



5 **IHE Quality, Research, and Public Health
Technical Framework Supplement**

10 **Family Planning
(FP)**

15 **Draft for Public Comment**

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25 **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.**

30 This is a supplement to the IHE Quality, Research and Public Health Technical Framework V0.1. 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 June 6, 2014 for public comment. Comments are invited and may be submitted at http://www.ihe.net/QRPH_Public_Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be received by July 5, 2014

35 This supplement describes changes to the existing technical framework documents.

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

<i>Amend Section X.X by the following:</i>
--

40 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: <http://ihe.net>.

45 Information about the IHE IT Infrastructure domain can be found at: http://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://ihe.net/IHE_Process and <http://ihe.net/Profiles>.

50 The current version of the IHE IT Infrastructure Technical Framework can be found at: http://ihe.net/Resources/Technical_Frameworks.

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Introduction to this Supplement

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

185 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).
- 190 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.
- 195 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.
- 200 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
- 205 6. Institute of Medicine (U.S.). Clinical preventive services for women: closing the gaps. Washington, D.C: National Academies Press; 2011.
- 210 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.
- 215 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.

220 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, state, 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, 225 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 some issues are unique to family planning (e.g., 230 patient’s pregnancy intention). 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.

235 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 240 among male patients. 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 245 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 Integration Profile. It is expected that the Form Filler and Form Manager will implement the RFD transaction as specified in the RFD, and this profile does not include any additional constraints or extensions on 250 the RFD transactions.

Open Issues and Questions

1. Ensure contraceptive method data element is displayed according to the tiers of effectiveness to allow for correct handling at granular level.
2. Privacy and confidentiality concerns exist for patients’ whose data are transmitted in the 255 Family Planning RFD. In the future, the Form Filler and Form Receiver will have the burden of ensuring that personal health identifiers are not retained and transmitted using

pseudonymization and deidentification techniques. One deployment pattern may be that the Form Manager and the Form Receiver may reside in the same secure system.

- 260
3. Data from the Family Planning RFD will be used in aggregate reporting to provide performance indicators at a variety of clinical and geographic levels to service delivery sites.
 4. 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?

265 **Closed Issues**

1. Will not confront the Form Processor issue until this is a published actor from an established Technical Framework.
2. Terminology, codes and value sets were initially selected for a variety of concept domains; however, these values were often too specific or not specific enough and thus
270 require a submission to the appropriate authority to enable semantic interoperability.
3. Templates (like the header) are generic enough for international use but are out of date for US use. US standards are too much in flux to attempt cross-committee updates.
4. Form Fillers are expected to provide as much patient information as possible in the pre-pop and not to provide a pre-pop dominated by null flavors in Use Case #2 and #3. Null
275 flavors should be reserved for missing data during data collection in a clinical setting, not as a method to avoid complex programming for fields that are complete in a Form Filler system.
5. Modeling for the location of several data elements: Sexual Activity, Total Pregnancies, Orders, and Last Cervical Cancer Screen could go in Pregnancy Status Review,
280 Pregnancy History, Care Plan or Results. Orders were placed in Care Plan. Total Pregnancies was placed in Pregnancy History Observation.
6. In the US extension, only positive HIV results are expected to be reported. Reporting all negative results is considered excess burden, especially in sites with low background
285 prevalence. This does not preclude the importance of clinical sites providing negative results back to clients.

General Introduction

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

290 Appendix A – Actor Summary Definitions

No new actors.

Appendix B – Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

295 No new transactions

Glossary

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

Glossary Term	Definition
Pregnancy Intention	<p>A patient’s plan or desire to either become pregnant or have a child in the near future or to prevent a future pregnancy. 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:</p> <ul style="list-style-type: none"> - 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	<p>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.</p>

Glossary Term	Definition
Tiers of effective contraception	<p>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.</p> <p>See: Trussell J. Contraceptive Efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar M. <i>Contraceptive Technology: Twentieth Revised Edition</i>. New York NY: Ardent Media, 2011.</p>

Volume 1 – Profiles

Copyright Licenses

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

305 There are no new copyright additions.

X Family Planning (FP) Profile

310 The Family Planning (FP) Profile provides a means to capture information needed for mandated reporting, monitoring and evaluation, and quality improvement initiatives related to family planning service delivery. The FP Profile is a content profile that defines the content of Family Planning information to be exchanged between systems. This profile uses several different mechanisms for capturing and communicating that information:

- Electronic data capture and form submission using the ITI Retrieve Form for Data Capture (RFD),
- 315 • Defined content in CDA documents.

X.1 FP 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://www.ihe.net/Technical_Frameworks (a work in progress).

320 The FP Profile uses actors and transactions from the ITI [RFD Profile](#) that support FP data collection, transformation, and reporting capabilities.

Figure X.1-1 shows the actors directly involved and their relevant transactions between them. Actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

325

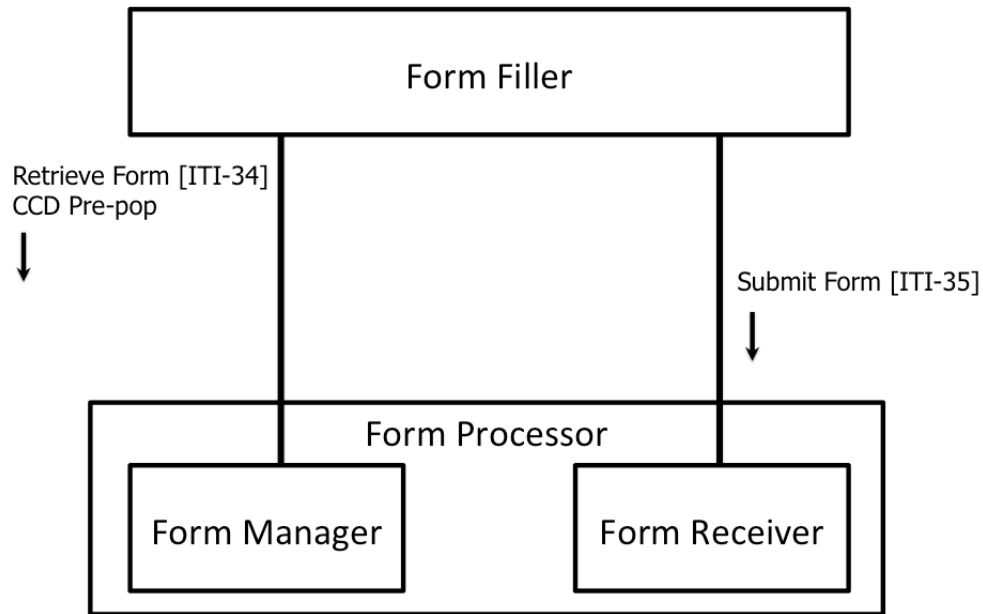


Figure X.1-1: FP Actor Diagram

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.

330

Table X.1-1 lists the transactions for each actor directly involved.

335

Table X.1-1: FP 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]	O	ITI TF-2b: 3.34
	Submit Form [ITI-35]	O	ITI TF-2b: 3.35

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

Actors	Content Modules	Optionality	Reference
Form Filler	1.3.6.1.4.1.19376.1.5.3.1.1.24	O	FP Volume 3
Form Manager	1.3.6.1.4.1.19376.1.5.3.1.1.24	R	FP Volume 3
Form Processor	1.3.6.1.4.1.19376.1.5.3.1.1.24	O	FP Volume 3

X.1.1 Actor Descriptions and Actor Profile Requirements

340 Most requirements are documented in Transactions (Volume 2) and 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. The Form Filler SHALL support XHTML and SHALL NOT support XFORMS of the Retrieve Form transaction (RFD ITI TF 2b: 3.34.4.2.3.2).

345 The Form Filler MAY support the Family Planning Pre-pop Option using a Family Planning Pre-pop document (1.3.6.1.4.1.19376.1.5.3.1.1.24) with the Retrieve Form transaction ITI-34.

X.1.1.2 Form Manager

The Form Manager is defined in the ITI RFD Profile. The Form Manger SHALL support XHTML.

350 The system fulfilling this role SHALL accept pre-pop data in the form of content defined by the Family Planning Document (FP) (1.3.6.1.4.1.19376.1.5.3.1.1.24) and return a form that has been appropriately pre-populated based on the mapping rules specified in this document (V3 6.3.1.D.4 Data Element Requirement Mappings for Form Pre-Population).

X.1.1.3 Form Receiver

355 The Form Receiver is defined in the ITI RFD Profile. 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. No further requirements are placed on the Form Processor within the scope of this profile.

X.2 FP Actor Options

FP Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1. Dependencies between options when applicable are specified in notes.

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

Actor	Option Name	Reference
Form Filler	Family Planning Pre-pop	X.2.1
Form Manager	None	--
Form Receiver	None	--
Form Processor	None	--

365 **X.2.1 Form Filler Family Planning Pre-Pop Option**

A Form Filler implementing the Family Planning Pre-pop Option SHALL supply a Family Planning Pre-pop document when initiating the Retrieve Form (ITI-34) transaction. The pre-pop element in RFD SHALL NOT be nil.

X.3 FP Required Actor Groupings

370 There are no additional required groupings with actors.

X.4 FP Overview

375 Family Planning services provide individuals and couples with the information and means to exercise personal choice in determining the number, spacing, and timing of the births of children, 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

380 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

385 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 with one of the lesser effective methods. The clinician has missed an important clinical assessment of other health factors, and the patient may return a short time later

390 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 typically report to clinics seeking STI screening. This is an opportunity to conduct STI

395 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.

400 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

405 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.

410 EMR systems do not typically provide a method to capture pregnancy intention as structured data, thus a clinician may not discuss or record the patient’s pregnancy plans or consider whether the contraceptive method aligns with the patient’s desires. The location of EMR templates also generates confusion and interrupts workflow for clinical providers, resulting in a time-consuming attempt to enter information or simply skipping the assessment or documentation of

415 contraceptive needs of a patient.

The benefit of creating a standardized Family Planning Profile would be to ensure that this important data is collected among reproductive-age patients in a systematic, structured, and more easily-extractable way. The ability to use EMR data to more accurately measure these variables would enable better estimates of the cost of unplanned pregnancies, the benefits of family

420 planning services, 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

425 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 FP Concepts

The Family Planning (FP) Profile will define structured data capture in forms to facilitate

430 interoperable exchange of information important for program reporting requirements, measurement of clinical quality, and monitoring and evaluation of family planning programs.

Similar Public Health interoperability challenges have been addressed using the IHE IT Infrastructure (ITI) committee’s Retrieve Form for Data Capture (RFD) when the solution to information needs of myriad stakeholders with diverse information systems infrastructure is a

435 standards-based, content-specific mechanism for structured data capture. The RFD can be used with a wide variety of EMRs currently in use. The RFD 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 RFD can eventually contribute to important social, behavioral, and medication information to Medical Summaries

440 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

445 A patient presents for a health 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 patient 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.

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

X.4.2.1.1 Use Case Description

455 A system implementing the Form Filler interacts with a Form Manager to provide a mechanism that allows users of the Form Filler system to manually enter structured data described in the Family Planning form. A patient 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 Family Planning 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 Family Planning document.

X.4.2.1.2.2 Main Flow

465 The Form Filler requests the family planning form.

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

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

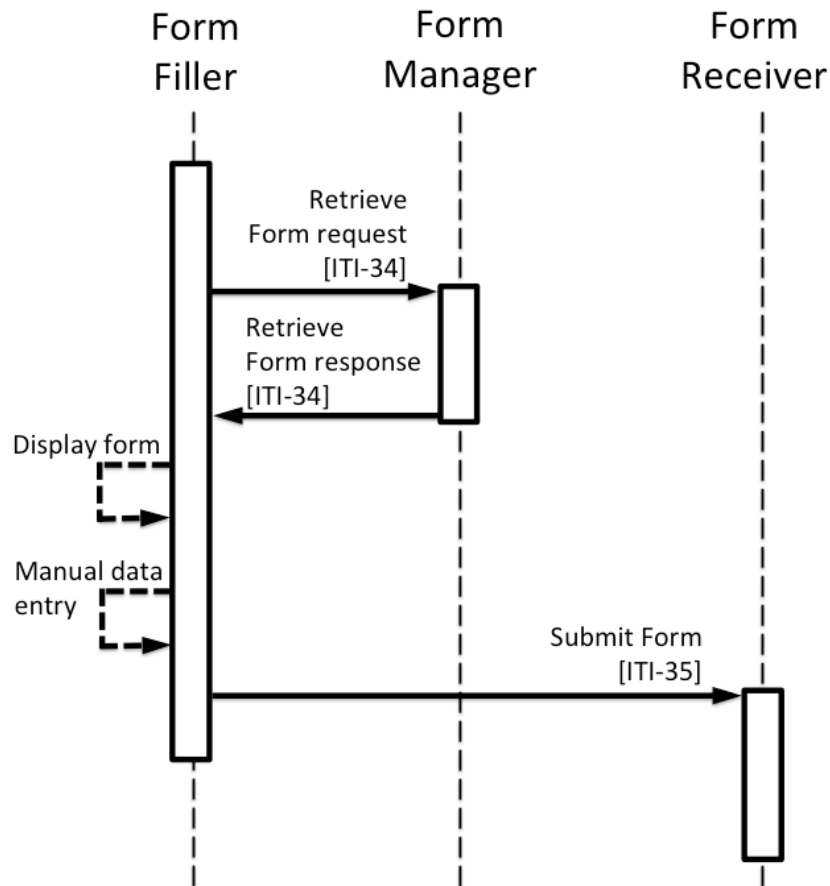


Figure X.4.2.1.1-2: Process Flow Diagram for Manual Data Entry

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

475 X.4.2.2.1 Use Case Description

A system implementing the Form Filler interacts with a Form Manager to provide a mechanism that allows users of the Form Filler system to provide data needed to populate a Family Planning form. To minimize data entry, the Form Filler may provide a Family Planning Document (FP) which the Form Manager can use to pre-populate the form. As the scope expands, the Form
480 Manager will re-package the data and disseminate it to a variety of content consumers using standard transactions.

X.4.2.2.2 Processing Steps

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
485 form, verifies the accuracy of all information, and submits the form.

X.4.2.2.2.1 Pre-conditions

The Form Filler has the capability to produce a Family Planning Document.

X.4.2.2.2.2 Main Flow

490 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 Volume 3.

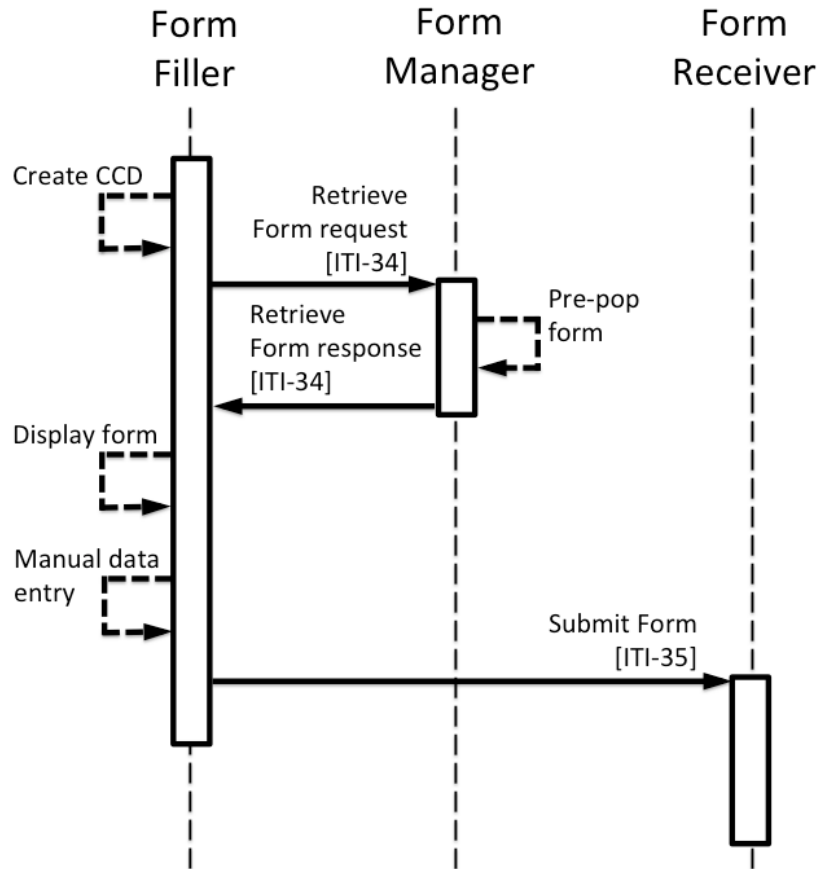
The user confirms that encounter data is correct as rendered by the Form Filler and adds any missing data.

495 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.



500

Figure X.4.2.2.1-2: Process Flow Diagram with Pre-pop Option

X.4.2.3 Use Case #3: FP with Pre-pop Option for Referral Confirmation

X.4.2.3.1 Use Case Description

505 A family planning client has received positive screening and positive supplemental testing that requires a medical visit with another health provider. The family planning service delivery site is responsible for documenting the positive findings, communicating this to the client, coordinating the referral, and confirming the date of the referred medical visit. The data from this form would be used to determine whether the visit was completed in a specified time. As new information is
 510 received (e.g., positive supplemental testing, communications with the client, and confirmation of the completed referral) the family planning service delivery site saves the form at each step in the process and finally submits the form when the referral process has been completed.

Thus, if a family planning encounter results in activities outside that encounter (e.g., supplemental laboratory testing, referral coordination) then the form should be saved by the
 515 Form Filler (the family planning service delivery site’s EMR) so that it can be retrieved and

updated at a later date. The Form Filler interacts with a Form Processor to provide a mechanism that allows users to save partially completed form data and submit the form data.

X.4.2.3.2 Processing Steps

520 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. The provider verifies the accuracy of all information, adds information related to the referral process, and submits the form.

X.4.2.3.2.1 Pre-conditions

The Form Filler has the capability to produce a Family Planning document.

525 X.4.2.3.2.2 Main Flow

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

The Form Processor provides a partially completed form for the current visit with pre-populated data elements described in Volume 3.

530 The user confirms that encounter data is 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.

535 Sometime later the user receives supplemental test results that are positive and coordinates a referral to another provider. The user retrieves, updates, and saves the form data.

Sometime later the user receives confirmation of the completed referral visit. The user retrieves, updates, and submits the completed form data.

The Form Filler submits the form.

The Form Processor receives the submitted data.

540 X.4.2.3.2.3 Post-conditions

The data are made available for quality improvement measures.

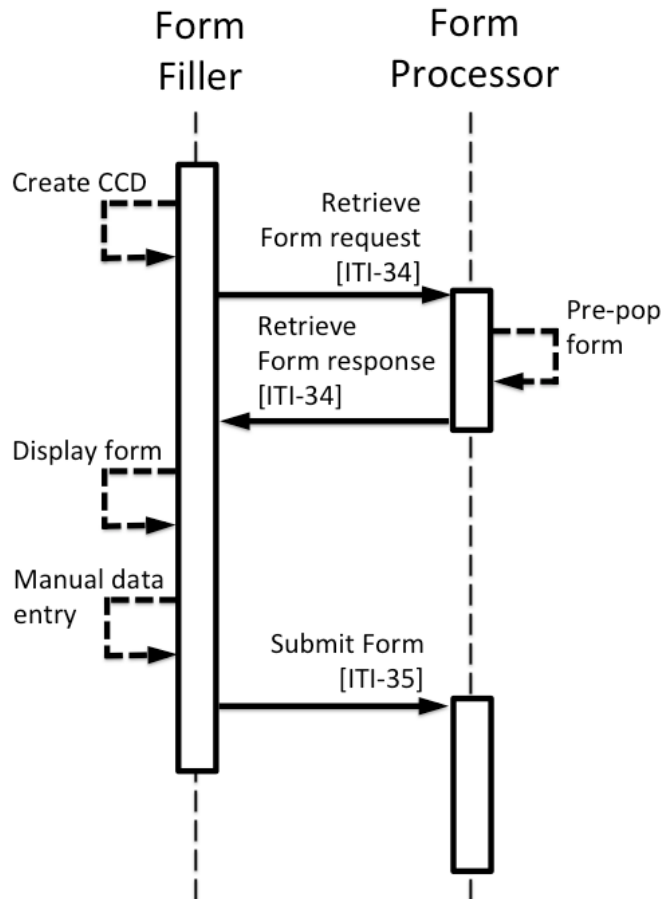


Figure X.4.2.3.1-2: Process Flow Diagram with Pre-pop Option

545

X.5 FP Security Considerations

FP includes clinical content related to the patient. As such, it is anticipated that actions that include patient information will be protected. The IHE ITI ATNA Integration 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) 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) MAY be used to support secure

560 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.

565 In some jurisdictions, consent may be needed to provide this information to public health. For these cases, the IHE ITI BPPC Integration Profile can be used to enable this consent management.

X.6 FP Cross Profile Considerations

Not applicable.

X.7 Data elements

570 This profile requires specific form data element content. That set of data that must be in the form in the course of pre-pop and in the form of data export. Those data elements are described in Appendix B.

Volume 1 – Appendices

Appendix A – Family Planning Form

575 The following sample form is implemented using Excel. The sample *Generic Family Planning Encounter Form* combines currently used concepts at some service delivery sites and data elements in this profile. This material is informative and not required of vendor implementations.

Generic Family Planning Encounter Form

Facility Wellness Now 123 Main Street Muncie, IN 47383		Provider & NPI CL Wilson, NP 1234567893	
Patient Identifier & Name _____		Sex <input type="radio"/> Female <input type="radio"/> Male	
Ethnicity <input type="radio"/> Hispanic or Latina/o <input type="radio"/> Not Hispanic or Latina/o		Limited Language Proficiency <input type="radio"/> English <input type="checkbox"/> Listening <input type="checkbox"/> Reading <input type="radio"/> Other _____ <input type="checkbox"/> Speaking <input type="checkbox"/> Writing	
Annual Household Income \$ _____		Race (check all that apply) <input type="checkbox"/> American Indian / Alaska Native <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> Asian <input type="checkbox"/> White <input type="checkbox"/> Black / African American	
Household Size _____		Primary Insurance <input type="radio"/> No insurance <input type="radio"/> Private/group <input type="radio"/> Veteran/military <input type="radio"/> Medicaid <input type="radio"/> Medicare <input type="radio"/> Other public <input type="radio"/> Self-pay <input type="radio"/> CHIP	
Visit Date ___/___/_____		Date of Birth ___/___/_____	
Height _____ in / cm		Systolic _____	
Weight _____ lbs / kg		Diastolic _____	
Smoking Status <input type="radio"/> Never <input type="radio"/> Smoker, unknown current <input type="radio"/> Former <input type="radio"/> Unknown <input type="radio"/> Current daily <input type="radio"/> Heavy <input type="radio"/> Current some day <input type="radio"/> Light			
Current Pregnancy Status (F Only) <input type="radio"/> Not Pregnant <input type="radio"/> Sterilized <input type="radio"/> Postmenopausal <input type="radio"/> Pregnant - patient report <input type="radio"/> Pregnant - test		Contraceptive Method - Intake <input type="radio"/> Implant <input type="radio"/> Male Condom <input type="radio"/> EC <input type="radio"/> IUD/IUS <input type="radio"/> Diaphragm or cap <input type="radio"/> None <input type="radio"/> Female sterilization <input type="radio"/> Female condom Reason for None <input type="radio"/> Vasectomy <input type="radio"/> FAM <input type="radio"/> Abstinence <input type="radio"/> Injectables <input type="radio"/> Withdrawal <input type="radio"/> Same sex partner <input type="radio"/> LAM <input type="radio"/> Spermicide <input type="radio"/> Other <input type="radio"/> Oral contraceptive pills <input type="radio"/> Sponge <input type="radio"/> Seeking pregnancy <input type="radio"/> Patch <input type="radio"/> M relying on F method <input type="radio"/> Declined all methods <input type="radio"/> Vaginal Ring <input type="radio"/> Decline to answer	
# Past Pregnancies (F only) _____		Contraceptive Method - Exit <input type="radio"/> Implant <input type="radio"/> Male Condom <input type="radio"/> EC <input type="radio"/> IUD/IUS <input type="radio"/> Diaphragm or cap <input type="radio"/> None <input type="radio"/> Female sterilization <input type="radio"/> Female condom Reason for None <input type="radio"/> Vasectomy <input type="radio"/> FAM <input type="radio"/> Abstinence <input type="radio"/> Injectables <input type="radio"/> Withdrawal <input type="radio"/> Same sex partner <input type="radio"/> LAM <input type="radio"/> Spermicide <input type="radio"/> Other <input type="radio"/> Oral contraceptive pills <input type="radio"/> Sponge <input type="radio"/> Seeking pregnancy <input type="radio"/> Patch <input type="radio"/> M relying on F method <input type="radio"/> Declined all methods <input type="radio"/> Vaginal Ring <input type="radio"/> Decline to answer	
Pregnancy Intention next 12 months <input type="radio"/> Yes <input type="radio"/> Not desired		Sexually Active Last 3 months <input type="radio"/> Yes <input type="radio"/> No	
Last Pap (F only) ___/___/_____		HPV Co-test Ordered (F only) ___/___/_____	
HIV Screen Ordered ___/___/_____		CT Ordered ___/___/_____	
HIV Screen (Initial) Result _____		GC Ordered ___/___/_____	
HIV Supplemental Result _____		Referral Recommended ___/___/_____	
		Referral Completed ___/___/_____	
Referral Provider & Location _____			

Appendix B – Data Elements

580 The following data elements are used in support of Family Planning programs. Details regarding optionality, structures, vocabularies, and value sets are documented in Volume 3:

Element	Description
Facility identifier	Clinical site at which services were provided
Clinical Provider identifier	The most senior clinical provider that provided services at the encounter
Patient identifier	Patient's medical record number or other persistent, unique identifier within the site's tracking systems
Visit Date	Date of the clinical encounter
Date of Birth	Patient's date of birth
Administrative Sex	Patient's sex per standard value set
Pregnancy History	The total number of times a female patient has been pregnant, regardless of outcome of the pregnancy.
Limited Language Proficiency	Patient requires care delivery in a language other than the national dominant language in 4 domains: listening, writing, reading, or speaking.
Ethnicity	Patient's self-reported ethnicity per standard value set
Race	Patient's self-reported race(s) per 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 client
Visit Payer	Principal health insurance coverage (private or public), confidential visit, unknown or uninsured
Current Pregnancy Status	Pregnancy status at visit as confirmed by a particular method
Pregnancy Intention	Patient reports seeking 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 in the past 3 months
Contraceptive Method at Intake ¹	Patient report of most effective contraceptive method used at last sexual encounter
Reason for no contraceptive method	Reason patient reported no contraceptive method used (at intake and exit)
Contraceptive Method at Exit ¹	Contraceptive method(s) recommended or prescribed by provider to patient at the end of the visit, after counseling and assessment
Date of Last Pap test	Date of last vaginal or cervical Pap test (self-report or lab result from this clinic or other clinic or date of this visit)
HPV Co-test Ordered	Date a vaginal or cervical HPV Co-test was ordered related to findings from the current visit
CT Screen Ordered	Date a <i>Chlamydia trachomatis</i> screen was ordered related to findings from the current visit
GC Screen Ordered	Date a <i>Neisseria gonorrhoeae</i> screen was ordered related to findings from the current visit
HIV Screen Ordered	Date HIV screen was ordered related to findings from the current visit
HIV Rapid Screen Result	Result of rapid, initial HIV screen at the current visit per standard value set

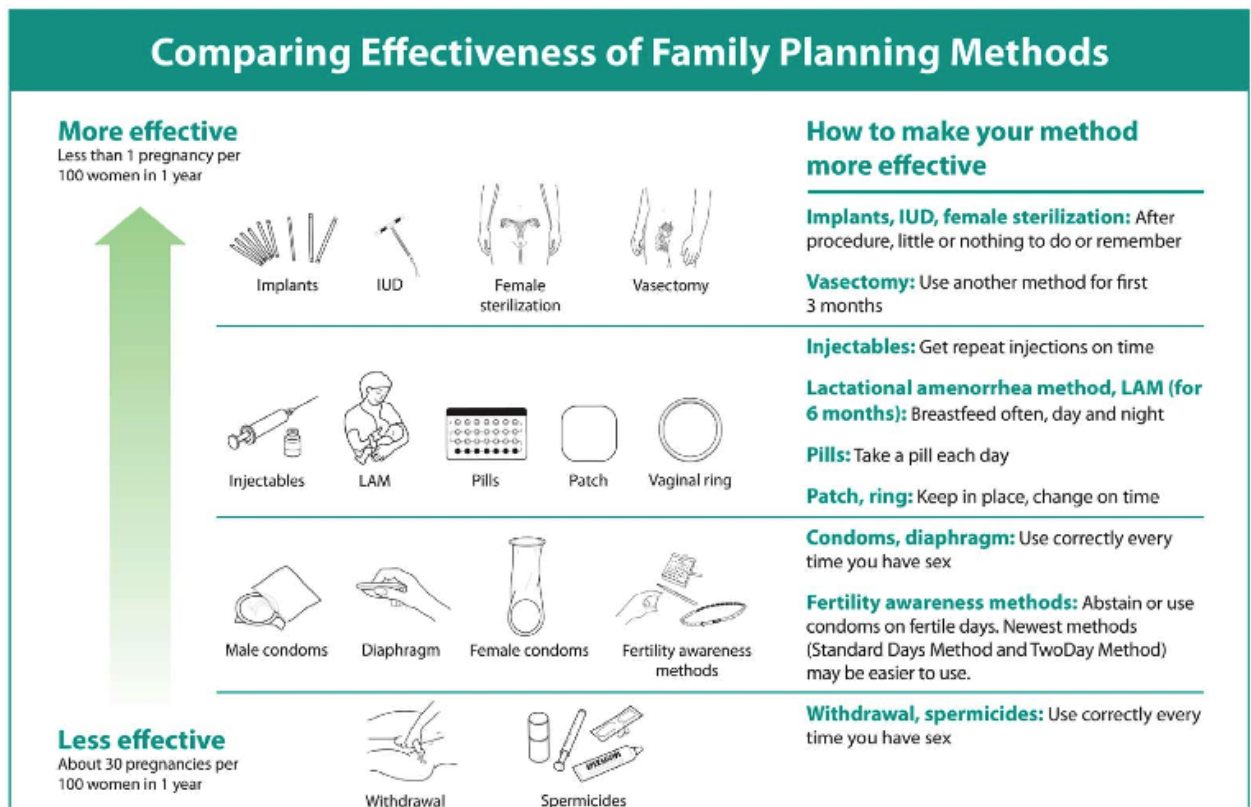
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Element	Description
HIV Supplemental Result	Result of supplemental HIV test intended to confirm HIV status
Referral Recommended Date	A date at which a clinician identifies that a clinical or laboratory finding requires a referral to a different provider for a medical visit and the patient 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.
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.
Systolic blood pressure	Systolic bp per mmHg with calibrated machine as preference but manual is allowed
Diastolic blood pressure	Diastolic bp per mmHg with calibrated machine as preference but manual is allowed
Height	Height value and units
Weight	Weight value and units
Smoking status	Smoking status per standard value set

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).

585 ¹ 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 B-1).

590



Sources:

Steiner MJ, Trussell J, Mehta N, Condon S, Subramaniam S, Bourne D. Communicating contraceptive effectiveness: a randomized controlled trial to inform a World Health Organization family planning handbook. *Am J Obstet Gynecol* 2006;195(1):85–91.

World Health Organization/Department of Reproductive Health and Research (WHO/RHR), Johns Hopkins Bloomberg School of Public Health (JHSPH)/Center for Communication Programs (CCP). *Family Planning: A Global Handbook for Providers*. Baltimore, MD and Geneva: CCP and WHO, 2007.

Trussell J. Choosing a contraceptive: efficacy, safety, and personal considerations. In: Hatcher RA, Trussell J, Stewart F, Nelson AL, Cates W Jr., Guest F, Kowal D, eds. *Contraceptive Technology, Nineteenth Revised Edition*. New York: Ardent Media, Inc., in press.

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Figure B-1: Tiers of Effectiveness for Family Planning Methods

595

Volume 2 – Transactions

There are no new transactions identified by this profile.

Appendices

None

Volume 2 Namespace Additions

600

<i>Add the following terms to the IHE General Introduction Appendix G:</i>
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No new Volume 2 namespace additions.

Volume 3 – Content Modules

5 Namespaces and Vocabularies

605

Add to Section 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

6 Content Modules

6.3.1 CDA Document Content Modules

<i>Add to Section 6.3.1.D Document Content Modules</i>
--

610 6.3.1.D1 Family Planning Pre-pop (FPP) Document Content Module

6.3.1.D1.1 Format Code

The XSDDocumentEntry format code for this content is **urn:ihe:qrph:fp:2013**

6.3.1.D1.2 Parent Template

615 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

620 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 CDA Release 2.0	http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition.zip
CDTHP	CDA for Common Document Types History and Physical Notes (DSTU)	http://www.hl7.org/documentcenter/ballots/2007SEP/support/CDAR2_HPRPT_DSTU_2008AUG.zip
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

625 6.3.1.D1.4.1 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 Pre-pop document. Table 6.3.1.D1.4-1 provides a high-level mapping from key Form Data Elements to Family Planning Pre-pop structures. Detailed data element mappings require realm-specific templates to be specified. See Volume 4 for available realm-specific detailed data element mappings.

630

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

Clinical Data Element	Optionality	CDA pseudo XPath
Patient Identifier	R	recordTarget.patientRole.id
Date of Birth	R	recordTarget.patientRole.patient.birthTime
Administrative Sex	R	recordTarget.patientRole.patient.administrativeGenderCode
Language of Communication	R	recordTarget.patientRole.patient.languageCommunication
Race	O	recordTarget.patientRole.patient.raceCode
Ethnicity	O	recordTarget.patientRole.patient.ethnicGroupCode
Clinical Provider	R	componentOf.encompassingEncounter.responsibleParty.assignedEntity
Visit Date	R	componentOf.encompassingEncounter.effectiveTime
Facility identifier	R	componentOf.encompassingEncounter.location.healthcareFacility
Number of Total Pregnancies	R	PregnancyHistory.PregnancyHistoryOrganizer.PregnancyObservation – Total Number of Pregnancies Code
Current Pregnancy Status	R	PregnancyStatusReview.PregnancyStatusOrganizer.PregnancyStatusObservation – Current Pregnancy Status Code
Pregnancy Intention	R	PregnancyStatusReview.PregnancyStatusOrganizer.PregnancyStatusObservation – Pregnancy Intention Code
Sexual Activity	O	PregnancyStatusReview.PregnancyStatusOrganizer.PregnancyStatusObservation – Sexual Activity Code
Contraceptive Method at Intake	R	PregnancyStatusReview.PregnancyStatusOrganizer.PregnancyStatusObservation – Current Contraceptive Method Code
Reason for No Contraceptive Method at Intake	R2	PregnancyStatusReview.PregnancyStatusOrganizer.PregnancyStatusObservation – No Contraceptive Reason Code
Last Cervical Cancer Screen	R2	PregnancyStatusReview.PregnancyStatusOrganizer.PregnancyStatusObservation – Last Cervical Cancer Screen
Contraceptive Method at Exit	R	CodedCarePlan.ObservationRequests
Reason for No Contraceptive Method at Exit	R2	CodedCarePlan.ObservationRequests.Observation.EntryRelationship.Observation
Chlamydia trachomatis Screen Order	R	CodedCarePlan.ObservationRequests
Neisseria gonorrhoeae Screen Order	R	CodedCarePlan.ObservationRequests

Clinical Data Element	Optionality	CDA pseudo XPath
HIV Screen Order	R	CodedCarePlan.ObservationRequests
HIV Rapid Screen Result	R2	CodedResults.SimpleObservation
HIV Supplemental Result	O	CodedResults.SimpleObservation
Referrals Planned	R2	CodedCarePlan.Encounters
Referrals Completed	R2	HistoryOfOutpatientVisits
Height	R	VitalSigns.vitalSignsOrganizer.vitalSignsObservation – Height Code
Weight	R	VitalSigns.vitalSignsOrganizer.vitalSignsObservation – Weight Code
Systolic Blood Pressure	R	VitalSigns.vitalSignsOrganizer.vitalSignsObservation – Systolic Blood Pressure Code
Diastolic Blood Pressure	R	VitalSigns.vitalSignsOrganizer.vitalSignsObservation – Diastolic Blood Pressure Code
Smoking Status	R	CodedSocialHistory.SocialHistoryObservation – Smoking Status Code
Annual Household Income	R2	CodedSocialHistory.SocialHistoryObservation – Household Annual Income Code
Household Size	R2	CodedSocialHistory.SocialHistoryObservation – Household Size Code

6.3.1.D1.5 FPP Document Content Module Specification

635

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

Template Name	Family Planning
Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.24
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).
General Description	This document is a document to record family planning intentions, including pregnancy history, contraceptive method and sexually transmitted disease screening
Document Code	(Request LOINC document code)

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Template Type	Template Title ¹	Opt and Card	templateId ²
Document	FamilyPlanning		1.3.6.1.4.1.19376.1.5.3.1.1.24
Header	FamilyPlanning Header	[1..1]	
	recordTarget	[1..1]	
	Patient Identifier, Date of Birth, Gender	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.1
	Race, Ethnicity	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.1.1
	Language of Communication	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.2.1
	Provider	[1..*]	n/a
	Visit Date	[1..1]	n/a
	Healthcare Facility	[1..1]	n/a
Section	Pregnancy History	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
Entry	Pregnancy History Observation - Number of Total Pregnancies	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.5
Section	Pregnancy Status Review	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.9.47
Entry	Pregnancy Status Review Organizer	[1..1]	
Entry	Pregnancy Status Review Observation Sexual Activity	[0..1]	
Entry	Pregnancy Status Review Observation - Current Pregnancy Status	[1..1]	
Entry	Pregnancy Status Review Observation - Current Pregnancy Intention	[1..1]	
Entry	Pregnancy Status Review Observation - Contraceptive Method on Intake	[1..1]	
Sub-Entry	Pregnancy Status Review Observation - Reason for No Contraceptive Method ³	[0..*]	
Entry	Last Cervical Cancer Screen	[0..1]	
Section	Coded Vital Signs	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2
Entry	Vital Signs Organizer	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.1
Entry	Vital Signs Observation – Height	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.2
Entry	Vital Signs Observation – Weight	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.2
Entry	Vital Signs Observation – Systolic Blood Pressure	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.2
Entry	Vital Signs Observation – Diastolic Blood Pressure	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.2
Section	Coded Social History	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.3.16.1

¹ If multiple data elements are listed in one row then this is because those data elements are grouped in the template.

² Data types are implicit in the template id. Refer to template id for data types.

³ Note that this field must be present if the Contraceptive Method on Intake or at Exit is “None”, or a null flavour. If there is a Contraceptive Method on Intake, this entry may be omitted.

Template Type	Template Title ¹	Opt and Card	templateId ²
Entry	Social History Observation – Smoking Status	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.4
Entry	Social History Observation - Household Income	[0..*]	1.3.6.1.4.1.19376.1.5.3.1.4.13.4
Entry	Social History Observation - Household Size	[0..*]	1.3.6.1.4.1.19376.1.5.3.1.4.13.4
Section	Coded Care Plan	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.3.36
Entry	Contraceptive Method on Visit Exit Order	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1
Sub-Entry	Reason for No Contraceptive Method ³	[0..*]	
Entry	Chlamydia trachomatis Screen Order	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1
Entry	Neisseria gonorrhoeae Screen Order	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1
Entry	HIV Screen Order	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1
Section	Coded Care Plan	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.3.36
Entry	Recommended Encounters/Referrals	[0..*]	1.3.6.1.4.1.19376.1.5.3.1.4.14
Section	Coded Results	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.3.28
Entry	HIV Screen Rapid Result	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13
Entry	HIV Supplemental Result	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13
Section	History of Outpatient Visits	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.3.9
Section	Payers	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7

640 **6.3.1.D1.5.1 General Document Constraints**

6.3.1.D1.6 FP Example

6.3.2 CDA Header Content Modules

6.3.3 CDA Section Content Modules

645 *Add to Section 6.3.3.10 Section Content Modules*

(CP to change Pregnancy Status Review Section)

6.3.3.10.S1 Pregnancy Status Review Section 1.3.6.1.4.1.19376.1.5.3.1.1.9.47

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.9.47		
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.		
LOINC Code	Opt	Description	

11449-6	R	Pregnancy Status-Reported
Entries	Opt	Description
TBD	R	Pregnancy Status Review Organizer

6.3.3.10.S2 Coded Social History Section 1.3.6.1.4.1.19376.1.5.3.1.3.16.1

650 The Coded Social History Section for the Family Planning Profile SHALL be encoded as in the IHE PCC Technical Framework Volume 2, except as listed below.

It SHOULD contain Social History Observations with the codes and optionalities in Table 6.3.3.10.S2-1.

Table 6.3.3.10.S2-1: Social History Observation Codes

Code	Code System	Description	Opt	Type	Units or Concept Domain
229819007	SNOMED-CT	Smoking	R	PQ	{pack}/d or {pack}/wk or {pack}/a
224168007	SNOMED-CT	Household Income	O	INT	N/A
224525003	SNOMED-CT	Household Size	O	INT	N/A

655

6.3.3.10.S3 Coded Care Plan Section 1.3.6.1.4.1.19376.1.5.3.1.3.36

6.3.3.10.S3.1 Coded Care Plan Observation (1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1)

Observation Entries in the Coded Care Plan for the Family Planning Profile SHALL be encoded as in the IHE PCC Technical Framework Volume 2, except as listed below

660 **6.3.3.10.S3.1.1** `<code code=" " displayName=" " codeSystem=" " codeSystemName=""/>`

The `<code>` element identifies the type care plan observation and SHALL be encoded using values from a value set bound to the concept domain UV_ObservationType

6.3.3.10.S3.2 Coded Care Plan Medication (1.3.6.1.4.1.19376.1.5.3.1.4.7)

665 Medication Entries in the Coded Care Plan for the Family Planning Profile SHALL be encoded as in the IHE PCC Technical Framework Volume 2, except as listed below

6.3.3.10.S3.2.1 `<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '>
<originalText><reference value=' '/></originalText></code>`

670 The `<code>` element of the `<consumable><manufacturedMaterial>` within a Medication Entry describes the medication. For the Family Planning Profile, this SHALL be encoded using values from a value set bound to the concept domain UV_ContraceptiveType

6.3.3.10.S4 Coded Care Plan Procedures (1.3.6.1.4.1.19376.1.5.3.1.4.19)

675 Coded Care Plan Procedures for the Family Planning Profile SHALL be encoded as in the IHE PCC Technical Framework Volume 2, except as listed below

6.3.3.10.S4.1 `<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '>`

`<originalText><reference value=' '/></originalText></code>`

680 The Procedure entry in the Family Planning Profile is used to record the contraceptive method at exit, when such method is a procedure. For the Family Planning Profile, the code element of the procedure SHALL be encoded using values from a value set bound to the concept domain UV_ContraceptiveType.

6.3.3.10.S5 Coded Care Plan Encounters (1.3.6.1.4.1.19376.1.5.3.1.4.14)

685 Coded Care Plan Encounters for the Family Planning Profile SHALL be encoded as in the IHE PCC Technical Framework Volume 2, except as listed below

6.3.3.10.S5.1 `<encounter classCode='ENC' moodCode='APT|ARQ|EVN'>`

This element is a referral, that is, a requested encounter. The classCode shall be 'ENC'. The moodCode shall be ARQ to describe a request for an appointment that has been made but not yet scheduled by a provider.

690 `<id root=" " extension=""/>`

6.3.3.10.S6 Simple Observations (1.3.6.1.4.1.19376.1.5.3.1.4.13)

Simple Observations in the Results Section for the Family Planning Profile SHALL be encoded as in the PCC Technical Framework Volume 2, except as listed below

695 **6.3.3.10.S6.1** `<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '>`

`<originalText><reference value=' '/></originalText></code>`

The code element of the simple observation SHALL be encoded using values from a value set bound to the concept domain UV_ResultType. It values in this value set represent the lab tests being ordered as a result of the visit.

700 **6.3.4 CDA Entry Content Modules**

6.3.4.E1 Pregnancy Status Review Organizer (OID TDB)

The pregnancy status review organizer collects observations of the responses the patient gave to a set of routine questions regarding potential pregnancy in females of child-bearing-age.

6.3.4.E1.1 Specification

```
705 <organizer classCode='CLUSTER' moodCode='EVN'>
    <templateId root=''/>
    <id root=' ' extension=''/>
    <code code=' ' displayName=' '
710     codeSystem=' '
        codeSystemName=''/>
    <statusCode code='completed'/>
    <effectiveTime value=''/>

    <!-- One or more components -->
715     <component typeCode='COMP'>
        <!-- Or a pregnancy status observation -->
        <observation classCode='OBS' moodCode='EVN'>
            <templateId root=''/>
            :
720         </observation>
        </component>
    </organizer>
```

6.3.4.E1.2 `<organizer classCode='CLUSTER' moodCode='EVN'>`

725 The pregnancy status review organizer is a cluster of pregnancy status review observations.

6.3.4.E1.3 `<templateId root=''/>`

The pregnancy status review organizer shall have the `<templateId>` element shown above to indicate that it conforms to this specification.

6.3.4.E1.4 `<id root=' ' extension=' '/>`

730 The organizer shall have an `<id>` element.

6.3.4.E1.5 `<code code="" displayName="" codeSystem="" codeSystemName=""/>`

735 The organizer shall contain a code describing the observations present. The recommended code is shown above.

6.3.4.E1.6 `<statusCode code='completed'/>`

The observations have all been completed.

6.3.4.E1.7 `<effectiveTime value=' '/>`

740 The effective time element shall be present to indicate the interval of the pregnancy status review.

6.3.4.E1.8 `<component typeCode='COMP'>`

The organizer shall have one or more <component> elements that are instances of pregnancy status review observations.

6.3.4.E2 Pregnancy Status Review Observation (OID HERE)

745 A pregnancy Status Review observation is a Simple Observation that uses a specific vocabulary to record observations about a patient's current pregnancy status.

6.3.4.E2.1 Parent Template

The parent of this template is [Simple Observation](#).

6.3.4.E2.1.1 Uses

750 See [Templates using Pregnancy Status Review Observation](#).

6.3.4.E2.2 Specification

Pregnancy Status Review Observation Example

```

755 <observation classCode='OBS' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />
      <templateId root='' />
      <id root='' extension='' />
      <code code='' displayName='' codeSystem='' codeSystemName='' />
      <text><reference value='#xxx' /></text>
760 <statusCode code='completed' />
      <effectiveTime value='' />
      <repeatNumber value='' />
      <value xsi:type='' ... />
      <interpretationCode code='' codeSystem='' codeSystemName='' />
765 <methodCode code='' codeSystem='' codeSystemName='' />
      <targetSiteCode code='' codeSystem='' codeSystemName='' />

      <!-- An optional entry relationship that indicates the reason for no contraceptive use -->
      <entryRelationship typeCode='RSON'>
770   <act classCode='ACT' moodCode='EVN'>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1' />
         <id root='' extension='' />
         </act>
       </entryRelationship>
775 </observation>

```

**6.3.4.E2.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />
<templateId root='' />**

780 These <templateId> elements identify this <observation> as a pregnancy status review observation, allowing for validation of the content. The <templateId> elements shall be recorded as shown above.

6.3.4.E2.4 <code code='' displayName='' codeSystem="" codeSystemName=''/>

785 A pregnancy status observation shall have a code describing what facet of patient's pregnancy status is being recorded. These codes should come from the list of codes shown below. Additional codes may be used to reflect additional information about the pregnancy status.

Table 6.3.4.E2.4-1: Pregnancy Status Review Observation Codes

Code	Description	Type	Units or Concept Domain
TBD	Sexual Activity	PQ	{}/d or {}/wk or {}/a
11449-6	Current Pregnancy Status	CD	UV_CurrentPregnancyStatus
TBD	Current Pregnancy Intention	BL	
TBD	Contraceptive Method on Intake	CD	UV_ContraceptiveType
TBD	Last Cervical Cancer Screen	TS	N/A

790 **6.3.4.E2.5** `<repeatNumber value=' '/>`

The <repeatNumber> element should not be present in a pregnancy status review observation.

6.3.4.E2.6 `<value xsi:type=' ' .../>`

The value of the observation shall be recording using a data type appropriate to the coded observation according to the table above.

795 **6.3.4.E2.7** `<interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>`
`<methodCode code=' ' codeSystem=' ' codeSystemName=' '/>`
`<targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>`

The <interpretationCode>, <methodCode>, and <targetSiteCode> should not be present in a pregnancy status review observation.

800 **6.3.4.E2.8** `<entryRelationship typeCode='RSON'>`

A pregnancy status review <observation> event may indicate one or more reasons for the observation. In particular, the pregnancy status review observation of Contraceptive Type requires a reason, if the contraceptive type is “none”. This entry shall contain one or more observation entries that conform to the specification in section Simple Observation of the PCC Technical Framework and should use the code and concept domain below.

Code	Description	Type	Units or Concept Domain
TBD	Reason for no Contraceptive Method	CD	UV_NoContraceptiveReason

6.4 Section not applicable

This heading is not currently used in a CDA document.

810 *Add to Section 6.5 Value Sets*

6.5 List of Concept Domains

UV Concept Domain
Pregnancy Status Review Section
UV_ContraceptiveType
UV_NoContraceptiveReason
UV_CurrentPregnancyStatus
Family Planning Coded Care Plan

UV_ContraceptiveType
Results
UV_ResultType

815 **6.5.1 UV_ContraceptiveType (OID TBD)**

This Concept Domain holds a list of coded results for contraceptive types for use in Family Planning.

Concept Name
Implant
IUD/IUS
Female sterilization
Vasectomy
Injectables
LAM
Oral contraceptive pills
Patch
Vaginal Ring
Male Condom
Diaphragm or cap
Female Condom
FAM
Withdrawal
Spermicide
Sponge
Male relying on female method
Decline to answer
Emergency Contraception
None

820 **6.5.2 UV_NoContraceptiveReason (OID TBD)**

This Concept Domain holds a list of concepts for the reason no contraceptive is used by the patient for use in Family Planning.

Concept Name
Abstinence
Same sex partner
Other
Seeking pregnancy
Declined all methods

825 **6.5.3 UV_CurrentPregnancyStatus (OID TBD)**

This Concept Domain holds a list of concepts for the current pregnancy status of the patient for use in Family Planning.

Concept Name
Not Pregnant
Sterilized
Postmenopausal
Pregnant, by patient report
Pregnant, by test result

830 **6.5.4 UV_ResultType (OID TBD)**

This Concept Domain holds a list of concepts for the result types for use in Family Planning

Concept Name
HIV Rapid Screen Result
HIV Supplemental Result

Volume 4 – National Extensions

835 *Add appropriate Country Section*

4 National Extensions

4.R1 National Extensions for US Realm

840 The national extensions documented in this section shall be used in conjunction with the definitions of integration profiles, actors, and transactions provided in Volumes 1-3 of the IHE QRPH Family Planning Supplement.

845 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 patients 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-855 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.

860 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 865 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.R1.1 Comment Submission

870 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

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4.R1.2 Family Planning (FP)

880 All requirement of the Family Planning Profile in the US Realm are as specified in Volumes 1-3 of the IHE Technical Framework, 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.R1.2.1 Family Planning Document Content Module Specification

Template Type	Template Title	Opt and Card	templateId
Document	FamilyPlanning		
Header	FamilyPlanning Header	[1..1]	
	Race, Ethnicity	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.1
Section	Coded Social History	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.3.16.1
Entry	Social History Observation – Smoking Status	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.4
Entry	Social History Observation - Household Income	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.4
Entry	Social History Observation - Household Size	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.4.13.4
Section	Payers	[1..1]	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7

885

4.R1.3 FP Value Set Binding for US Realm Concept Domains

UV Concept Domain	US Realm Vocabulary Binding or Single Code Binding	Value Set OID
Header		
FP_Race	US_Race	2.16.840.1.114222.4.11.7204
FP_Ethnicity	US_Ethnicity	2.16.840.1.114222.4.11.6066
FP_Payers	US_Payers	2.16.840.1.114222.4.11.3591

890 4.R1.3.1 US_Race (2.16.840.1.114222.4.11.7204)

This value set holds a list of values for race for use in Family Planning and should allow for multiple options to be selected for one patient.

Code	Concept Name	Code System Name	Code System OID
1002-5	American Indian or Alaska Native	Race Category including Refused	2.16.840.1.114222.4.11.7204
2028-9	Asian	Race Category including Refused	2.16.840.1.114222.4.11.7204
2054-5	Black or African American	Race Category including Refused	2.16.840.1.114222.4.11.7204
2076-8	Native Hawaiian or Other Pacific Islander	Race Category including Refused	2.16.840.1.114222.4.11.7204
2131-1	Other Race	Race Category including Refused	2.16.840.1.114222.4.11.7204
PHC1175	Refused to answer	Race Category including Refused	2.16.840.1.114222.4.11.7204
UNK	Unknown	Race Category including Refused	2.16.840.1.114222.4.11.7204
2106-3	White	Race Category including Refused	2.16.840.1.114222.4.11.7204

895 4.R1.3.2 US_Ethnicity (2.16.840.1.114222.4.11.6066)

This value set holds a list of values for ethnicity for use in Family Planning.

Code	Concept Name	Code System Name	Code System OID
H	Hispanic or Latino	Ethnic Group (HL7)	2.16.840.1.113883.12.189
N	Not Hispanic or Latino	Ethnic Group (HL7)	2.16.840.1.113883.12.189
U	Unknown	Ethnic Group (HL7)	2.16.840.1.113883.12.189

4.R1.3.3 US_PAYERS (2.16.840.1.114222.4.11.3591)

This value set holds the list of values for payer type for use in Family Planning.

900

Code	Concept Name	Code System Name	Code System OID
33	Indian Health Service or Tribe	Source of Payment Typology	2.16.840.1.113883.3.221.5
2	MEDICAID	Source of Payment Typology	2.16.840.1.113883.3.221.5
23	CHIP	Source of Payment Typology	2.16.840.1.113883.3.221.5
1	MEDICARE	Source of Payment Typology	2.16.840.1.113883.3.221.5
99	No Topology Code available for payment source	Source of Payment Typology	2.16.840.1.113883.3.221.5
38	Other Government (Federal, State, Local not specified)	Source of Payment Typology	2.16.840.1.113883.3.221.5
5	PRIVATE HEALTH INSURANCE	Source of Payment Typology	2.16.840.1.113883.3.221.5
81	Self-pay	Source of Payment Typology	2.16.840.1.113883.3.221.5
311	TRICARE (CHAMPUS)	Source of Payment Typology	2.16.840.1.113883.3.221.5
9999	Unavailable/Unknown	Source of Payment Typology	2.16.840.1.113883.3.221.5