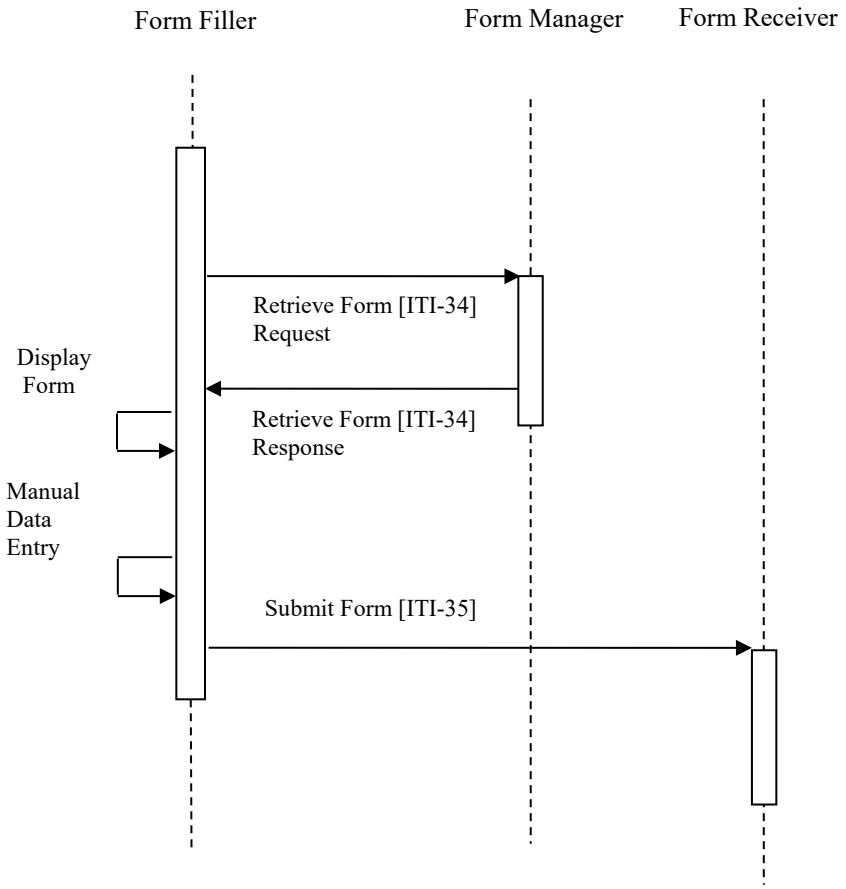


Figure X.4.2.1.2.3-1: Process Flow Diagram for Manual Data Entry

X.4.2.2 Use Case #2: FP with Pre-pop Option

X.4.2.2.1 Use Case Description

The provider EMR renders the Family Planning form providing a document from the pre-pop Family Planning document for Pre-population by the Form Manager. The provider completes the form, verifies the accuracy of all information, and submits the form.

X.4.2.2.2 Processing Steps

X.4.2.2.2.1 Pre-conditions

The Form Filler has the capability to produce a Family Planning Document. The Form Manager has the capability to return all data elements.

X.4.2.2.2.2 Main Flow

The Form Filler requests the Family Planning form and includes the Summary Document for Pre-pop in the request.

The Form Manager provides a partially completed form for the current visit with pre-populated data elements described in QRPH TF-3: 6.3.1.D1.4 along with a form instance id.

The user confirms that encounter data are correct as rendered by the Form Filler and adds any missing data.

The Form Filler submits the form.

The Form Receiver receives the submitted data.

X.4.2.2.2.3 Post-conditions

The data are made available for quality improvement measures.

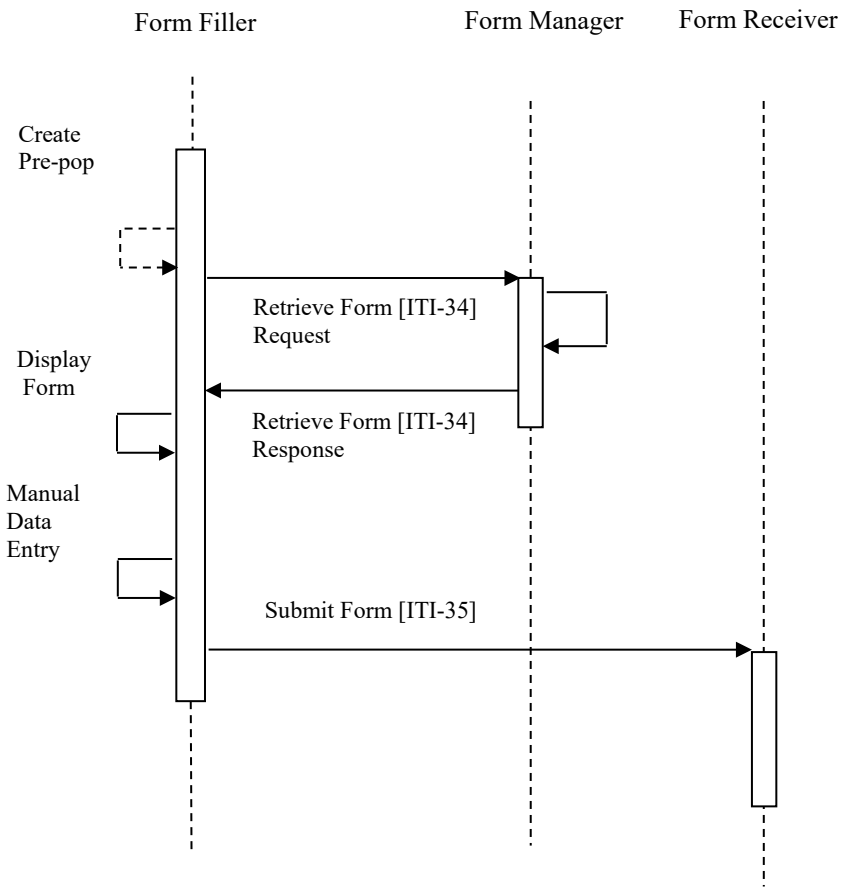


Figure X.4.2.2.2.3-1: Process Flow Diagram with Pre-pop Option

X.4.2.3 Use Case #3: FP with Pre-pop Option with Supplemental Data

X.4.2.3.1 Use Case Description

A family planning client has completed their Family Planning visit, but needs some lab tests performed. The provider EMR renders the Family Planning form providing a document from the Family Planning Pre-pop by the Form Processor with information completed from the visit at which the need for a referral was documented along with a form instance id. The provider verifies the accuracy of all information, adds information related to the referral process, and submits the form. When the lab results are received, the delivery site retrieves the form using the form instance id, adds the new information, and finally submits the form when completed.

X.4.2.3.2 Processing Steps

X.4.2.3.2.1 Pre-conditions

The Form Filler has the capability to produce a Family Planning version 2 document. The Form Processor has the capability to return all data elements.

X.4.2.3.2.2 Main Flow

The Form Filler requests the Family Planning form and includes the Summary Document for Pre-pop in the request.

The Form Processor provides a partially completed form for the current visit with pre-populated data elements described in QRPH TF-3: 6.3.1.D1 along with a form instance id.

The user confirms that encounter data are correct as rendered by the Form Filler and adds any known missing data.

The user expects new information based on supplemental testing results that are not yet available and saves the form.

Sometime later the user receives supplemental test results. The user retrieves the form using the form instance id, updates the form with the new data, and submits the completed form data.

The Form Filler submits the form.

The Form Processor receives the submitted data.

X.4.2.3.2.3 Post-conditions

The data are made available for quality improvement measures.

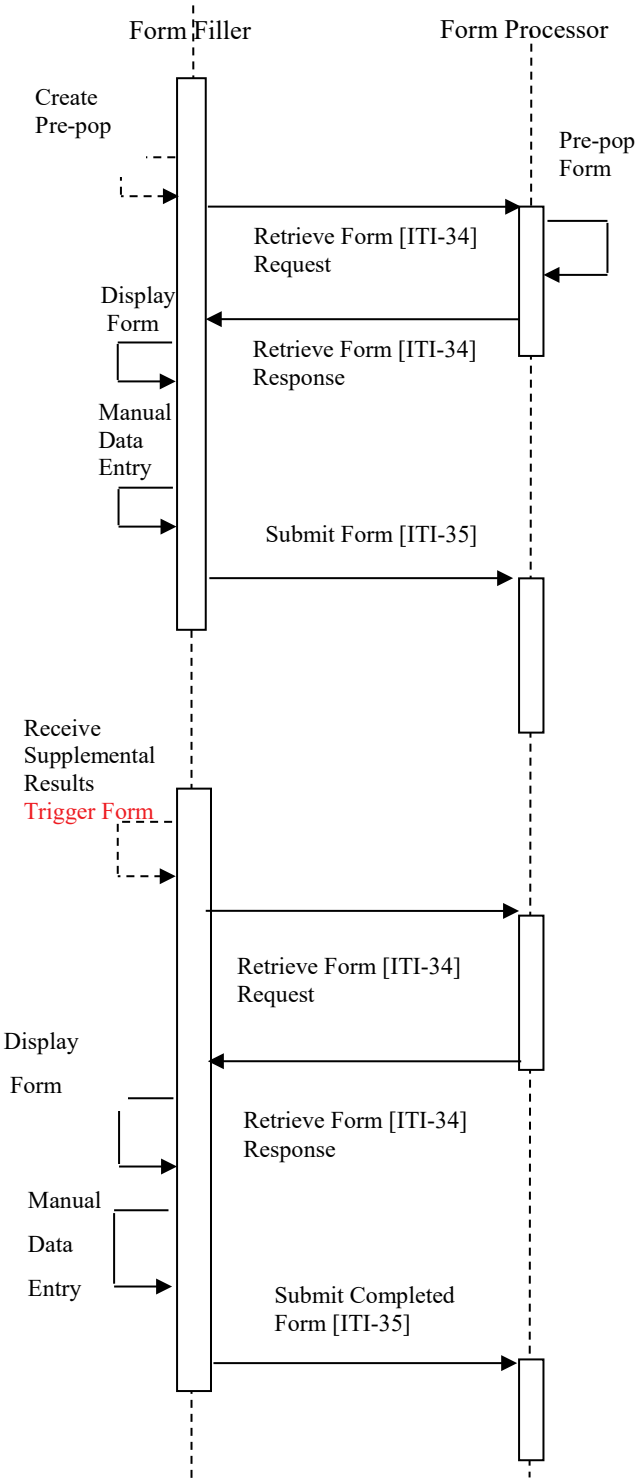


Figure X.4.2.3.2.3-1: Process Flow Diagram with Pre-pop Option

X.4.2.4 Use Case #4: Forms Data Capture with Document Submission

X.4.2.4.1 Use Case Description

When the Family Planning encounter has been documented in the system, a Summary Document is created with visit summary information. This summary document is provided as pre-population data to a public health IHE ITI Retrieve Form for Data Capture (RFD) Forms Manager. The provider EMR renders the Family Planning form. The provider verifies the accuracy of all information, adds information related to the referral process, and submits the form. The RFD Form Receiver provides the content to the population health unit by way of a transform to the corresponding Family Planning version 2 CDA Document.

X.4.2.4.2 Processing Steps

X.4.2.4.2.1 Pre-conditions

A Family Planning encounter has been documented in the EHR system.

X.4.2.4.2.2 Main Flow

The Form Filler requests the Family Planning form and includes the Family Planning Pre-pop in the request.

The Form Manager provides a partially completed form for the current visit with pre-populated data elements described in QRPH TF-3: 6.3.1.D1.4.

The user confirms that encounter data are correct as rendered by the Form Filler and adds any missing data.

The Form Filler submits the form.

The Form Receiver/CDA Exporter receives the submitted data.

The Form Receiver/CDA Exporter transforms the form into a Family Planning version 2 document and submits it to population health

X.4.2.4.2.3 Post-conditions

The data are made available for quality improvement measures.

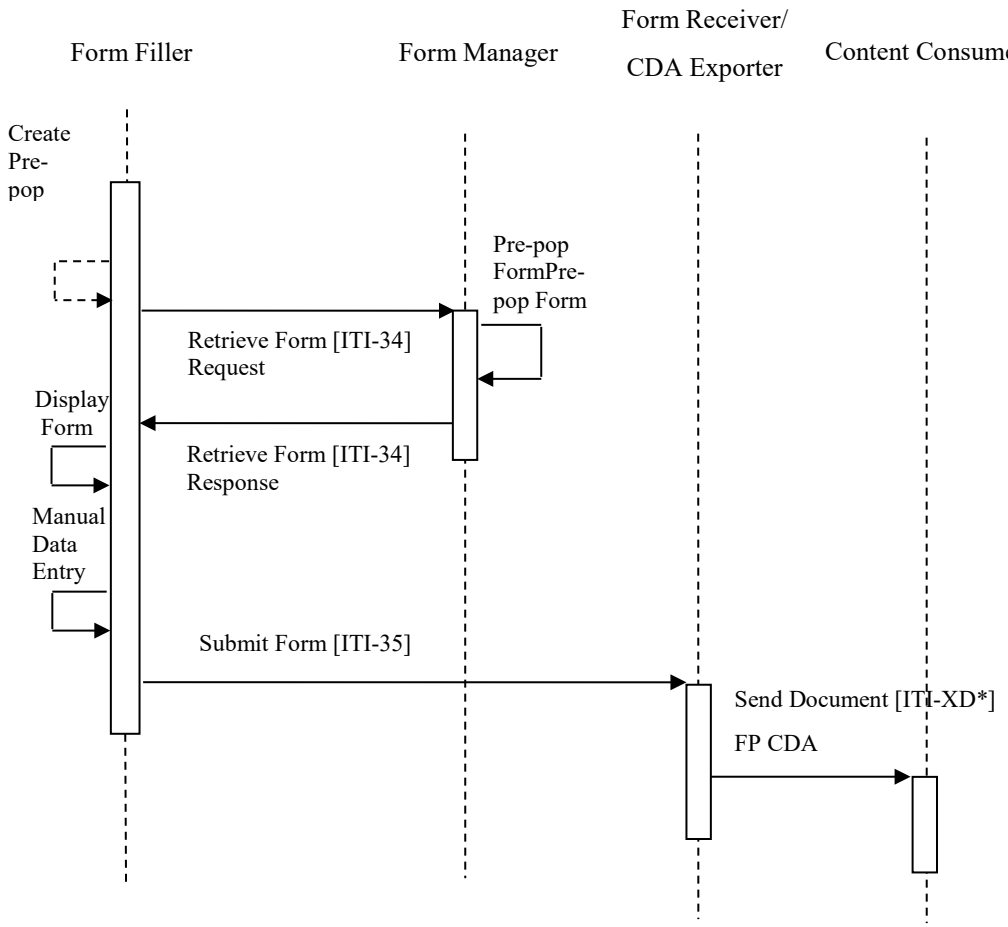


Figure X.4.2.4.2.3-1: Use Case 2 - Forms Data Capture with Document Submission

X.4.2.5 Use Case #5: EHR FP Document Submission

X.4.2.5.1 Use Case Description

When the Family Planning encounter has been documented in the system, the EHR system creates the QRPH FPv2 document and sends it to population affairs.

X.4.2.5.2 Processing Steps

X.4.2.5.2.1 Pre-conditions

A Family Planning encounter has been documented in the EHR system and all of the required data, including lab test results, are available. This may be at the close of the encounter, if all data

are available then, or may be at a later date when supplemental data, such as lab results, are complete.

X.4.2.5.2.2 Main Flow

The Content Creator sends an FPv2 document to the Content Consumer

X.4.2.5.2.3 Post-conditions

The data are made available for quality improvement measures.

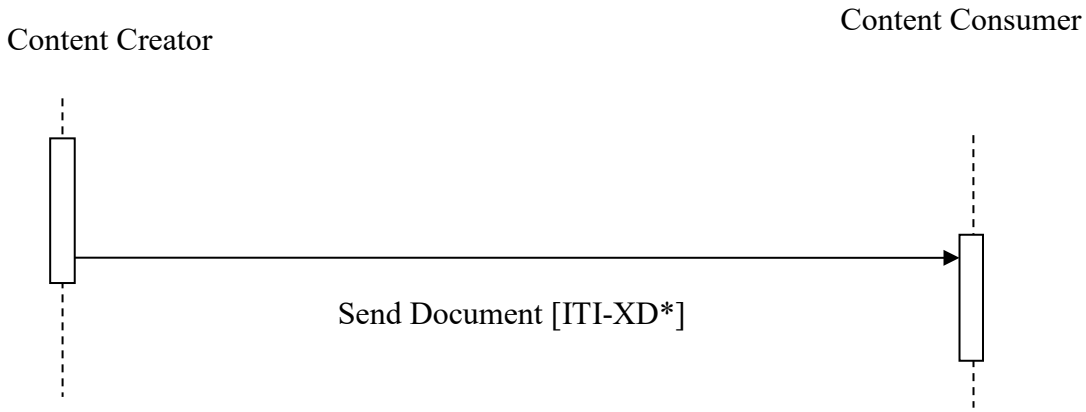


Figure X.4.2.5.2.3-1: Use Case 5 - EHR FPv2 Document Submission

X.5 FPv2 Security Considerations

FPv2 includes clinical content related to the patient. As such, it is anticipated that actions that include patient information will be protected. The ITI Audit Trail and Node Authentication (ATNA) Profile SHOULD be implemented by all of the actors involved in the IHE transactions specified in this profile to protect node-to-node communication and to produce an audit trail of the actions that include patient information related actions when they exchange messages, though other private security mechanisms MAY be used to secure content within enterprise managed systems.

The Form Manager relies upon the information submitted in the request and therefore MAY request the inclusion of a digital signature using the ITI Document Digital Signature (DSG) Profile to ensure the data are unaltered in transition. The Form Filler relies on the information provided in the response and MAY request a digital signature in the form response.

If the Form Manager includes information from another source, other than the Family Planning document, then Cross-Enterprise User Assertion (XUA) Profile MAY be used to support secure

assertion of the identity of the user and the location to identify the data source. If the Form Manager needs to restrict access it may do so using XUA content to assert the identity of the user and location. The Form Receiver MAY request the identity of the Form Filler and may do so using XUA content to assert the identity of the user and location.

In some jurisdictions, consent may be needed to provide this information to public health. For these cases, the ITI Basic Patient Privacy Consents (BPPC) Profile can be used to enable this consent management.

X.5.1 Security Audit Considerations – Retrieve Form [ITI-34]

The Retrieve Form Transaction is a PHI-Export event, as defined in ITI TF-2a: Table 3.20.6-1. The actors involved in the transaction SHOULD create audit data in conformance with Retrieve Form (ITI-34] audit messages as defined in QRPH Trial Implementation Supplement CRD: 5.Z.3.1 Retrieve Form [ITI-34] audit messages, in accordance with local law and/or policy in the jurisdiction where the system is implemented.

X.5.2 Security Audit Considerations – Submit Form [ITI-35] audit messages

The Submit Form Transaction MAY be a PHI-Export event, as defined in ITI TF-2a: Table 3.20.6-1. The actors involved in the transaction SHOULD create audit data in conformance with Submit Form [ITI-35] audit messages as defined in QRPH Trial Implementation Supplement CRD: 5.Z.3.2 Submit Form [ITI-35] audit messages, in accordance with local law and/or policy in the jurisdiction where the system is implemented.

X.6 FPv2 Cross Profile Considerations

The following informative narrative is offered as implementation guidance.

X.6.1 XDS.b, XDM, or XDR – Cross Enterprise Document Sharing. B, Cross Enterprise Document Media Interchange, or Cross Enterprise Document Reliable Interchange

The use of the IHE XD* family of transactions is encouraged to support standards-based interoperability between systems acting as Content Creator and Content Consumer. The grouping of Content Creator and Content Consumer Actors with ITI XD* Actors is defined in the PCC Technical Framework (PCC TF-1:3.7.1). Below is a summary of recommended IHE transport transactions that MAY be utilized by systems playing the roles of Content Creator or Content Consumer to support the use cases defined in this profile:

- A Document Source in XDS.b, a Portable Media Creator in XDM, or a Document Source in XDR might be grouped with the FP Content Creator. A Document Consumer in XDS.b, a Portable Media Importer in XDM, or a Document Recipient in XDR might be grouped with the FP Content Consumer. A registry/repository-based infrastructure is defined by the IHE Cross Enterprise Document Sharing (XDS.b) that includes profile support that can be leveraged to facilitate retrieval of public health related information

695 from a document sharing infrastructure: Multi-Patient Query (MPQ), Document Metadata Subscription (DSUB).

- A media-based infrastructure is defined by the IHE Cross Enterprise Document Media Interchange (XDM) Profile. A Portable Media Creator in XDM might be grouped with the FP Content Creator. A Portable Media Importer in XDM might be grouped with the
700 FP Content Consumer.

A reliable messaging-based infrastructure is defined by the IHE Cross Enterprise Document Reliable Interchange (XDR) Profile. A Document Source in XDR might be grouped with the FP Content Creator. A Document Recipient in XDR might be grouped with the FP Content Consumer.

705 ## X.7 Data elements

This profile requires specific form data element content. These data elements are used to create the FPv2 CDA Document, and populate a form defined to gather the required structured data, such as the OPA FPAR form. Those data elements are described in Appendix A.

Appendices

Appendix A – Data Elements

The following data elements are used in support of Family Planning services. Details regarding optionality, structures, vocabularies, and value sets are documented in QRPH TF-3: 6.3.1.D1:

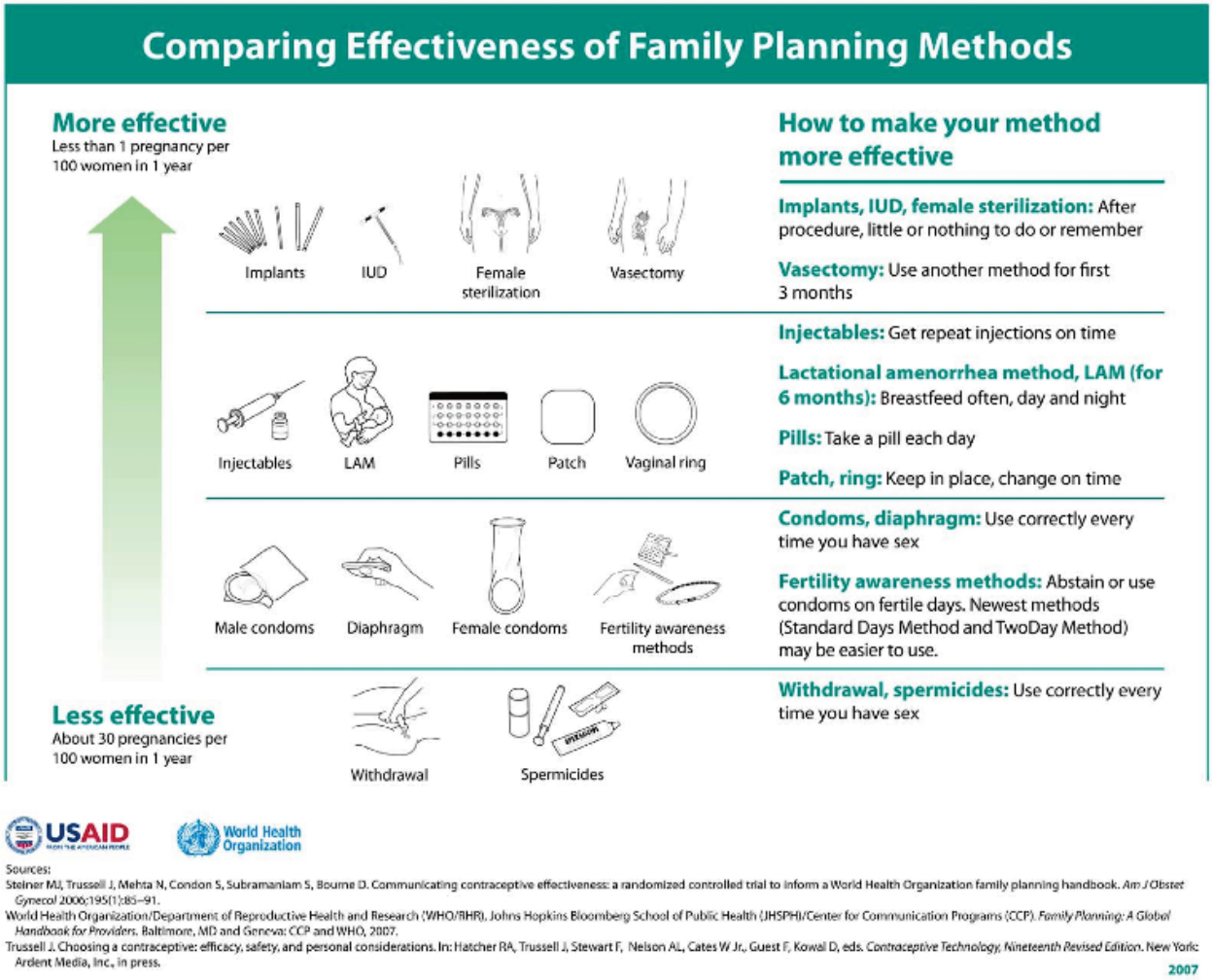
Element	Description
Facility Identifier	Clinical site at which services were provided
Clinical Provider Identifier	The identifier of the most senior clinical provider that provided services at the encounter
Clinical Provider Role	The role of the most senior clinical provider that provided services at the encounter
Visit Date	The date of service when the clinical family planning services were provided to the client.
Patient identifier	Patient's medical record number or other persistent, unique identifier within the site's tracking systems
Date of Birth	Patient's date of birth
Administrative Sex	Patient's sex at birth as a standard value set
Ethnicity	Patient's self-reported ethnicity as a standard value set
Race	Patient's self-reported race(s) as a standard value set
Language of Communication	Patient's ability to communicate in various languages in 4 domains: listening, writing, reading, or speaking.
Smoking Status	Smoking status as a standard value set
Annual Household Income	Patient's self-report of the numeric value of the annual household income where the patient resides
Household Size	Patient's self-report of the numeric value of the total number of persons living in the household, including the patient
Insurance Coverage Type	Patient's insurance coverage status at encounter
Height	Patient's height
Weight	Patient's weight
Systolic Blood Pressure	Systolic bp per mmHg
Diastolic Blood Pressure	Diastolic bp per mmHg
Pregnancy History - Parity	The number of pregnancies reaching parity
Pregnancy History – Gravidity	They number of pregnancies, current and past, regardless of pregnancy outcome
Current Pregnancy Status	Pregnancy status at visit
Pregnancy Status Reporting Method	Method used to determine pregnancy status
Pregnancy Test Result	Lab Test result used to determine pregnancy
Pregnancy Intention	Patient self-report of intention to seek pregnancy in the next year (including male client's report of seeking pregnancy with a female partner)
Sexual Activity	Patient self-report of being sexually active never, ever, in the past 3 months, or in the last 12 months.

Element	Description
Contraceptive Methods at Intake[4]	Patient report of contraceptive method(s) used at last sexual encounter
Reason for no contraceptive method at Intake	Reason Patient reported no contraceptive method used at intake
Date of Last Cervical Cancer Screen	Date of last vaginal or cervical Cancer Screen (Date of this visit if test was performed. Otherwise date of lab result from this clinic or other clinic, or self-report if test result not available)
Cervical Cancer Screen Result	Result from this visit if test was performed. Otherwise result of last Pap test
Date of Last HPV Test	Date of last vaginal or cervical HPV Co-test (Date of this visit if test was performed. Otherwise date of lab result from this clinic or other clinic, or self-report if test result not available)
HPV Co-test Result	Result from this visit if test was performed. Otherwise result of last HPV Co-test
Date of Last CT Screen	Date of last *Chlamydia trachomatis* screen (Date of this visit if test was performed. Otherwise date of lab result from this clinic or other clinic, or self-report if test result not available)
CT Screen Result	Result from this visit if test was performed. Otherwise result of last CT Screen
Date of Last GC Screen	Date of last *Neisseria gonorrhoeae* screen (Date of this visit if test was performed. Otherwise date of lab result from this clinic or other clinic, or self-report if test result not available)
GC Screen Result	Result from this visit if test was performed. Otherwise result of last GC Screen
Date of Last HIV Screen	Date of last HIV screen (Date of this visit if test was performed. Otherwise date of lab result from this clinic or other clinic, or self-report if test result not available)
HIV Screen Result	Result of rapid, initial HIV screen at the current visit per standard value set
Contraceptive Methods at Exit[4]	Contraceptive method(s) recommended or prescribed by provider to Patient at the end of the visit, after counseling and assessment
Reason for No Contraceptive Method at Exit	Reason Patient has no contraceptive method used at exit
How was Contraceptive method provided at exit	Method the provider used to give contraceptive method to the patient at end of visit
Contraceptive Counseling Provided	If an interaction in which provider spends time discussing the patient's choice of contraceptive method took place during the visit
Counseling to achieve pregnancy	If an interaction in which provider gives services or counseling related to achieving pregnancy or addressing infertility took place during this encounter
HIV Referral Recommended Date	A date at which a clinician identifies that a clinical or laboratory finding on HIV status requires a referral to a different provider for a medical visit and the client has been provided knowledge of that referral. The referred provider and location is summarized as well as any relevant diagnostic or billing codes that help document the need for the referral. This date would be considered the start date for a performance measure that evaluates the time that it takes for a necessary referral period to be completed.

[4] Options for the contraceptive method data element should be displayed in order of Tiers of Effectiveness, as established by the World Health Organization (WHO) and the US Agency for International Development (USAID). It is the responsibility of the Form Manager to ensure that the form is structured such that when entering data manually, the form SHALL present contraception options in the WHO recommended order (see Figure A-1).

Element	Description
HIV Referral Visit Completed Date	The site that found a need for a referral receives documentation that the medical visit took place and enters the date of that visit. This date would be considered the end date for a performance measure that evaluates the time that it takes for a necessary referral period to be completed.

Note: Null flavors are an option for many data elements. Null flavors include NI = No information (not reported), UNK = Unknown (proper value applicable but not known), ASKU = Asked but not known (refused to state).



720 **Figure A-1: Tiers of Effectiveness for Family Planning Methods**

Volume 2 – Transactions

There are no new transactions identified by this profile.

Appendices

Volume 2 Namespace Additions

There are no new Volume 2 Namespace additions

Volume 3 – Content Modules

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5 Namespaces and Vocabularies

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.1	LOINC	Logical Observation Identifier Names and Codes
2.16.840.1.113883.6.96	SNOMED-CT	Systematized Nomenclature Of Medicine Clinical Terms
2.16.840.1.113883.6.8	UCUM	Unified Code for Units of Measure

Add to Section 5.1.1 IHE Format Codes

Profile	Format Code	Media Type	Template ID
Family Planning version 2	urn:ihe:qrph:fp:2017	txt/xml	1.3.6.1.4.1.19376.1.7.3.1.1.27.1

735

Add to Section 5.1.2 IHE ActCode Vocabulary

Code	Description
None	NA

740 *Add to Section 5.1.3 IHE RoleCode Vocabulary*

Code	Description
None	NA

6 Content Modules

6.3.1 CDA Document Content Modules

6.3.1.D1 Family Planning version 2 Document Content Module

6.3.1.D1.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:qrph:fp:2017.**

6.3.1.D1.2 Parent Template

This document is a specialization of the IHE PCC Medical Document template (OID = 1.3.6.1.4.1.19376.1.5.3.1.1.1).

Note: The Medical Document includes requirements for various header elements; name, addr and telecom elements for identified persons and organizations; and basic participations record target, author, and legal authenticator.

6.3.1.D1.3 Referenced Standards

All standards which are reference in this document are listed below with their common abbreviation, full title, and link to the standard.

Table 6.3.1.D1.3-1: Referenced Standards

Abbreviation	Title	URL
CDAR2	HL7®[5] CDA Release 2.0	http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition.zip
C-CDA R1.1	HL7 Consolidated CDA Release 1.1	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
IHE PCC TF Vol. 2	IHE PCC Technical Framework, Volume 2	http://www.ihe.net/technical_frameworks/
IHE PCC Content Modules	IHE PCC Content Modules	http://www.ihe.net/technical_frameworks/
LOINC	Logical Observation Identifiers, Names and Codes	https://loinc.org/
SNOMED-CT	Systematized Nomenclature of Medicine - Clinical Terms	http://www.ihtsdo.org/snomed-ct/

6.3.1.D1.4 Data Element Requirement Mappings to CDA

This section specifies the mapping of data from the specified form data elements for this profile into the Family Planning (FP) summary document for the Universal Realm. This mapping

[5] HL7 is the registered trademark of Health Level Seven International.

760 SHALL be used by the Form Receiver CDA Exporter to generate the CDA document content. See Volume 4 for available realm-specific data element mappings.

Table 6.3.1.D1.4-1: FPP-Data Element Mappings to CDA

Clinical Data Element	Optionality	CDA-DIR in FP	Concept Domain or Value Set
Facility Identifier	R	ClinicalDocument/componentOf/encompassingEncounter/location/healthcareFacility/id	
Clinical Provider Identifier	R2	ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/id	
Clinical Provider Role	R	ClinicalDocumenr/componentOf/encompassingEncounter/responsibleParty/assignedEntity/code	UV_ClinicalProviderRole
Visit Date	R	ClinicalDocument/componentOf/encompassingEncounter/effectiveTime	
Patient Identifier	R	ClinicalDocument/recordTarget/patientRole/id	
Date of Birth	R	ClinicalDocument/recordTarget/patientRole/patient/birthtime	
Administrative Sex	R	ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode	Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1
Ethnicity	O	ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode	UV_Ethnicity
Race	O	ClinicalDocument/recordTarget/patientRole/patient/raceCode	UV_Race
Language of Communication	O	ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/languageCode	Language 2.16.840.1.113883.1.11.11526
Language Proficiency	O	ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/proficiencyLevelCode	LanguangeProficiency Code 2.16.840.1.113883.5.61
Smoking Status	R	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4']]/value Where ../code[@code='229819007']] OR Where ../code[@code='72166-2']]	
Annual Household Income	R2	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4']]/value Where ../code[@code=' 77244-2']]	

Clinical Data Element	Optionality	CDA-DIR in FP	Concept Domain or Value Set
Household Size	R2	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4']]/value Where ../code[@code='LOINC-2']]	
Insurance Coverage Type	O	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7']]/entry/act[code@code='48768-6']/entryRelationship/act[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.18']/code	UV_InsuranceTypes
Height	R	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observation/value Where …/code[@code= '8302-2']	
Weight	R	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observation/value Where ../code[@code= '29463-7']	
Systolic Blood Pressure	R	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observation/value Where ../code[@code= '8480-6']	
Diastolic Blood Pressure	R	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observation/value Where ../code[@code= '8462-4']	
Pregnancy History - Parity	R	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4']]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5']]/value Where …/code[@code='11977-6'] Parity, LOINC	

Clinical Data Element	Optionality	CDA-DIR in FP	Concept Domain or Value Set
Pregnancy History – Gravidity	R	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4’]]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5’]]/value Where …/code[@code=’11996-6’] Gravidity, LOINC	
Current Pregnancy Status	R	ClinicalDocument/component/structuredBody/component/section[templateId[@root=’1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4’]]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5’]]/value Where …/code[@code=’11449-6’] Pregnancy Status (Reported), LOINC AND/OR ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4’]]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5’]]/value Where …/code[@code=’LOINC-3’] Pregnancy Status (Finding), LOINC	UV_PregnancyStatus
Pregnancy Status Confirmation Result	O	ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4’]]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5’]]/entryRelationship/observation/value Where ../…/../code[@code=’LOINC-3’]Pregnancy Status (Finding), LOINC And Where „/code is one of the codes from Table 6.3.4.E1.1-1	
Pregnancy Intention	R	ClinicalDocument/ component/structuredBody/component/section[templateId[@root=’1.3.6.1.4.1.19376.1.5.3.1.1.9.47’]]/entry/organizer[templateId[@root=’1.3.6.1.4.1.19376.1.5.3.1.4.22‘]]/component /observation/value Where ../code[@code=’LOINC-4’] Pregnancy Intention, LOINC	UV_PregnancyIntention

Clinical Data Element	Optionality	CDA-DIR in FP	Concept Domain or Value Set
Sexual Activity	O	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.47']]/entry/organizer[templateId[@root=' 1.3.6.1.4.1.19376.1.5.3.1.4.22']]/component /observation/value Where ../code[@code='LOINC-5a'] Sexually Active Never, LOINC OR Where ../code[@code='LOINC-5b'] Sexually Active Last 3 Months, LOINC OR Where ../code[@code='LOINC-5c'] "Sexually Active Last 12 Months, LOINC	
Contraceptive Methods at Intake	R	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.47']]/entry/organizer[templateId[@root=' 1.3.6.1.4.1.19376.1.5.3.1.4.22']]/component /observation/value Where ../code[@code='LOINC-6'] Contraceptive Method, LOINC	UV_ContraceptiveMethod
Reason for No Contraceptive Method at Intake	O	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.47']]/entry/organizer[templateId[@root=' 1.3.6.1.4.1.19376.1.5.3.1.4.22']]/component /observation/entryRelationship/observation/value Where ../../../code[@code='LOINC-6'] Contraceptive Method, LOINC And Where ../code[@code='LOINC-7'] Reason For No Contraceptive Method, LOINC	UV_ReasonForNoContraceptive
Date of Last Cervical Cancer Screen	R	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/ observation/effectiveTime Where …/code is one of the codes from the value set FPv2 Cervical Cancer Screen Tests (OID TBD)	

Clinical Data Element	Optionality	CDA-DIR in FP	Concept Domain or Value Set
Cervical Cancer Screen Result	R2	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/ observation/value Where …/code is one of the codes from the value set FPv2 Cervical Cancer Screen Tests (OID TBD)	UV_CervicalCancerTests
Date of Last HPV Co-test	R	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']/ observation/effectiveTime Where …/code is one of the codes from the value set FPv2 HPV Tests (OID TBD)	
HPV Co-test Result	R2	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/ /observation/value Where …/code is one of the codes from the value set FPv2 HPV Tests (OID TBD)	UV_HPVTests
Date of Last Chlamydia trachomatis Screen	R	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/ /observation/effectiveTime Where …/code is one of the codes from the value set FPv2 Chlamydia Tests (OID TBD)	
Chlamydia Trachomatis Result	R2	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/ observation/value Where …/code is one of the codes from the value set FPv2 Chlamydia Tests (OID TBD)	UV_ChlamydiaTests
Date of Last Neisseria gonorrhoeae Screen	R	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']] /observation/effectiveTime Where …/code is one of the codes from the value set FPv2 Gonorrhea Tests (OID TBD)	
Neisseria gonorrhoeae Result	R2	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']] observation/value Where …/code is one of the codes from the value set FPv2 Gonorrhea Tests (OID TBD)	UV_GonorrheaTests

Clinical Data Element	Optionality	CDA-DIR in FP	Concept Domain or Value Set
Date of Last HIV Screen	R	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/ observation/effectiveTime Where …/code is one of the codes from the value set FPv2 HIV Tests (OID TBD)	
HIV Screen Result	R2	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.28']]/ observation/value Where …/code is one of the codes from the value set FPv2 HIV Tests (OID TBD)	UV_HIVTests
Contraceptive Counseling Provided	R	ClinicalDocument/ component/structuredBody component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11']]/entry/procedure/code	
Counseling to Achieve Pregnancy Provided	R2	ClinicalDocument/ component/structuredBody component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11']]/entry/procedure/code	
HIV Referral Recommended Date	R2	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11']]/entry/procedure/effectiveTime/low Where ../code[@code='LOINC-13'] Contraceptive Method, LOINC	
HIV Referral Completed Date	R2	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11']]/entry/procedure/effectiveTime/high Where ../code[@code='LOINC-13'] Contraceptive Method, LOINC	
Contraceptive Method at Exit	R	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.1.13.7']]/entry/observation/value Where ../code[@code='LOINC-10'] Contraceptive Method, LOINC	UV_ContraceptiveMethod

Clinical Data Element	Optionality	CDA-DIR in FP	Concept Domain or Value Set
Reason for No Contraceptive Method at Exit	O	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.1.13.7']]/entry/observation/entryRelationship/observation/value Where ../../../code[@code='LOINC-10'] Contraceptive Method, LOINC And Where ../code[@code='LOINC-11'] Reason For No Contraceptive Method, LOINC	UV_ReasonNoContraceptive
How was Contraceptive method provided at exit	O	ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.7.3.1.1.13.7']]/entry/observation/value Where ../code[@code='LOINC-12'] Contraceptive Method, LOINC	UV_ProvisioningMethod

6.3.1.D1.5 Family Planning version 2 (FPv2) Document Content Module Specification

This section specifies the header, section, and entry content modules which comprise the Family Planning version 2 (FPv2) Document Content Module, using the Template ID (1.3.6.1.4.1.19376.1.7.3.1.1.27.1) as the key identifier.

Sections that are used according to the definitions in other specifications are identified with the relevant specification document. Additional constraints on vocabulary value sets, not specifically constrained within the section template, are also identified.

Table 6.3.1.D1.5-1: FPv2 Document Content Module Specification

Template Name	Family Planning version 2 (FPv2)
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.27.1
Parent Template	Medical Document Specification 1.3.6.1.4.1.19376.1.5.3.1.1.1 (PCC)
General Description	Document summary specification to support communication of family planning content to public health management
Document Code	SHALL be LOINC-1 Family Planning document (CodeSystem: 2.16.840.1.113883.6.1 LOINC)

Template Title	Opt and Card	Condition	Template Type	templateId	Constraints
Family Planning version 2 Content	R[1..1]		document	1.3.6.1.4.1.19376.1.7.3.1.1.27.1	
Facility Identifier	[1..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	
Clinical Provider Identifier	[0..*]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	
Clinical Provider Role	[1..*]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	6.3.2.H.1
Visit Date	[1..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	
Patient Identifier	[1..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	
Date of Birth	[1..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	
Administrative Gender	[1..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	6.3.2.H.2
Ethnicity	[0..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	6.3.2.H.3
Race	[0..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	6.3.2.H.4
Language of Communication	[0..*]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	6.3.2.H.5
Coded Social History Section	[1..1]		Section	1.3.6.1.4.1.19376.1.7.3.1.3.24.2	6.3.3.10.S1
Smoking Status	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.4	6.3.3.10.S1.1
Annual Household Income	[0..*]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.4	6.3.3.10.S1.2
Household Size	[0..*]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.4	6.3.3.10.S1.3
Payers Section	[0..1]		Section	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7	
Insurance Coverage Type	[1..*]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.18	
Coded Vital Signs Section	[1..1]		Section	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2	6.3.3.10.S2
Height	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.1	6.3.3.10.S2.1
Weight	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.1	6.3.3.10.S2.2
Systolic Blood Pressure	[1..*]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.1	6.3.3.10.S2.3
Diastolic Blood Pressure	[1..*]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.1	6.3.3.10.S2.4
Coded Pregnancy History Section	[1..1]		Section	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4	6.3.3.10.S3
Pregnancy History – Parity	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.5	6.3.3.10.S3.1

Template Title	Opt and Card	Condition	Template Type	templateId	Constraints
Pregnancy History – Gravidity	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.5	6.3.3.10.S3.2
Current Pregnancy Status	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.5	6.3.3.10.S3.3
Pregnancy Status Review Section	[1..1]		Section	1.3.6.1.4.1.19376.1.5.3.1.1.9.47	6.3.3.10.S4
Pregnancy Intention	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.22.1	6.3.3.10.S4.1
Sexual Activity	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.22.1	6.3.3.10.S4.2
Contraceptive Methods at Intake	[1..*]		Entry	1.3.6.1.4.1.19376.1.7.3.1.4.27.2	6.3.3.10.S4.3
Reason for No Contraceptive Method at Intake	[0..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13	6.3.3.10.S4.3
Coded Results Section	[1..1]		Section	1.3.6.1.4.1.19376.1.5.3.1.3.28	6.3.3.10.S5
Cervical Cancer Screen Result	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13	6.3.3.10.S5.1
HPV Co-test Result	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13	6.3.3.10.S5.2
Chlamydia Trachomatis Result	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13	6.3.3.10.S5.3
Neisseria gonorrhoeae Result	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13	6.3.3.10.S5.4
HIV Screen Result	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13	6.3.3.10.S5.5
Procedures and Interventions	[1..1]		Section	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11	6.3.3.10.S6
Contraceptive Counseling Provided	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.19	6.3.3.10.S6.1
Counseling to Achieve Pregnancy Provided	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.19	6.3.3.10.S6.1
HIV Referral Recommended Date	[0..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.1.25.1.4.1	6.3.3.10.S6.1
HIV Referral Completed Date	[0..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.1.25.1.4.1	6.3.3.10.S6.1
Coded Event Outcomes Section	[1..1]		Section	1.3.6.1.4.1.19376.1.7.3.1.1.13.7	6.3.3.10.S7
Contraceptive Method at Exit	[1..*]		Entry	1.3.6.1.4.1.19376.1.7.3.1.4.27.2	6.3.3.10.S7.1
Reason for No Contraceptive Method at Exit	[0..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13	6.3.3.10.S7.1

Template Title	Opt and Card	Condition	Template Type	templateId	Constraints
How was Contraceptive method provided at exit	[0..*]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13	6.3.3.10.S7.1

6.3.1.D1.6 FPv2 Conformance and Example

CDA Release 2.0 documents that conform to the requirements of this document content module shall indicate their conformance by the inclusion of the <templateId> XML elements in the header of the document.

A CDA Document may conform to more than one template. This content module inherits from the *<template name(s) and template ID(s)>* <e.g., CDA-PN, 2.16.840.1.113883.10.20.18.1, and the PCC TF Medical Document, 1.3.6.1.4.1.19376.1.5.3.1.1.1, content modules> and so must conform to the requirements of those templates as well this document specification, *<templateName and templateID>* <e.g., Cardiac Imaging Report template, 1.3.6.1.4.1.19376.1.4.1.1.1>.

A complete example of the Family Planning Version 2 (FPv2) Document Content Module is available on the IHE ftp server at: ftp://ftp.ihe.net/TF_Implementation_Material/QRPH/.

Note that this is an example and is meant to be informative and not normative. This example shows the <templateId (OIDs)> elements for all of the specified templates.

Add to Section 6.3.2 Header Content Modules

6.3.2 CDA Header Content Modules

6.3.2.H Family Planning version 2 Header Content Module

No new Header Elements are added in this supplement. Header constraints for the FPv2 document SHALL conform to header constraints defined by the Medical Summary Specification parent template (1.3.6.1.4.1.19376.1.5.3.1.1.1) except as detailed in this section.

6.3.2.H.1 Clinical Provider Role Vocabulary Constraint

The value for ClinicalDocumenr/componentOf/encompassingEncounter/responsibleParty/assignedEntity/code SHALL be drawn from a value set bound to the Concept Domain UV_ClinicalProviderRole.

6.3.2.H.2 Gender Vocabulary Constraint

The value for ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode SHALL be drawn from value set 2.16.840.1.113883.1.11.1 AdministrativeGender (HL7 V3).

6.3.2.H.3 Ethnicity Vocabulary Constraint

The value for ClinicalDocument/recordTarget/patientRole/patient/ethnicGroupCode SHALL be drawn from a value set bound to the Concept Domain UV_Ethnicity.

6.3.2.H.4 Race Vocabulary Constraint

The value for ClinicalDocument/recordTarget/patientRole/patient/raceCode SHALL be drawn from a value set bound to the Concept Domain UV_Race.

6.3.2.H.5 Language of Communication Vocabulary Constraint

The value for ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/languageCode SHOULD be drawn from value set 2.16.840.1.114222.4.11.831 Language ISO 639-2 Alpha3.

The value for ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/proficiencyLevelCode SHALL be drawn from value set 2.16.840.1.113883.5.61 LanguangeProficiencyCode.

6.3.3 CDA Section Content Modules

Add to Section 6.3.3.10 Section Content Modules

6.3.3.10.S1 Coded Social History – Family Planning version 2 Section

Table 6.3.3.10.S1-1: Coded Social History Section

Template Name	Coded Social History -Family Planning version 2 Section
Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.16.1
Parent Template	IHE Social History Section 1.3.6.1.4.1.19376.1.5.3.1.3.16
General Description	The social history section shall contain a narrative description of the person's beliefs, home life, community life, work life, hobbies, and risky habits. It shall include Social History Observations.
Section Code	29762-2, LOINC, "Social History"
Author	If not the author from the encompassing context, include author. Role and entity must be specified if not inherited.
Informant	If not the informant from the encompassing context, include informant. Role and entity must be specified if not inherited.
Subject	If not the subject from the encompassing context, include subject. Role and entity must be specified if not inherited.

Opt and Card	Condition	Data Element or Section Name	Template ID	Specification Document	Constraint
Subsections					
Entries					
R [1..1]		Social History Observation	1.3.6.1.4.1.19376.1.5.3.1.4.13.4	IHE PCC TF-2	6.3.3.10.S1.1

6.3.3.10.S1.1 Social History Observation Constraints

Within the Coded Social History – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Social History Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13.4 [PCC TF-2])

reflecting the ***Smoking Status***

- encoding the value in ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.4.13.4"]]/value
- where the value attribute indicates the number of times of the act performed, and the units represent the frequency, using the PQ data type and having a unit in the form {xxx}/d, {xxx}/wk or {xxx}/a represent the number of items per day, week or year respectively
    - where ../code[@code=' 229819007 '] Smoking, SNOMED-CT OR ../code[@code='72166-2'] Tobacco Smoking Status, LOINC.

Within the Coded Social History – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHOULD be able to create a Social History Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13.4 [PCC TF-2])

reflecting the ***Household Income***

- encoding the value in ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.4.13.4"]]/value
- Identifying the Range or Actual number
    - where …/code[@code=' 77244-2 '] Household income in last Y , LOINC

Within the Coded Social History – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHOULD be able to create a Social History Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13.4 [PCC TF-2])

reflecting the ***Household Size***

- encoding the value in ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1']]/entry/observation[templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.4.13.4"]]/value
- Identifying the Range or Actual number
    - where …/code[@code=' LOINC-2 '] Household income in last Y , LOINC

6.3.3.10.S2 Coded Vital Signs – Family Planning version 2 Section

Template Name		Coded Vital Signs – Family Planning version 2 Section			
Template ID		1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2			
Parent Template		IHE Vital Signs Section 1.3.6.1.4.1.19376.1.5.3.1.3.25			
General Description		The vital signs section contains coded measurement results of a patient's vital signs.			
Section Code		8716-3, LOINC, "Vital Signs"			
Author		If not the author from the encompassing context, include author. Role and entity must be specified if not inherited.			
Informant		If not the informant from the encompassing context, include informant. Role and entity must be specified if not inherited.			
Subject		If not the subject from the encompassing context, include subject. Role and entity must be specified if not inherited.			
Opt and Card	**Condition**	**Data Element or Section Name**	**Template ID**	**Specification Document**	**Constraint**
Subsections					
Entries					
R [1..*]		Vital Signs Organizer	1.3.6.1.4.1.19376.1.5.3.1.4.13.1		6.3.3.10.S2.1

6.3.3.10.S2.1 Vital Signs Observation Constraints

Within the Coded Vital Signs – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Vital Signs Organizer entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13.1 [PCC TF-2])

for ***Height,*** which SHALL be included

- encoding the measurement date in ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observation/effectiveTime
- encoding the value in ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observation/value
- For height measurement, this field shall be valued using UCUM codes to indicate inches ('[in_i]') and/or feet ('[ft_i]'); or centimeters ('cm') and/or meters ('m').
    - Where for standing heights that are measured, …/code[@code='8302-2'] Body Height, LOINC

Within the Coded Vital Signs – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Vital Signs Organizer entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13.1 [PCC TF-2])

For ***Weight,*** which SHALL be included

- encoding the measurement date in

  ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observation/effectiveTime
- encoding the value in

  ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observation/value
- For weight measurement, this field shall be valued using UCUM codes to indicate pounds ('[lb_av]') and/or ounces ('[oz_av]'); or kilograms ('kg') and/or grams ('g').
    - Where …/code[@code=' 29463-7'] Body weight

Within the Coded Vital Signs – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Vital Signs Organizer entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13.1 [PCC TF-2])

For ***Systolic Blood Pressure*** which SHALL be included

- encoding the value in

ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observation/value

- For blood pressure measurement, this field shall be valued using UCUM codes to indicate millimeter mercury ('mm[Hg]').
    - Where …/code[@code='8480-6'] Systolic blood pressure, LOINC

Within the Coded Vital Signs – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Vital Signs Organizer entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13.1 [PCC TF-2])

For ***Diastolic Blood Pressure*** which SHALL be included

- encoding the value in

  ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2']]/entry/organizer[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1']]/component/observationvalue

- For blood pressure measurement, this field shall be valued using UCUM codes to indicate millimeter mercury ('mm[Hg]').
    - Where …/code[@code='8462-4'] Diastolic blood pressure, LOINC

6.3.3.10.S3 Pregnancy History – Family Planning version 2 Section

Template Name		Pregnancy History – Family Planning version 2 Section			
Template ID		1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4			
Parent Template					
General Description		The pregnancy history section contains coded entries describing the patient history of pregnancies.			
Section Code		10162-6, LOINC, "History of Pregnancies"			
Author		If not the author from the encompassing context, include author. Role and entity must be specified if not inherited.			
Informant		If not the informant from the encompassing context, include informant. Role and entity must be specified if not inherited.			
Subject		If not the subject from the encompassing context, include subject. Role and entity must be specified if not inherited.			
Opt and Card	**Condition**	**Data Element or Section Name**	**Template ID**	**Specification Document**	**Constraint**
Subsections					

Entries					
R [1..*]		Pregnancy Observation	1.3.6.1.4.1.19376.1.5.3.1.4.13.5		6.3.3.10.S3.1
R[1..1]		Pregnancy Status Observation – Family Planning version 2	1.3.6.1.4.1.19376.1.7.3.1.4.27.1		6.3.3.10.S3.2

6.3.3.10.S3.1 Pregnancy Observation Constraints

Within the Pregnancy History – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Pregnancy Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13.5 [PCC TF-2])

reflecting the ***Parity*** by encoding the value in

- ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4]]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5"]]/value
  - Where …/code[@code='11977-6'] Parity, LOINC

Within the Pregnancy History – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Pregnancy Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13.5 [PCC TF-2])

reflecting the ***Gravidity*** by encoding the value in

- ClinicalDocument/component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4]]/entry/observation[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5"]]/value
  - Where …/code[@code='11996-6'] Gravidity, LOINC

6.3.3.10.S3.2 Pregnancy Status Observation Constraints

Within the Pregnancy History – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Pregnancy Status Observation – Family Planning version 2 Entry (1.3.6.1.4.1.19376.1.7.3.1.4.27.1) as described in Section 6.3.4.E1.

6.3.3.10.S4 Pregnancy Status Review – Family Planning version 2 Section

Template Name	Pregnancy Status Review – Family Planning version 2 Section
Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.9.47
Parent Template	

General Description		The pregnancy status review section shall contain a description of the responses the patient gave to a set of routine questions regarding potential pregnancy in females of child-bearing-age. It shall include a Pregnancy Status Organizer.			
Section Code		11449-6, LOINC, "Pregnancy Status - Reported"			
Author		If not the author from the encompassing context, include author. Role and entity must be specified if not inherited.			
Informant		If not the informant from the encompassing context, include informant. Role and entity must be specified if not inherited.			
Subject		If not the subject from the encompassing context, include subject. Role and entity must be specified if not inherited.			
Opt and Card	**Condition**	**Data Element or Section Name**	**Template ID**	**Specification Document**	**Constraint**
Subsections					
Entries					
R [1..1]		Pregnancy Status Review Organizer	1.3.6.1.4.1.19376.1.5.3.1.4.22		6.3.3.10.S4.1

6.3.3.10.S4.1 Pregnancy Status Review Observation Constraints

Within the Pregnancy Status Review – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Pregnancy Status Review Organizer entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.22 [PCC CDA Content Modules])

for ***Pregnancy Intention,*** which SHALL be included

- encoding the value in ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.47']]/entry/organizer[templateId[@root=' 1.3.6.1.4.1.19376.1.5.3.1.4.22']]/component /observation/value
- where the value SHALL be taken from the value set bound to the Concept Domain UV_PregnancyIntention.
    - Where …/code[@code='LOINC-4'] Pregnancy Intention, LOINC

Within the Pregnancy Status Review – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create the following Pregnancy Status Review Organizer entries (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.22 [PCC CDA Content Modules]), at least one of which SHALL be present:

for ***Never Sexually Active***

- encoding the value in ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.47']]/entry/organizer[templateId[@root=' 1.3.6.1.4.1.19376.1.5.3.1.4.22']]/component /observation/value
- where the value SHALL be a Boolean
    - Where …/code[@code='LOINC-5a'] Never Sexually Active, LOINC

Within the Pregnancy Status Review – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Pregnancy Status Review Organizer entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.22 [PCC CDA Content Modules])

for ***Sexually Active last 3 months***

- encoding the value in ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.47']]/entry/organizer[templateId[@root=' 1.3.6.1.4.1.19376.1.5.3.1.4.22']]/component /observation/value
- where the value SHALL be a Boolean
    - Where …/code[@code='LOINC-5b'] Sexually Active Last 3 Months, LOINC

Within the Pregnancy Status Review – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Pregnancy Status Review Organizer entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.22 [PCC CDA Content Modules])

for ***Sexually Active Last 12 Months***

- encoding the value in ClinicalDocument/ component/structuredBody/component/section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.1.9.47']]/entry/organizer[templateId[@root=' 1.3.6.1.4.1.19376.1.5.3.1.4.22']]/component /observation/value
- where the value SHALL be a Boolean
    - Where …/code[@code='LOINC-5c'] Sexually Active Last 12 Months, LOINC

Within the Pregnancy Status Review – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Contraceptive Method Observation – Family Planning version 2 Entry (1.3.6.1.4.1.19376.1.7.3.1.4.27.2) as described in section 6.3.4.E2.

6.3.3.10.S5 Coded Results– Family Planning version 2 Section

Template Name	Coded Results – Family Planning version 2 Section				
Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.28				
Parent Template	1.3.6.1.4.1.19376.1.5.3.1.3.27				
General Description	The results section shall contain a narrative description and coded entries for the most recent results for relevant tests, as described below.				
Section Code	30954-2, LOINC, "Relevant Diagnostic Tests/Laboratory Data"				
Author	If not the author from the encompassing context, include author. Role and entity must be specified if not inherited.				
Informant	If not the informant from the encompassing context, include informant. Role and entity must be specified if not inherited.				
Subject	If not the subject from the encompassing context, include subject. Role and entity must be specified if not inherited.				
Opt and Card	**Condition**	**Data Element or Section Name**	**Template ID**	**Specification Document**	**Constraint**
Subsections					
Entries					
R [1..*]		Simple Observation	1.3.6.1.4.1.19376.1.5.3.1.4.13		6.3.3.10.S5.1

6.3.3.10.S5.1 Coded Results Constraints

Within the Coded Results section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Simple Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13 [PCC TF-2]) for ***Cervical Cancer Screen***

- encoding the date of the test in

  ClinicalDocument/ component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/effectiveTime

- encoding the value in

  ClinicalDocument/ component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/value

- Where …/code SHALL be drawn from a value set bound to the Concept Domain UV_CervicalCancerTests.

Within the Coded Results section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Simple Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13 [PCC TF-2]) for ***HPV Test Result***

- encoding the date of the test in

ClinicalDocument/component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/effectiveTime

- encoding the value in

ClinicalDocument/component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/value

- Where …/code SHALL be drawn from a value set bound to the Concept Domain UV_HPVTests.

Within the Coded Results section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Simple Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13 [PCC TF-2]) for ***Chlamydia Test Result***

- encoding the date of the test in

ClinicalDocument/component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/effectiveTime

- encoding the value in

ClinicalDocument/component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/value

- Where …/code SHALL be drawn from a value set bound to the Concept Domain UV_ChlamydiaTests.

Within the Coded Results section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Simple Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13 [PCC TF-2]) for ***Gonorrhea Test Result***

- encoding the date of the test in

ClinicalDocument/component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/effectiveTime

- encoding the value in

ClinicalDocument/component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/value

- Where …/code SHALL be drawn from a value set bound to the Concept Domain UV_GonhorrheaTests.

Within the Coded Results section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Simple Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13 [PCC TF-2]) for ***HIV Test Result***

- encoding the date of the test in

ClinicalDocument/component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/effectiveTime

- encoding the value in

ClinicalDocument/component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.3.28]]/entry/observation/value

- Where …/code SHALL be drawn from a value set bound to the Concept Domain UV_HIVTests.

6.3.3.10.S6 Procedures and Interventions– Family Planning version 2 Section

Template Name	Procedures and Interventions – Family Planning version 2 Section
Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11
Parent Template	
General Description	The Procedures and Interventions section shall contain a narrative description of the actions performed by a clinician.
Section Code	29554-3, LOINC, “Procedure”
Author	If not the author from the encompassing context, include author. Role and entity must be specified if not inherited.
Informant	If not the informant from the encompassing context, include informant. Role and entity must be specified if not inherited.
Subject	If not the subject from the encompassing context, include subject. Role and entity must be specified if not inherited.

Opt and Card	Condition	Data Element or Section Name	Template ID	Specification Document	Constraint
Subsections					
Entries					
R [1..*]		Procedures	1.3.6.1.4.1.19376.1.5.3.1.4.19		6.3.3.10.S6.1

6.3.3.10.S6.1 Procedures and Interventions Section Additional Constraints

Within the Procedures and Interventions section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Procedure entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.19 [PCC TF-2]) for each of Pregnancy Counseling, and Contraceptive Counseling procedures which SHALL be present

- Where the negation indicator

  ClinicalDocument/ component/structuredBody/component/section [templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11]]/entry/procedure/negationInd

  Is present and set to True (1) to indicate the procedure did not take place, and absent if the procedure did take place

- And where the procedure code is recorded in

  ClinicalDocument/ component/structuredBody/component/section [templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11]]/entry/procedure/code

Within the Procedures and Interventions – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Procedure entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.19 [PCC TF-2]) for ***HIV Referral***

- encoding the Start date of the referral in

  ClinicalDocument/ component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11]]/entry/procedure/effectiveTime/low

- encoding the End date of the referral in

  ClinicalDocument/ component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11]]/entry/procedure/effectiveTime/high

    - Where …/code[@code='LOINC-13] HIV Referral, LOINC

6.3.3.10.S7 Coded Event Outcomes – Family Planning version 2 Section

Template Name	Coded Event Outcomes – Family Planning version 2 Section
Template ID	1.3.6.1.4.1.19376.1.7.3.1.1.13.7
Parent Template	1.3.6.1.4.1.19376.1.5.3.1.1.21.2.9
General Description	The Coded Event Outcome Section shall include a narrative description of the outcomes following a procedure, an intervention or a problem, and outcomes related to the labor and delivery process such as live birth or stillborn. It shall include entries for observation as described in the Simple Observation entry, or optionally as Problem Entry observations.
Section Code	42545-4, LOINC, "Event Outcome"
Author	If not the author from the encompassing context, include author. Role and entity must be specified if not inherited.
Informant	If not the informant from the encompassing context, include informant. Role and entity must be specified if not inherited.
Subject	If not the subject from the encompassing context, include subject. Role and entity must be specified if not inherited.

Opt and Card	Condition	Data Element or Section Name	Template ID	Specification Document	Constraint
Subsections					
Entries					
R [1..*]		Simple Observation	1.3.6.1.4.1.19376.1.5.3.1.4.13		6.3.3.10.S7.1
R2 [0..*]		Patient Transfer	1.3.6.1.4.1.19376.1.5.3.1.1.25.1.4.1		6.3.3.10.S7.2
O		Problem Entry	1.3.6.1.4.1.19376.1.5.3.1.4.5		

6.3.3.10.S7.1 Observation Constraints

Within the Coded Event Outcomes section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Simple Observation (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.13 [PCC TF-2]) for ***Method of Contraceptive Provisioning***

- encoding the value in

ClinicalDocument/
component/structuredBody/component/section[templateId[@root=1.3.6.1.4.1.19376.1.7.3.1.1.13.7]]/entry/observation/value

- Where the value SHALL be taken from the value set bound to the Concept Domain UV_ProvisioningMethod
  - Where …/code[@code='LOINC-12'] Method of Contraceptive Provisioning.

Within the Coded Event Outcomes – Family Planning version 2 section the Form Receiver CDA Exporter or Content Creator SHALL be able to create a Contraceptive Method Observation –

Family Planning version 2 Entry (1.3.6.1.4.1.19376.1.7.3.1.4.27.2) as described in section 6.3.4.E2.

6.3.4 CDA Entry Content Modules

Add to Section 6.3.4.E Entry Content Modules

6.3.4.E1 Pregnancy Status Observation – Family Planning version 2 Entry Content Module

Table 6.3.4.E1-1: Current Pregnancy Status Observation – Family Planning version 2 Entry

Template Name	Current Pregnancy Status Observation – Family Planning version 2
Template ID	1.3.6.1.4.1.19376.1.7.3.1.4.27.1
Parent Template	Pregnancy Status 1.3.6.1.4.1.19376.1.5.1.4.13.4 [PCC TF-2]
General Description	This is an observation for recording whether or not the patient is currently pregnant, and the method by which this pregnancy status was determined.

Class/Mood	Code	Data Type	Value
OBS	11449-6 LOINC, "Pregnancy Status (Reported)" LOINC-3 LOINC, "Pregnancy Status (Finding)	CE	UV_PregnancyStatus

Opt and Card	entryRelationship	Description	Template ID	Specification Document	Vocabulary Constraint
[0..1][6]	SPRT	Pregnancy Status Finding Observation	1.3.6.1.4.1.19376.1.5.3.1.4.13	PCC-TF-2	6.3.4.E1.1 Pregnancy Status Finding

6.3.4.E1.1 Pregnancy Status Finding Constraints

The Pregnancy Status Finding recorded in the entry relationship for the Pregnancy Status SHALL be present for any Pregnancy Status with LOINC code LOINC-3 and SHALL consist of

[6] If the Observation is a finding (LOINC-3 "Pregnancy Status (Finding)" this entry relationship SHALL be present and SHALL contain the lab result used to confirm the pregnancy status.

a Simple Observation recording the laboratory finding used to confirm the patient's pregnancy status. This observation SHOULD come from the list of codes below.

Table 6.3.4.E1.1-1: Pregnancy Tests

LOINC CODE	Description	Type	Units or Vocabulary
2106-3	Choriogonadotropin (pregnancy test) in Urine	BL	N/A
2118-8	Choriogonadotropin (pregnancy test) in Serum or Plasma	BL	N/A
190880-1	Choriogonadotropin in Serum or Plasma	INT	Units/Value
21198-7	Choriogonadotropin beta subunit in Serum or Plasma	INT	Units/Volume
2110-5	Choriogonadotropin beta subunit in Serum or Plasma	BL	N/A
80385-8	Choriogonadotropin in Serum by Rapid immunoassay	BL	N/A

6.3.4.E2 Contraceptive Method Observation – Family Planning version 2 Entry Content Module

Table 6.3.4.E1.1-2: Contraceptive Method Observation – Family Planning version 2 Entry

Template Name	Contraceptive Method Observation – Family Planning version 2
Template ID	1.3.6.1.4.1.19376.1.7.3.1.4.27.2
Parent Template	Pregnancy Status Review Organizer Entry 1.3.6.1.4.1.19376.1.5.3.1.4.22
General Description	This is an observation for recording what type of contraceptive is in use by a patient, and the reason for not using a contraceptive, if not.

Class/Mood	Code	Data Type	Value
OBS	LOINC-6 LOINC, "Contraceptive Method"	CE	UV_ContraceptiveMethod

Opt and Card	entryRelationship	Description	Template ID	Specification Document	Vocabulary Constraint

[0..1] [7]	RSON	Reason for No Contraceptive Observation	1.3.6.1.4.1.19376.1.5.3.1.4.13		6.3.4.E2.1 Reason for No Contraceptive Method

6.3.4.E2.1 Reason for No Contraceptive Observation Constraints

The Reason for No Contraceptive Observation recorded in the entry relationship for the Contraceptive Method Observation SHALL be present for any Contraceptive Method Observation indicating no contraceptive is being used and SHALL consist of a Simple Observation recording the reason no contraceptive is being used. The value for this observation SHALL be taken from the value set bound to the Concept Domain UV_ReasonForNoContraceptive.

6.4 Section not applicable

This heading is not currently used in a CDA document but remains for numbering consistency

Add to Sections 6.5 Value Sets

6.5 FPv2 Value Sets and Concept Domains

UV Concept Domains and Value Sets
Header
UV_ClinicalProviderRole
UV_Ethnicity
UV_Race
Payer Section
UV_InsuranceType
Coded Social History Section
Smoking Status
Pregnancy History
UV_CurrentPregnancyStatus
Pregnancy Status Review Section
UV_PregnancyIntention
UV_SexualActivity

[7] If the value for the Contraceptive Method indicates that there is no contraceptive method being used, the Reason for No Contraceptive Observation SHALL be present.

UV Concept Domains and Value Sets
UV_ContraceptiveType
UV_ReasonForNoContraceptive
UV_ProvisioningMethod
Coded Results
UV_CervicalCancerTests
UV_HPVTests
UV_ChlamydiaTests
UV_GonorrheaTests
UV_HIVTests

6.5.1 UV_ClinicalProviderRole

This Concept Domain holds a list of coded results for the Role of the Provider in the encounter. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_ClinicalProviderRole (see Table 6.5.1-1).

Table 6.5.1-1: US_ClinicalProviderRole Value Set

Concept	SNOMED Code
Doctor (MD/DO)	SNOMED-1
Registered Nurse (RN)	SNOMED-2
Nurse Midwife (CNM/CM)	SNOMED-3
Nurse Practitioner (NP)	SNOMED-4
Physician Assistant (PA)	SNOMED-5
Other	SNOMED-6

6.5.2 UV_Ethnicity

This Concept Domain holds a list of coded values for the Ethnicity of a person. The Default Binding for this Concept Domain is to be bound to the value set 2.16.840.1.113883.1.11.15836 Ethnicity.

6.5.3 UV_Race

This Concept Domain holds a list of coded values for the Race of a person. The Default Binding for this Concept Domain is to be bound to the value set 2.16.840.1.113883.1.11.14914 Race.

6.5.4 UV_InsuranceCoverage

This Concept Domain holds a list of coded values for type of insurance coverage provided by a payer. The Default Binding for this Concept Domain is to be bound to the value set 2.16.840.1.113883.3.88.12.3221.5.2 Health Insurance Type

6.5.5 UV_CurrentPregnancyStatus

This Concept Domain contains a list of coded values describing the current pregnancy status of a patient. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_PregnancyStatus (see Table 6.5.5-1).

Table 6.5.5-1: US_PregnancyStatus Value Set

Concept Name	SNOMED-CT Code
Pregnant	77386006
Not Pregnant	60001007

6.5.6 UV_PregnancyIntention

This Concept Domain contains a list of coded values describing the patient's intentions towards becoming pregnant in the next year. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_PregnancyIntention (See Table 6.5.6-1).

Table 6.5.6-1: US_PregnancyIntention Value Set

Concept Name	SNOMED Code
Yes	SNOMED-11
No	SNOMED-11
Unsure	SNOMED-11
OK Either way	SNOMED-11

6.5.7 UV_ContraceptiveMethod

This Concept Domain contains a list of coded values describing types of contraceptive. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_ContraceptiveMethod (see Table 6.5.7-1).

Table 6.5.7-1: US_ContraceptiveMethod Value Set

Concept Name	SNOMED Code
Implantable Rod	SNOMED-15
IUD with Progestin	SNOMED-16

Concept Name	SNOMED Code
IUD Copper	SNOMED-17
IUD Unspecified	SNOMED-18
Female sterilization	SNOMED-19
Vasectomy	SNOMED-20
Injectables	SNOMED-21
Combined Oral Contraceptive Pills	SNOMED-22
Progestin Only Contraceptive Pills	SNOMED-23
Contraceptive Patch	SNOMED-24
Vaginal Ring	SNOMED-25
Male Condom	SNOMED-26
Diaphragm or cervical cap	SNOMED-27
Female condom	SNOMED-28
Withdrawal	SNOMED-29
Spermicide	SNOMED-30
Sponge	SNOMED-31
Fertility Awareness based methods	SNOMED-32
Lactational amenorrhea method	SNOMED-33
Male relying on female method	SNOMED-34
Emergency contraception	SNOMED-35
Declined to answer	SNOMED-36
None	SNOMED-37

6.5.8 UV_ReasonForNoContraceptive

This Concept Domain contains a list of coded values describing the patient's reason for not using a contraceptive method. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_ReasonForNoContraceptive (see Table 6.5.8-1).

Table 6.5.8-1: US_ReasonForNoContraceptive Value Set

Concept Name	SNOMED Code
Pregnant	SNOMED-XX
Abstinence	SNOMED-38
Other	SNOMED-39
Sterile for non-contraceptive reasons	SNOMED-40
Seeking pregnancy	SNOMED-41
Same sex partner	SNOMED-42

6.5.9 UV_ProvisioningMethod

This Concept Domain contains a list of coded values describing how contraceptives are provisioned. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_ProvisioningMethod (See Table 6.5.9-1).

Table 6.5.9-1: US_ProvisioningMethod Value Set

Concept Name	SNOMED Code
Provided on site	SNOMED-38
Referral	SNOMED-39
Prescription	SNOMED-40

6.5.10 UV_CervicalCancerTests

This Concept Domain contains a list of coded values for tests used to detect Cervical Cancer. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_CervicalCancerTests (See Table 6.5.10-1).

Table 6.5.10-1: US_CervicalCancerTests Value Set

Concept	LOINC CODE
Microscopic observation [Identifier] in Cervix by Cyto stain	10524-7
Microscopic observation [Identifier] in Cervix by Cyto stain.thin prep	18500-9
Microscopic observation [Identifier] in Cervical or vaginal smear or scraping by Cyto stain	19765-7
Microscopic observation [Identifier] in Cervical or vaginal smear or scraping by Cyto stain Narrative	19766-5
Cytology study comment Cervical or vaginal smear or scraping Cyto stain	19774-9
Cytology Cervical or vaginal smear or scraping study	33717-0
Cytology report of Cervical or vaginal smear or scraping Cyto stain.thin prep	47527-7
Cytology report of Cervical or vaginal smear or scraping Cyto stain	47528-5
General categories [Interpretation] of Cervical or vaginal smear or scraping by Cyto stain	19762-4
Statement of adequacy [Interpretation] of Cervical or vaginal smear or scraping by Cyto stain	19764-0

6.5.11 UV_HPVTests

This Concept Domain contains a list of coded values for tests to be used to detect HPV. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_HPVTests (See Table 6.5.11-1).

Table 6.5.11-1: US_HPVTests Value Set

Concept	LOINC CODE
Human papilloma virus 16+18+31+33+35+39+45+51+52+56+58+66 DNA [Presence] in Tissue by DNA probe	73959-9
Human papilloma virus rRNA [Presence] in Unspecified specimen by Probe and target amplification method	6516-9
Human papilloma virus identified in Cervix	11083-3
Human papilloma virus 16+18 Ag [Presence] in Cervix	14503-7
Human papilloma virus 16+18 Ag [Presence] in Vaginal fluid	14504-5
Human papilloma virus 16+18 Ag [Presence] in Urethra	14506-0
Human papilloma virus 16+18 Ag [Presence] in Genital specimen	12223-4
Human papilloma virus 6+11+16+18+31+33+35+39+42+43+44+45+51+52+56+58+59+68 DNA [Presence] in Cervix by Probe and signal amplification method	38372-9
Human papilloma virus rRNA [Presence] in Genital specimen by Probe and target amplification method	6514-4
Human papilloma virus 16+18 Ag [Presence] in Unspecified specimen	17400-3
Human papilloma virus 16+18+31+33+35+45+51+52+56 DNA [Presence] in Cervix by DNA probe	21440-3
Human papilloma virus DNA [Presence] in Cervix by DNA probe	44550-2
Human papilloma virus 16+18+31+33+35+39+45+51+52+56+58+59+68 DNA [Presence] in Cervix by Probe and signal amplification method	30167-1
Human papilloma virus 16+18+31+33+35+39+45+51+52+56+58+59+66+68 DNA [Presence] in Cervix by Probe and signal amplification method	59420-0
Human papilloma virus 16+18+31+33+35+39+45+51+52+56+58+59+68 DNA [Presence] in Unspecified specimen by Probe and target amplification method	49896-4
Human papilloma virus E6+E7 mRNA [Presence] in Cervix by Probe and target amplification method	69002-4

6.5.12 UV_ChlamydiaTests

This Concept Domain contains a list of coded values for tests to be used to detect Chlamydia. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_ChlamydiaTests (See Table 6.5.12-1).

Table 6.5.12-1: US_ChlamydiaTests Value Set

Concept	LOINC CODE
Chlamydia trachomatis DNA [Presence] in Urine by Probe and target amplification method	6357-8
Chlamydia trachomatis DNA [Presence] in Genital specimen by Probe and target amplification method	6356-0
Chlamydia trachomatis rRNA [Presence] in Vaginal fluid by Probe and target amplification method	53926-2
Chlamydia trachomatis rRNA [Presence] in Urethra by Probe and target amplification method	53925-4

Concept	LOINC CODE
Chlamydia trachomatis rRNA [Presence] in Cervix by Probe and target amplification method	50387-0
Chlamydia trachomatis rRNA [Presence] in Unspecified specimen by DNA probe	4993-2
Chlamydia trachomatis DNA [Units/volume] in Unspecified specimen by Probe and target amplification method	49096-1
Chlamydia trachomatis DNA [Identifier] in Unspecified specimen by Probe and target amplification method	47212-6
Chlamydia trachomatis L2 DNA [Presence] in Unspecified specimen by Probe and target amplification method	47211-8
Chlamydia trachomatis DNA [Presence] in Vaginal fluid by Probe and target amplification method	45084-1
Chlamydia trachomatis rRNA [Presence] in Vaginal fluid by DNA probe	45080-9
Chlamydia trachomatis rRNA [Presence] in Cervix by DNA probe	45078-3
Chlamydia trachomatis DNA [Presence] in Unspecified specimen by Probe and signal amplification method	43404-3
Chlamydia trachomatis rRNA [Presence] in Unspecified specimen by Probe and target amplification method	43304-5
Chlamydia trachomatis rRNA [Presence] in Urine by Probe and target amplification method	42931-6
Chlamydia trachomatis rRNA [Presence] in Genital fluid by DNA probe	23838-6
Chlamydia trachomatis DNA [Presence] in Unspecified specimen by Probe and target amplification method	21613-5
Chlamydia trachomatis rRNA [Presence] in Urethra by DNA probe	21192-0
Chlamydia trachomatis DNA [Presence] in Urethra by Probe and target amplification method	21191-2
Chlamydia trachomatis DNA [Presence] in Cervix by Probe and target amplification method	21190-4
Chlamydia trachomatis DNA [Presence] in Cervical mucus by Probe and target amplification method	21189-6
Chlamydia trachomatis rRNA [Presence] in Urine by DNA probe	16601-7
Chlamydia trachomatis rRNA [Presence] in Genital specimen by DNA probe	16600-9
Chlamydia sp DNA [Presence] in Unspecified specimen by Probe & target amplification method	35729-3
Chlamydia trachomatis DNA [Presence] in Urine by Probe and target amplification method	6357-8
Chlamydia trachomatis DNA [Presence] in Genital specimen by Probe and target amplification method	6356-0
Chlamydia trachomatis rRNA [Presence] in Vaginal fluid by Probe and target amplification method	53926-2
Chlamydia trachomatis rRNA [Presence] in Urethra by Probe and target amplification method	53925-4
Chlamydia trachomatis rRNA [Presence] in Cervix by Probe and target amplification method	50387-0
Chlamydia trachomatis rRNA [Presence] in Unspecified specimen by DNA probe	4993-2
Chlamydia trachomatis DNA [Units/volume] in Unspecified specimen by Probe and target amplification method	49096-1
Chlamydia trachomatis DNA [Identifier] in Unspecified specimen by Probe and target amplification method	47212-6
Chlamydia trachomatis L2 DNA [Presence] in Unspecified specimen by Probe and target amplification method	47211-8

Concept	LOINC CODE
Chlamydia trachomatis DNA [Presence] in Vaginal fluid by Probe and target amplification method	45084-1
Chlamydia trachomatis rRNA [Presence] in Vaginal fluid by DNA probe	45080-9
Chlamydia trachomatis rRNA [Presence] in Cervix by DNA probe	45078-3
Chlamydia trachomatis DNA [Presence] in Unspecified specimen by Probe and signal amplification method	43404-3
Chlamydia trachomatis rRNA [Presence] in Unspecified specimen by Probe and target amplification method	43304-5
Chlamydia trachomatis rRNA [Presence] in Urine by Probe and target amplification method	42931-6
Chlamydia trachomatis rRNA [Presence] in Genital fluid by DNA probe	23838-6
Chlamydia trachomatis DNA [Presence] in Unspecified specimen by Probe and target amplification method	21613-5
Chlamydia trachomatis rRNA [Presence] in Urethra by DNA probe	21192-0
Chlamydia trachomatis DNA [Presence] in Urethra by Probe and target amplification method	21191-2
Chlamydia trachomatis DNA [Presence] in Cervix by Probe and target amplification method	21190-4
Chlamydia trachomatis DNA [Presence] in Cervical mucus by Probe and target amplification method	21189-6
Chlamydia trachomatis rRNA [Presence] in Urine by DNA probe	16601-7
Chlamydia trachomatis rRNA [Presence] in Genital specimen by DNA probe	16600-9
Chlamydia sp DNA [Presence] in Unspecified specimen by Probe & target amplification method	35729-3
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Unspecified specimen by DNA probe	45076-7
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Urine by DNA probe	45074-2
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Vaginal fluid by DNA probe	45070-0
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Genital specimen by DNA probe	45069-2
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Cervix by Probe and target amplification method	45068-4
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Cervix by DNA probe	45067-6
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Genital specimen by Probe and target amplification method	44807-6
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Urine by Probe and target amplification method	44806-8
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Unspecified specimen by Probe and signal amplification method	43406-8
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Identifier] in Unspecified specimen by Probe and target amplification method	36903-3
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Unspecified specimen by Probe and target amplification method	36902-5

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6.5.13 UV_GonorrheaTests

This Concept Domain contains a list of coded values for tests to be used to detect Gonorrhea. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD) US_GonorrheaTests (See Table 6.5.13-1).

1215 **Table 6.5.13-1: US_GonorrheaTests Value Set**

Concept	LOINC CODE
Neisseria gonorrhoeae [Presence] in Unspecified specimen by Organism specific culture	698-1
Neisseria gonorrhoeae [Presence] in Vaginal fluid by Organism specific culture	693-2
Neisseria gonorrhoeae [Presence] in Genital lochia by Organism specific culture	692-4
Neisseria gonorrhoeae [Presence] in Genital specimen by Organism specific culture	691-6
Neisseria gonorrhoeae [Presence] in Cervix by Organism specific culture	688-2
Neisseria gonorrhoeae Ag [Presence] in Genital specimen by Immunoassay	6487-3
Neisseria gonorrhoeae rRNA [Presence] in Urethra by Probe and target amplification method	53927-0
Neisseria gonorrhoeae rRNA [Presence] in Vaginal fluid by Probe and target amplification method	53879-3
Neisseria gonorrhoeae rRNA [Presence] in Cervix by Probe and target amplification method	50388-8
Neisseria gonorrhoeae rRNA [Presence] in Unspecified specimen by DNA probe	5028-6
Neisseria gonorrhoeae DNA [Presence] in Genital specimen by Probe and target amplification method	47387-6
Neisseria gonorrhoeae DNA [Presence] in Unspecified specimen by Probe and signal amplification method	43403-5
Neisseria gonorrhoeae rRNA [Presence] in Unspecified specimen by Probe and target amplification method	43305-2
Neisseria gonorrhoeae DNA [Presence] in Vaginal fluid by Probe and target amplification method	32705-6
Neisseria gonorrhoeae rRNA [Presence] in Urethra by DNA probe	32199-2
Neisseria gonorrhoeae rRNA [Presence] in Cervix by DNA probe	32198-4
Neisseria gonorrhoeae DNA [Presence] in Unspecified specimen by Probe and target amplification method	24111-7
Neisseria gonorrhoeae DNA [Presence] in Urine by Probe and target amplification method	21416-3
Neisseria gonorrhoeae DNA [Presence] in Urethra by Probe and target amplification method	21415-5
Neisseria gonorrhoeae DNA [Presence] in Cervical mucus by Probe and target amplification method	21414-8
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Unspecified specimen by DNA probe	45076-7
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Urine by DNA probe	45074-2
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Vaginal fluid by DNA probe	45070-0
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Genital specimen by DNA probe	45069-2
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Cervix by Probe and target amplification method	45068-4
Chlamydia trachomatis+Neisseria gonorrhoeae rRNA [Presence] in Cervix by DNA probe	45067-6

Concept	LOINC CODE
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Genital specimen by Probe and target amplification method	44807-6
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Urine by Probe and target amplification method	44806-8
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Unspecified specimen by Probe and signal amplification method	43406-8
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Identifier] in Unspecified specimen by Probe and target amplification method	36903-3
Chlamydia trachomatis+Neisseria gonorrhoeae DNA [Presence] in Unspecified specimen by Probe and target amplification method	36902-5

6.5.14 UV_HIVTests

This Concept Domain contains a list of coded values for tests to be used to detect HIV. The Default Binding for this Concept Domain is to be bound to the value set (OID TBD)
1220 US_HIVTests (See Table 6.5.14-1).

Table 6.5.14-1: US_HIVTests Value Set

Concept	LOINC CODE
HIV 1+2 Ab [Presence] in Serum or Plasma by Immunoassay	31201-7
HIV 1 RNA [Log #/volume] in Serum or Plasma by Probe & target amplification method detection limit = 1.7 log copies/mL	48510-2
HIV 1 RNA [#/volume] in Serum or Plasma by Probe & target amplification method detection limit = 50 copies/mL	48511-0
HIV 1 RNA [Presence] in Unspecified specimen by Probe & target amplification method	5018-7
HIV 1 Ab [Presence] in Serum by Immunoblot (IB)	5221-7
HIV 2 Ab [Presence] in Serum by Immunoassay	30361-0
HIV 1 Ab [Presence] in Serum, Plasma or Blood by Rapid immunoassay	68961-2

Appendices

None

Volume 3 Namespace Additions

Add the following terms to the IHE Namespace:

None

Volume 4 – National Extensions

Add appropriate Country section

4 National Extensions

4.I National Extensions for US Realm

The national extensions documented in this section shall be used in conjunction with the Family Planning (FP) Profile. See QRPH TF-1: X and QRPH TF-3: 6.3.1.D1.

The Title X Family Planning program, administered by the United States Department of Health and Human Services (DHHS) Office of Population Affairs (OPA), is the only federal program solely dedicated to the provision of contraceptive services and related preventive health services in the United States. The purpose of a family planning encounter is to provide family planning and related preventive health services to female and male clients who want to avoid unintended pregnancies or achieve intended pregnancies. Currently key performance and utilization data on approximately 5 million clients seen in 4,200 family planning clinical settings annually are assessed through a siloed, aggregate reporting system with a long time lag. Reporting sites also use a variety of paper and electronic methods to maintain data and then submit performance and utilization reports. OPA would like to move to an encounter-level reporting system with closer to real-time data submission that can improve the networks' ability to monitor data submissions and data quality and can improve the quality of family planning services through standard assessment and performance metric feedback. There are also method effectiveness measures that are being pilot tested for eventual submission to the National Quality Forum for consideration as an NQF-endorsed health quality outcome measure. Data capture about some FP methods and services currently exists in IHE profiles related to post-partum events, but quality data regarding contraceptive methods, STI screening, and pregnancy intention are applicable to a wider patient population.

Finally, OPA is interested in standardizing the way in which pregnancy intention, current contraceptive use, and other variables required for the Family Planning Annual Report (FPAR) is entered into and pulled directly from EMR and Electronic Practice Management (EPM) systems in use by the clinics who receive Title X funding. We envision that the future FPAR system, managed by an intermediary health information technology and services provider, will therefore need to be an exchange system requiring interoperability with the multitude of EMR and EPM systems in use in a diverse, national network.

This section includes extensions and restrictions to effectively support the regional practice of healthcare in the United States.

4.I.1 Comment Submission

This national extension document was authored under the sponsorship and supervision of Title X, who welcome comments on this document. Comments should be directed to:

US Department of Health and Human Services

Office of Population Affairs

Emily Dekkar

1101 Wootton Parkway, Suite 700

Rockville, MD 20852

mailto:emily.dekkar@hhs.gov

4.I.2 Family Planning version 2 (FPv2)

All requirements of the Family Planning Profile in the US Realm are as specified in QRPH TF-1: X and QRPH TF-3: 6.3.1.D1 with the exception of those listed below. Due to the anticipated excess burden of reporting negative HIV screening results in areas of low prevalence, only positive tests are required reporting in the Title X Family Planning Annual Report.

4.I.2.1 FPv2 Additional Content Module Specifications

Table 4.I.2.1-1: FPv2 Document Content Module Specification

Template Title	Opt and Card	Condition	Template Type	templateId	Vocabulary Constraints
Family Planning version 2 Content	R[1..1]		document	TBD	
Clinical Provider Identifier (NPI)	[1..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	4.I.2.2.1
Clinical Provider Identifier (Other)	[0..*]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	4.I.2.2.1
Ethnicity	[1..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	
Race	[1..*]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	
Language of Communication	[1..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	4.I.2.2.2
Language Proficiency	[1..1]		Header	1.3.6.1.4.1.19376.1.5.3.1.1.1	
Coded Social History Section	[1..1]		Section	1.3.6.1.4.1.19376.1.7.3.1.3.24.2	4.I.2.3
Smoking Status	[1..1]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.13.4	4.I.2.3.1
Payers Section	[1..1]		Section	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7	4.I.2.4
Insurance Coverage Type	[1..*]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.18	4.I.2.4.1
Visit Payer	[1..*]		Entry	1.3.6.1.4.1.19376.1.5.3.1.4.18	4.I.2.4.2

4.I.2.2 Family Planning Header Additional Constraints

4.I.2.2.1 Clinical Provider ID Additional Constraints

For the purposes of Family Planning reporting in the US Realm, one of the values recorded for the Clinical Provider Identifier in ClinicalDocument/componentOf/encompassingEncounter/responsibleParty/assignedEntity/id

SHALL be the National Provider Identifier (NPI). Other identifiers may also be recorded if available.

4.I.2.2.2 Language of Communication Additional Constraints

For the purposes of Family Planning reporting in the US Realm, the value recorded for the Language of Communication in ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/languageCode

SHALL be set to “en-US’.

4.I.2.3 Coded Social History - Family Planning version 2 Section

4.I.2.3.1 Smoking Status Observation Additional Constraints

Within the Coded Social History section the Form Receiver CDA Exporter or Content Creator SHALL be able to create an entry conformant with the Consolidated CDA Smoking Status Observation (templateID 2.16.840.1.113883.10.20.22.4.78 [C-CDA R1.1])

reflecting the ***Smoking Status*** in

- encoding the value in ClinicalDocument/component/structuredBody/component/section[templateId[@root=’1.3.6.1.4.1.19376.1.5.3.1.3.16.1’]]/entry/observation[templateId[@root="2.16.840.1.113883.10.20.22.4.78"]]/value/code and the code SHALL be selected from the value set 2.16.840.1.113883.11.20.9.38 Smoking Status specified in section 4.R1.3.1 US_SmokingStatus.

4.I.2.4 Coded Vital Signs - Family Planning version 2 Section

4.I.2.4.1 Vital Signs Observation Additional Constraints

Where more than one reading is available for diastolic and systolic blood pressure, enter only the most clinically relevant one. If unsure, use the lowest reading.

4.I.2.5 Payers - Family Planning version 2 Section

Template Name	Payers – Family Planning version 2 Section

Template ID		1.3.6.1.4.1.19376.1.7.3.1.3.27.1			
Parent Template		2.16.840.1.113883.10.20.22.2.18			
General Description		The Payers section contains data on the patient's payers, including insurance, self-pay, guarantor, etc.			
Section Code		48768-6, LOINC, "Payer"			
Author		If not the author from the encompassing context, include author. Role and entity must be specified if not inherited.			
Informant		If not the informant from the encompassing context, include informant. Role and entity must be specified if not inherited.			
Subject		If not the subject from the encompassing context, include subject. Role and entity must be specified if not inherited.			
Opt and Card	**Condition**	**Data Element or Section Name**	**Template ID**	**Specification Document**	**Constraint**
Subsections					
Entries					
R [1..1]		Coverage Activity	2.16.840.1.113883.10.20.22.4.60		6.3.3.10.S5.1
R[1..1]		Visit Payer Entry	1.3.6.1.4.1.19376.1.7.3.1.4.27.3		6.3.3.10.S5.2

4.I.2.5.1 Insurance Type Observation Additional Constraints

Within the Payers section the Form Receiver CDA Exporter or Content Creator SHALL be able to create an entry conformant with the Consolidated CDA Coverage Activity (templateID 2.16.840.1.113883.10.20.22.4.60 [C-CDA R1.1])

reflecting the ***Insurance Type*** in

- encoding the value in ClinicalDocument/component/structuredBody/component/section[templateId[@root='2.16.840.1.113883.10.20.22.2.18']]/entry/act[templateId[@root="2.16.840.1.113883.10.20.22.4.60"]]/entryRelationship/act[templateId[@root="2.16.840.1.113883.10.20.22.4.61"]]/code/code and the code SHALL be selected from the value set (OID TBD) US_InsuranceType specified in section 4.R1.3.1 US_InsuranceType.

4.I.2.5.2 Visit Payer Additional Constraints

Within the Payers section the Form Receiver CDA Exporter or Content Creator SHALL be able to create an entry conformant with the IHE Payer Entry (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.18 [PCC TF-2]) except as follows:

The Visit Payer entry will reflect the ***Visit Payer***

- encoding the value in ClinicalDocument/component/structuredBody/component/section[templateId[@root=’2.16.840.1.113883.10.20.22.2.18’]]/entry/act/performer/code and the code SHALL be selected from the value set OID TBD US_Payers
- where ClinicalDocument/component/structuredBody/component/section[templateId[@root=’2.16.840.1.113883.10.20.22.2.18’]]/entry/act/code[@code=’LOINC-9] Visit Payer, LOINC

4.I.3 FP Value Set Binding for US Realm Concept Domains

UV Concept Domain	US Realm Vocabulary Binding or Single Code Binding	Value Set OID
Coded Social History Section		
	US_Smoking Status	2.16.840.1.113883.11.20.9.38
Payers Section		
UV_InsuranceCoverage	US_InsuranceCoverage	OID TBD
UV_Payers	US_Payers	OID TBD

4.I.3.1 US_SmokingStatus (2.16.840.1.113883.11.20.9.38)

This value set holds a list of values for smoking status for use in Family Planning in the US Realm.

4.I.3.2 US_InsuranceCoverage (OID TBD)

This value set holds the list of values for payer type for use in Family Planning. Selection of codes based on reported insurance coverage, billing, and client confidentiality as well as summarization of more detailed codes to this value set are described in Title X program requirements and instructions.

Table 4.I.3.2-1: US_InsuranceCoverage Value Set

Concept	SNOMED Code
Uninsured	SNOMED-7
Public Insurance	SNOMED-8
Private Insurance	SNOMED-9
Unknown	SNOMED-10

4.I.3.3 US_Payers (OID TBD)

This value set holds the list of values for payer type for use in Family Planning. Selection of codes based on reported insurance coverage, billing, and client confidentiality as well as summarization of more detailed codes to this value set are described in Title X program requirements and instructions.

Concept Name	SNOMED Code
Clinic covered/confidential	SNOMED-51
Medicaid	SNOMED-52
Self-pay	SNOMED-53
Private/group	SNOMED-54
Medicare	SNOMED-55
CHIP	SNOMED-56
Veteran/Military	SNOMED-57
Other public	SNOMED-58
Unavailable/Unknown	SNOMED-59

Appendix A – De-Identification for Family Planning

This appendix provides the US realm specific de-identification algorithms for the IHE QRPH Family Planning CDA data elements.

For an understanding of how these algorithms were selected, please see the supporting whitepaper entitled "IHE ITI Whitepaper Analysis of Optimal De-Identification Algorithms for Family Planning Data Elements". As per the whitepaper, we are assuming that de-identification will be performed by an expert third party and individual service sites will not need to do de-identification.

Open Issues and Questions

- Is there a problem with the length of Universally Unique Identifiers (UUIDs)? Probably not, but the Comma Separated Value (CSV) rows will end up being fairly long.

Closed Issues

- What format should be used to publish the de-Identified data? The input data will be received in Clinical Document Architecture (CDA) format. Is CDA format preferred for the de-Identified output?
    - For data elements where the de-identification algorithm transforms the data element away from its original data type, is it possible to transmit the new data type in CDA? *This is not possible using base CDA, an extension would need to be defined.*
    - Defining a CDA extension for this data set is not worth the effort that this will impose on users and implementers. Due to the small number of de-identification points anticipated, and the use of CSV formats for analysis, CSV format is preferred.
- For data elements that may be either a string or a number, can we leave the format as "String or Number" or is that too difficult for implementers? I.e., for visit date where the value may either be "42" for the 42nd week of the year, or "3 visits in week 42":
    - Do you prefer that we leave this as String or Number; or
    - Define this as a String; or
    - Another solution?
        - This issue is closed, as there should only be one Family Planning CDA document per visit, and therefore only one visit date per input CDA document.
- For administrative sex, what happens if a patient's sex changes between encounters as a result of the generalization of "other" sexes to either male or female? Is this too identifiable? Should the CDA entry for "other" simply be redacted?

- Changing “other” to “Female” only will not significantly impact statistical distribution or any of the performance measures that rely on Administrative Sex. Conclusion: Change all entries of “Other” to “Female” when de-Identifying.

- Where should we put the minimums and maximums for height and weight?
  - Min/Max Height is 59 inches to 76 inches
  - Min/Max Weight is 100-299 lbs
  - Decisions based on average height and weight data listed here: ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2010/samadult_freq.pdf

4.R2 De-Identification for Family Planning data

De-Identified family planning data elements are required for performance measurement and federal reporting uses in the US realm. The users involved in those uses are:

- Clinicians who deliver services
- Quality managers or administrators at the site level
- Program managers
- Grant managers
- Regional monitors
- Office of Population Affairs (OPA) Health IT subject matter experts
- 3rd party analysts under contract to OPA

Analysis of these de-identification algorithms indicates that while they substantially reduce the risk of individual disclosure, it is not sufficient to allow the resulting data to be disclosed to a large group of stakeholders. As a result, there will need to be access and security controls on the resulting dataset to limit access to only authorized users, and establish different levels of access for different users.

If a dataset is to be made public and published, additional de-identification steps will be needed.

4.R2.1 Algorithms for the De-Identification of Family Planning data

The information elements in the Family Planning Clinical Document Architecture (CDA) document shall be processed as shown in Table 4.R2.1-1. Each CDA document describing an encounter shall result in a single line in a Comma Separated Value (CSV) file. CSV column and format assignments are described below.

Table 4.R2.1-1: De-identification Algorithms for Family Planning Data

CDA Element	De-identification Algorithm	CSV column number	CSV column format
Facility Identifier	Mapping table (see Section 4.R2.1.1).	1	String
Clinical Provider ID	Mapping table (see Section 4.R2.1.2).	2	String
Clinical Provider Role	Unchanged.	3	String
Visit Date	Generalized to week of year plus indicator of visit order (see Section 4.R2.1.4).	4	String or Number
Patient Identifier	Mapping table (see Section 4.R2.1.3).	5	String
Date of Birth	Convert to age in whole years, with no rounding. For clients over 49, grouped and mapped to "50 or over".	6	String or Number
Administrative Gender	For values of "Male" or "Female" forward the data unchanged. For Administrative Sex values of "other" change them to "Female" (see Section 4.R2.1.5).	7	String
Ethnicity	Only the values "2186-5 Not Hispanic or Latino" or "2135-2 Hispanic or Latino" may be used. Any other input value must be converted to "2186-5 Not Hispanic or Latino".	8	String
Race	Collapse to 5 OMB categories plus Other. For each county, establish which races are below the threshold of 50 people per county. For those races, group them into "Other" (see Section 4.R2.1.7).	9	String
Language of Communication	Unchanged.	10	String
Language Proficiency			
Systolic blood pressure	Unchanged.	11	Number
Diastolic blood pressure	Unchanged.	12	Number
Height	Unchanged, except for values below 59 inches or above 76 inches. For values below 59 inches, convert to 59 inches. For values above 76 inches, convert to 76 inches.	13	Number
Weight	Unchanged, except for values below 100lbs or above 299lbs. For values below 100lbs, convert to 100lbs. For values above 299lbs, convert to 299 lbs.	14	Number
Smoking Status	Unchanged.	15	String
Annual Household Income	Convert to percentage of Federal Poverty Level (FPL) percentage.	16	Number
Household Size			
Insurance Coverage Type	Unchanged	17	String

CDA Element	De-identification Algorithm	CSV column number	CSV column format
Visit Payer	Convert to Public Health Information Network (PHIN) Vocabulary Access and Distribution System (VADS). See the mapping table posted on the FTP site here: ftp://ftp.ihe.net/IT_Infrastructure/iheitiyr13-2015-2016/Technical_Cmte/Workitems/DeIndentification%20of%20Family%20Planning/ReferenceCodes/	18	String
Pregnancy History	Unchanged	19	String
Current Pregnancy Status	Convert to YES/NO/Unknown	20	String
Pregnancy Finding Result	Convert to YES/NO	21	String
Pregnancy Intention	Unchanged.	22	String
Sexual Activity	Unchanged.	23	String
Contraceptive Method at Intake	Unchanged.	24	String39
Reason for no contraceptive method	Unchanged.	25	String
Cervical Cancer Screening Result	Unchanged.	26	String
Cervical Cancer Screening Date	Unchanged.	27	Date
HPV Result	Delete STD reporting will be handled separately.	28	String
HPV Test Date	Delete STD reporting will be handled separately.	29	Date
Chlamydia Result	Delete STD reporting will be handled separately.	30	String
Chlamydia Result Date	Delete STD reporting will be handled separately.	31	Date
Gonorrhea Result	Delete STD reporting will be handled separately.	32	String
Gonorrhea Result Date	Delete STD reporting will be handled separately.	33	Date
HIV Screening Result	Delete STD reporting will be handled separately.	34	String
HIV Screening Result Date	Delete STD reporting will be handled separately.	35	Date
Contraceptive Counseling Provided	Unchanged.	36	Boolean
Pregnancy Counseling Provided	Unchanged.	37	Boolean

CDA Element	De-identification Algorithm	CSV column number	CSV column format
Contraceptive method at Exit	Unchanged.	38	String
Reason for no contraceptive method at exit	Unchanged.	39	String
How was contraceptive method provided	Unchanged.	40	String
HIV Referral Recommended Date	Delete STD reporting will be handled separately.	41	Date
HIV Referral Completed Date	Delete STD reporting will be handled separately.	42	Date
All other elements and attributes.	CDA documents permit additional elements and attributes beyond the minimum specified in a profile. If any such elements or attributes are present, they shall be removed.	-	-

4.R2.1.1 Facility Identifier Mapping Table

A mapping table shall be maintained by the de-identifier that associates a real facility identifier with a pseudonymous identifier. These pseudonyms shall be created as version 4 (random) Universally Unique Identifiers (UUIDs). The Facility Identifiers from the inputted CDA documents shall be converted to the UUIDs from the mapping table and output in the Facility Identifier column in a row in the CSV file.

The de-identifier shall maintain this mapping table under strictest access and security controls. There is no need to share it with any other party.

4.R2.1.2 Clinical Provider ID Mapping Table

A mapping table shall be maintained by the de-identifier that associates a real Clinical Provider identifier with a pseudonymous identifier. These pseudonyms shall be created as version 4 (random) UUIDs. The Clinical Provider Identifiers from the inputted CDA documents shall be converted to the UUIDs from the mapping table and output in the Clinical Provider Identifier column in a row in the CSV file.

The de-identifier shall maintain this mapping table under strictest access and security controls. There is no need to share it with any other party.

4.R2.1.3 Patient Identifier ID Mapping Table

A mapping table shall be maintained by the de-identifier that associates a real Patient Identifier with a pseudonymous identifier. These pseudonyms shall be created as version 4 (random) UUIDs. The Patient Identifiers from the inputted CDA documents shall be 160 converted to the

UUIDs from the mapping table and output in the Patient Identifier column in a row in the CSV file.

The de-identifier shall maintain this mapping table under strictest access and security controls. There is no need to share it with any other party.

4.R2.1.4 Visit Date

Visit dates shall be transformed into an Integer denoting which year, and which week (out of 52 or 53, see ISO 8601) of the year the visit date took place on with the addition of a letter indicating the visit order if there are multiple visits that occur in the week. The format shall be yyyyWww-A. For example: 2nd visit of the fifth week of 2014 would be formatted as: 2014W05-B.

Note: This approach relies on there being a separate Family Planning CDA document for each visit, even if there are multiple visits in a day or a week.

4.R2.1.5 Administrative Sex

Administrative Sex is not a clinical or genetic statement; it is used for administrative purposes.

Where Administrative Sex is Male or Female in the input CDA document, this value shall be forwarded without modification.

Where Administrative Sex is listed as “other” this value shall be de-Identified by converting the values to “Female”.

4.R2.1.6 Limited English Proficiency (Language)

The two CDA entries for language (Language of Communication, Language Proficiency) shall be collapsed into one value, either LEP TRUE or LEP FALSE.

The value shall be LEP TRUE for Limited English Proficiency in the US according to the following derivation rules:

- IF LanguageCommunication.LanguageCode=Eng AND LanguageCommunication.LanguageProficiency=Poor THEN LimitedEnglishProficiency=TRUE

In English terms, this means:

- If the Language of Communication is English AND the Limited English Proficiency is true, then the LEP value is TRUE; or

Otherwise, LEP FALSE shall be used.

4.R2.1.7 Race

All values for Race from the Input CDA document that are not one of the 5 OMB categories below shall be converted to the most appropriate of the following categories:

- 1002-5 American Indian or Alaska Native
- 2028-9 Asian
- 2054-5 Black or African American
- 2076-8 Native Hawaiian or Other Pacific Islander
- 2106-3 White

Where one of the above categories contains fewer than 50 clients per region over the course of a year, convert all values for that category to:

- 2131-1 UNK Other Race

Please note that CCDA allows for reporting of two or more races. If two or more races are reported, de-identify each one as above.

4.R2.2 Example of De-Identified Family Planning Data

JB is a 16-year-old G-0 P-0 in the clinic for STI screening and well woman exam. Last menstrual period (LMP) was 3 weeks ago. No history of STI. BP: 110/75. Height: 157.5 cm. Weight: 58 kg. Intermittent condom use. Last unprotected sex was 2 weeks ago after which she used oral emergency contraception. Since JB's condom use is only intermittent and emergency contraception is not an effective method, her method at intake is listed as "none". Wants to have children "at some point, but no time soon". Wants to use pills for contraception going forward. Non-smoker. Rapid HIV test is negative. Post visit, chlamydia results are positive and gonorrhea results are negative. No insurance can be billed at the time of the visit. Demographics: White, native US English speaker. JB's household size is 3, and her family's annual income is $9000 therefore the Income for JB is approximately 44% of the Federal Poverty Level (see ASPE here: http://aspe.hhs.gov/2015-poverty-guidelines#guidelines).

Visit date: 22 Dec 2014

Geographic location: HHS Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee)

Data Element	Original Data	Data after application of de-identification
Facility identifier	[facility ID and address from service site, but from HHS Region 4]	[Mapped facility ID = 111-111]
Clinical Provider ID	[provider ID from service siteservice site]	[Mapped Provider ID = 222-222]
Clinical Provider Role	Doctor/MD	Doctor/MD
Visit Date	22 Dec 2014	W52 2014
Patient Identifier	[patient ID fromservice site service site]	[Mapped patient ID=333-333]
Date of Birth	5 June 1998	16

Data Element	Original Data	Data after application of de-identification
Administrative Gender	Female	Female
Ethnicity	Not Hispanic or Latina=2186-5	2186-5
Race	White=2106-3	2106-3
Language of Communication	en-US	LEP FALSE
Language Proficiency	Good	
Height	157.5 cm	62 inches
Weight	58 kg	128
Systolic Blood Pressure	110	110
Diastolic Blood Pressure	75	75
Smoking Status	Never smoker=266919005	266919005
Annual Household Income	$9,000	FPL 44%
Household Size	3	DELETED
Insurance	Unknown	Unknown
Visit Payer	No Insurance=NA	NA
Parity	2	2
Gravidity	3	3
Current Pregnancy Status	Not pregnant, by test=2	NO
Pregnancy Finding Result	hCG 3.0 mIU/ml	NO
Pregnancy Intention	No, but maybe in the future	NO
Sexual Activity	True	True
Contraceptive Method at Intake	None=20	Moderate
Reason for No Contraceptive Method at Intake	NULL	NULL
Cervical Cancer Screen Result	NEGATIVE	NEGATIVE
Cervical Cancer Screen Date	22 Dec 2014	2014W52-A
HPV Test Result	NEGATIVE	DELETED
HPV Test Date	22 Dec 2014	DELETED
Chlamydia Rest Result	NEGATIVE	DELETED
Chlamydia Test Date	22 Dec 2014	DELETED
Gonorrhea Test Result	POSITIVE	DELETED
Gonorrhea Test Date	22 Dec 2014	DELETED
HIV Screening Result	NEGATIVE	DELETED
HIV Screening Date	22 Dec 2014	DELETED
Contraceptive Counseling Provided	YES	YES
Pregnancy Counseling Provided	NO	NO
Contraceptive Method at Exit	OCP=7	7
Reason for No Contraceptive Method at Exit	NULL	NULL

Data Element	Original Data	Data after application of de-identification
HIV Referral Date	NULL	DELETE
HIV Referral Completed Date	NULL	DELETE

In an excel spreadsheet, the de-Identified row for the above encounter would look like this:

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8	Column 9	Column 10	Column 11	Column 12	Column 13	Column 14	Column 15	Column 16	Column 17	Column 18	Column 19	Column 20	Column 21	Column 22	Column 23	Column 24	Column 25	Column 26	Column 27	Column 28	Column 29	Column 30
111-111	222-222	333-333	W52 2014	under 18	Female	LEP False	2186-5	2106-3	44	NA	2	3	NO	N	TRUE	Moderately Effective	NULL	7	W52 2014	NULL	W52 2014	W52 2014	W52 2014	NULL	110	75	62	128	266919005
facility id	prov id	patient id	visit date	date of bi	sex	LEP	ethnicity	race	income	payer	Parity	Gravidity	preg stat	preg inte	sexual ac	contraceptive	reason	contrace	pap test	hpv	ct	gc	hiv screen	referal vis	systolic	diastolic	height	weight	smoking

The corresponding comma-delimited (CSV) row for JB's de-Identified family planning encounter is:

```
111-111,222-222,Doctor/MD,2014W52,333-333,Under 18,Female,2186-5,2106-3,LEP FALSE,62,128,110,75,266919005,44,Unknown,NA,2,3,NO,NO,NO,True,20,NULL,NEGATIVE,2014W52-A,YES,NO,7,NULL,NULL,NULL
```

Note: UUIDs for the Facility, Provider and Patient ID are provided as an example only. Correct UUIDs are hexadecimal numbers that are 32 characters long separated by dashes.

Note: The above example should be only one line long, but document formatting splits inappropriately.

