

Integrating the Healthcare Enterprise



IHE PCC

Technical Framework Supplement

Perinatal Workflow (PW)

Draft for Public Comment

Date: March 1, 2010
Author: Keith W. Boone
Email: keith.boone@ge.com

Foreword

This is a supplement to the IHE PCC Technical Framework V5.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

For Public Comment: This supplement is submitted for Public Comment between March 1, 2010 and April 15, 2010. Comments are invited and may be submitted to the IHE forums at <http://forums.rsna.org/forumdisplay.php?f=309>. In order to be considered in development of the Trial Implementation version of the supplement comments must be received by April 15, 2010. Please use the Public Comment Template provided in the thread and submit comments by posting the completed template as an attachment to a Reply or New Thread.

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

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

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

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

Information about the IHE PCC may be found at: <http://www.ihe.net/Domains/index.cfm>

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

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

CONTENTS

Introduction.....	4
Profile Abstract	4
Open Issues and Questions	4
Closed Issues.....	4
Volume 1 – Integration Profiles.....	6
1.7 History of Annual Changes.....	6
2.1 Dependencies among Integration Profiles	6
2.2.X Perinatal Workflow (PW) Integration Profile	7
X Perinatal Workflow (PW) Integration Profile	7
X.1 Actors/ Transactions.....	10
X.1.1 Patient Registration	12
X.1.2 Health Information Exchange	12
X.1.2 Care Manager	12
X.1.3 Order Placer.....	13
X.1.4 Imaging Order Filler.....	13
X.1.5 Laboratory Order Filler	14
X.1.6 Enterprise Report Repository	14
X.1.7 Remove/Central Viewer	14
X.1.8 Device Gateway	14
X.1.9 Personal Health Record	14
X.1.10 Form Manager.....	15
X.1.11 Form Reciever.....	15
X.1.12 Clinical Decision Support Service	15
X.2 Perinatal Workflow (PW) Integration Profile Options	17
X.2.1 Patient Registration Option	18
X.2.2 Obstetrics Option.....	18
X.2.3 Labor and Delivery Option.....	18
X.2.4 Newborn Care Option	18
X.2.5 Content Creator Option	18
X.2.6 Imaging Data Option	19
X.2.7 Administrative Services Option	19
X.2.8 Clinical Decision Support	19
X.3 Perinatal Workflow (PW) Process Flow	19
X.3.1 Registration	19
X.3.2 Initial Visit.....	20
X.3.3 Prenatal Care	20
X.3.4 Labor and Delivery.....	22
X.3.5 After Delivery.....	23
X.3.6 Postpartum Care	24
X.4 Perinatal Workflow (PW) Security Considerations	25
X.4.1 Misidentified Patient	25

X.4.2 Malicious attempts to obtain patient information.....	25
X.4.3 Accidental Release of Protected Health Information	26
X.4.4 Inability to Communicate Orders due to System Failure or Malicious Attack	26
X.4.5 Inappropriate Communication of Mother / Child Identity in Adoption Cases.....	26
X.4.6 Externally sourced data may be inaccurate or unreliable.....	27
Volume 2 - Transactions	28
3.0 Exchange Content	28
3.0.1 Scope	28
3.0.2 Use Case Roles	28
3.0.3 Referenced Standard	28
3.0.4 Interaction Diagram.....	28
6.2 Folder Specifications.....	31
6.2.A Antepartum Folder Specification.....	32
6.2.L Labor and Delivery Folder Specification.....	33
6.2.N Newborn Folder Specification	34
6.2.P Postpartum Folder Specification.....	35

Introduction

This profile principally updates Volume I of the IHE PCC Technical Framework and references transactions, content profiles and Actors from other IHE domains, including IT Infrastructure, Laboratory, Patient Care Devices, Quality, Public Health and Research, and Radiology.

Profile Abstract

Perinatal workflows involve communication between ambulatory providers, laboratories, imaging facilities and labor and delivery centers. The Perinatal Workflow profile simplifies exchanges between these various providers of care by utilizing profiles and transactions from several IHE domains to support the continuum of care of expectant mothers and newborns.

Open Issues and Questions

1. An episode of care identifier is needed for folders used in this profile. How should that episode of care identifier be conveyed in XDS Metadata?
2. LOINC Submissions are needed for X-Antepartum Records, X-Newborn Records, and X-Postpartum Records.
3. The LOINC Code used for the Labor and Delivery Folder (15508-5 Labor and Delivery Records) is presently the same as is used for the Labor and Delivery Summary. We will need advice from LOINC on what the right codes are to use.

Closed Issues

1. It isn't clear which transaction should be used for ADT. Should it be ITI-8 (PIX), ITI-30 (PAM), LAB-1 (LTW) or RAD-1 (SWF) or some combination thereof. I would recommend PAM. ITI Recommended us of PAM, so we are using ITI-30.
2. The Section Import Option is rarely used, should it be referenced as an option for this profile? We will not call out this option.
3. How do we handle exchange of content. Should there be options supporting topology, or should there be a required grouping with actors from XDS, XDR and XDM. I would recommend the latter. We will require systems grouped with XDS, XDR or XDM to support all content in the grouping.
4. Should the Order Filler actor be divided into an Laboratory Order Filler and an Imaging Order Filler actor? Yes
5. Do we need to address care prior to conception (e.g., fertility treatment) in the perinatal episode of care? Care prior to conception is addressed in the Antepartum Folder. These documents may be included in the folder if the care provider deems them relevant.

6. What do we do about patient monitoring in the Labor and Delivery center (e.g, Fetal Heart Monitor). Added the Device Gateway and Remove/Central Viewer Actors.
7. What about Personal Health Records? Added the Personal Health Record Actor.
8. Vital Records need to be addressed in the Newborn Option, question from Mike on National vs. State requirements. Added Forms Manager and Forms Reciever and Vital Records option on Care Manager.
9. Should PCC-0 Exchange Content require use of PIX/PDQ at least once per patient (as we have been demonstrating annually for the last 5 years)? We will recommend this behavior where needed, but not require it.

Volume 1 – Integration Profiles

1.7 History of Annual Changes

<Brief overview of “what’s new” in the given year of the Technical Framework.>

Add the following bullet to the end of the bullet list in section 1.7

- Added the Perinatal Workflow (PW) profile to simplify exchanges between various providers of perinatal care utilizing profiles and transactions from several IHE domains to support the continuum of care of expectant mothers and newborns.

2.1 Dependencies among Integration Profiles

Add the following to Table 2-1

PW	CT	All actors of the PW Profile must be grouped with the Time Client Actor of the CT Profile.	A consistent time base is necessary to ensure accurate logging and security.
PW	ATNA	Actors that implement the PCC-0 transaction must be grouped with the Secure Node or Secure Application Actor of the ATNA profile.	ATNA is required of XDS, XDR and XDM.
PW	APS, APE, APHP, APL, PPVS	A Care Manager implementing the Obstetric Option must demonstrate the ability to be a Content Creator and Content Consumer of these profiles. All Care Managers must demonstrate the ability to implement the View Option of the Content Consumer these profiles.	Systems designed for obstetric use will support creation of necessary content for providers in those settings, and viewing of all content that may be generated during the pregnancy under this profile.
PW	APE, APL	All Care Managers must demonstrate the ability to implement the View Option of the Content Consumer for these Profiles	Systems designed for obstetric use will support viewing of all content that may be generated during the pregnancy under this profile.

PW	LDHP, LDS, MDS	A Care Manager implementing the Labor and Delivery Option must demonstrate the ability to be a Content Creator of the Labor and Delivery History and Physical (LDHP). All Care Managers must demonstrate the ability to implement the View Option of the Content Consumer for the LDHP profile.	Systems designed for labor and delivery use will support creation of necessary content for providers in those settings, and viewing of all content that may be generated during the pregnancy under this profile.
PW	NDS, NBS	A Care Manager implementing the Newborn Option must demonstrate the ability to be a Content Creator of the Newborn Discharge Summary (NDS). All Care Managers must demonstrate the ability to implement the View option of the Content Consumer of the NDS profile.	Systems designed for labor and delivery use will support creation of necessary content for providers in those settings, and viewing of all content that may be generated during the pregnancy under this profile.
PW	XDS	All Content Creators must support the Folder Management option if used with the XDS Document Source actor.	Folders are used by this profile to organize episodes of care.

Add the following section to section 2.2

2.2.X Perinatal Workflow (PW) Integration Profile

Perinatal workflows involve communication between ambulatory providers, laboratories, imaging facilities and labor and delivery centers. The Perinatal Workflow profile simplifies exchanges between these various providers of care by utilizing profiles and transactions from several IHE domains to support the continuum of care of expectant mothers and newborns.

Add Section X

X Perinatal Workflow (PW) Integration Profile

Perinatal workflows involve communication between ambulatory providers, laboratories, imaging facilities and labor and delivery centers. The Perinatal Workflow profile simplifies exchanges between these various providers of care by utilizing profiles and transactions from several IHE domains to support the continuum of care of expectant mothers and newborns.

The period of perinatal care constitutes an episode of care that covers the period from conception through delivery of the newborn and finishes at the final postpartum visit. This episode of care is further subdivided into the antepartum period (from conception to delivery), the labor and delivery period, and the post-partum period (from delivery to the final post partum visit). Each period of care may also include several encounters and documentation of several services performed within each encounter.

Critical information from each of these subdivisions must often be carried over to the next. For example, specific lab test values available in a laboratory report should be transferred into the Antepartum Summary. Documents summarizing care for the current episode of care are transferred into the next episode for continuity of care. For example, the maternal discharge summary will also appear in the records for the post-partum episode of care.

The Antepartum Workflow profile describes the movement of this information through the various healthcare IT systems that consume and produce it. It provides guidelines on what information should be transferred, and rules for how those transfers should occur within information systems. These ensure the interoperable exchange of data necessary to ensure appropriate care continuity.

During a normal pregnancy, a patient will undergo several encounters in an obstetric setting. These encounters will track the progression of the pregnancy. Diagnostic tests, such as labs and imaging studies will be ordered, and the results incorporated into the record of care for the antepartum period. As the expectant mother nears her delivery date, many of these records will be shared with the delivery location.

In the delivery setting, the patient will undergo an admission history and physical. The mother and baby will be monitored as labor progresses and additional diagnostic tests may be ordered. The mother may be placed on an infusion pump for anesthesia. Eventually the delivery will be performed. The baby (or babies in the case of multiple birth) may be monitored, as may the mother post delivery. A labor and delivery summary will be produced which describes the outcome for both the mother and the newly delivered baby (or babies).

The baby will be admitted, and undergo a more complete evaluation at that time. Additional tests on the newborn will be performed (e.g., the newborn blood spot test and hearing screenings). Vital records data will be collected and sent to the appropriate authorities to issue a certificate of birth, and social services may be contacted if necessary to provide necessary services to the mother and child. The results of newborn screening tests (and possibly others) will be summarized in the newborn's discharge summary. Finally, the outcome of the delivery will also be summarized in the mother's discharge summary.

After the delivery, the mother will undergo follow up care, and again more diagnostic tests and or procedures may be performed. Finally, the mother will complete a final post-partum visit, which will summarize all the events that occurred before. Figure X-1 below provides an incomplete example of these information flows.

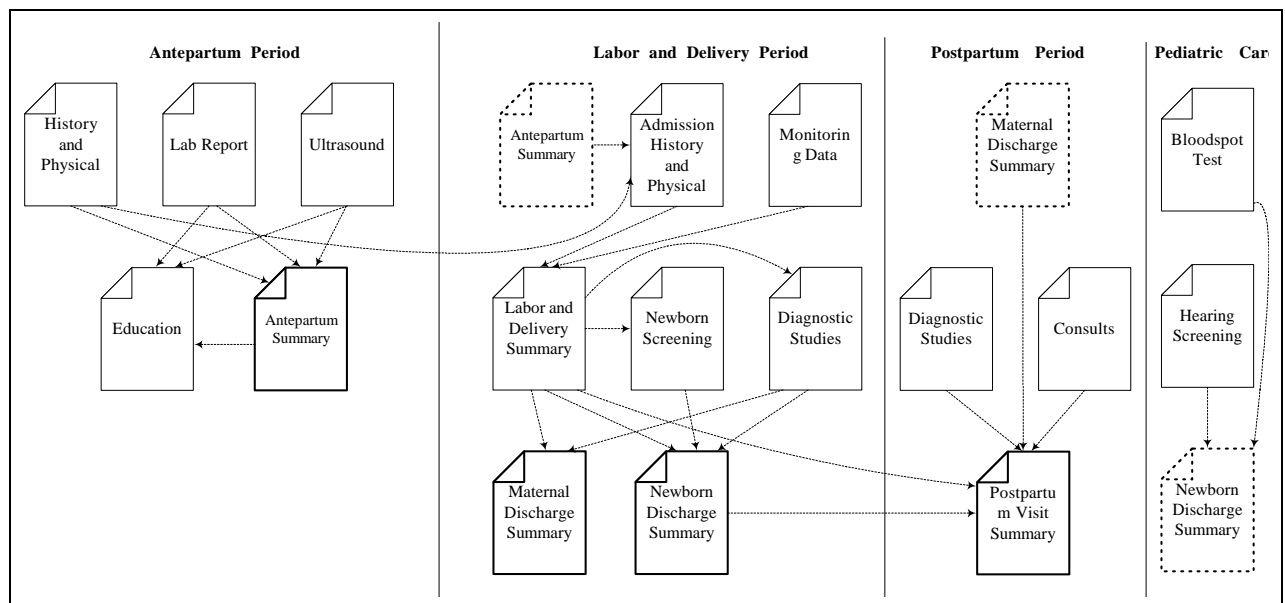


Figure X-1 Information Flow

Note that each period of care includes a document that summarizes the care that went on in that period (shown in bold) and supports transfers of care into the next period. This document transfers into the next period (dotted outline) and is used to supply relevant data during that period of care.

Records for each period are maintained in folders in the information exchange. The folders are marked with codes that describe their content. The codes used for these folders are prescribed by each region that implements the profile in National Extensions as different countries use different coding systems to represent these collections of data. IHE recommends a set of codes that may be used, and the codes that are selected by the national extensions should represent the same concepts. The folders also have textual names that describe the data that they contain. This profile makes some recommendations about the names, but leaves the formal specification of these textual names to be defined by the affinity domain. To ensure patient privacy, patient identifying characteristics should not be used in folder names (e.g., Jane Doe's First Pregnancy).

This profile specifies four folders that are created by the Care Manager Actors covering the antepartum, labor and delivery and postpartum periods for the mother and the newborn period for the baby. These are specified in PCC TF-2:6.A, 6.L, 6.N and 6.P. These folders must be created at the appropriate times by the Care Manager Actor when it shares content. Where possible¹, the Care Manager Actor must first search for a folder of an appropriate type in the Health Information Exchange. If an appropriate folder can be found, it should be verified by

¹ The "Health Information Exchange" actor can be implemented using XDS, XDR or XDM. XDS and XDM provide mechanisms to locate existing folders. XDR does not. Note that XDM only provides this capability when adding information to pre-existing media.

user of the Care Manager before new documents are added to it. If an appropriate folder cannot be found the Care Manager Actor must create it in the first submission that is exchanged.

X.1 Actors/ Transactions

There are 11 actors in this profile. Each actor represents a different information system or component of an information system. Figure X.1-1 shows the actors directly involved in the Perinatal Workflow (PW) Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in other related profiles are not necessarily shown.

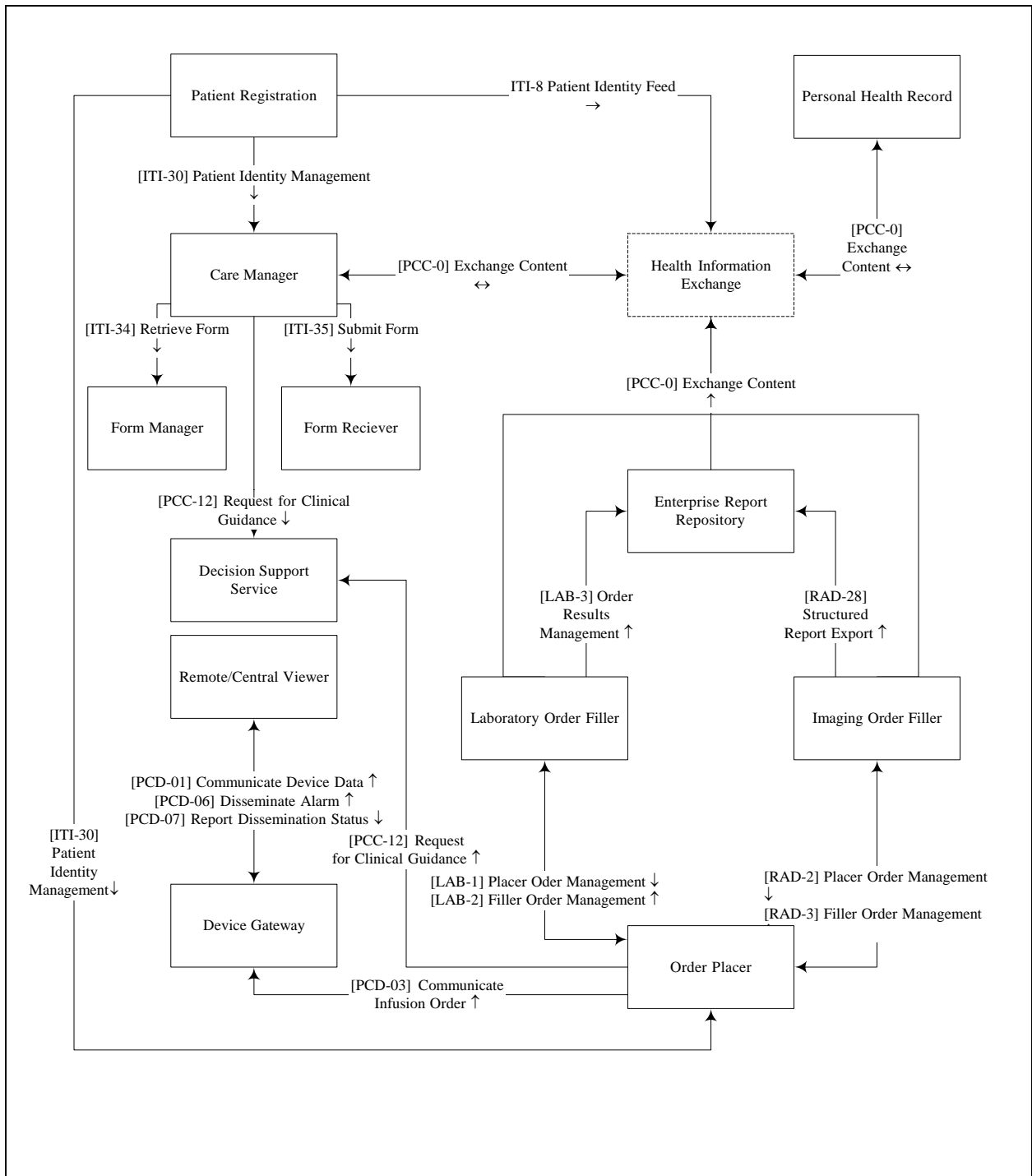


Figure X.1-1. Perinatal Workflow (PW) Actor Diagram

X.1.1 Patient Registration

The Patient Registration actor is responsible for communicating patient demographics and administrative data (e.g., insurance) to other actors in this profile. These other actors may choose to accept this information from the patient registration actor, or may provide another mechanism to support registration. The actors that support the Patient Registration Option will accept this communication from the Patient Registration Actor. Actors that support this option must accept the information as specified in the ITI-30 Patient Administration Management transaction specified in section 3.30 of ITI TF Volume 2.

X.1.2 Health Information Exchange

The Health Information Exchange Actor is virtual in this profile. This actor represents the necessary components of a Health Information Exchange. When the PCC-0 Content Exchange transaction is performed using XDS actors, the Health Information Exchange represents an XDS Registry and Repository. When these exchanges are performed using the XDR or XDM profiles, the Health Information Exchange Actor serves no purpose since the exchange occurs directly between the other actors of this profile using either point-to-point communications or media.

The Health Information Exchange actor accepts patient identity information using the ITI-8 Patient Identity Feed when XDS is used for the exchange. This is because the Health Information Exchange is only interested in a limited set of demographics used to uniquely identify the patient. It does not require additional information such as insurance or other administrative data.

X.1.2 Care Manager

The Care Manager actor represents the component of the electronic health record that a healthcare provider interacts with. Its principal responsibility in this profile is to create the content appropriate to its setting and to share that information with other Care Manager actors in similar and other settings and with the patient's Personal Health Record. The Care Manager Actor has two options specific to the care setting, at least one of which must be implemented. A Care Manager Actor implementing the Obstetric Option is intended to support obstetric care of the mother. A Care Manager Actor implementing the Labor and Delivery Option is intended to support care of mother and newborn in a labor and delivery setting. Care Managers are required to produce the set of documents appropriate to the healthcare settings they support. All Care Manager Actors must demonstrate the ability to access clinical documents from any setting. This is because more than one Obstetric setting or Labor and Delivery setting may be involved during the entire pregnancy, and providers at these settings may need to access documents produced in a physically different settings serving the same function (obstetric care or labor and delivery). For example, while traveling a mother may experience premature labor. Her records of the successfully halted labor would still be needed at the labor and delivery setting where the final delivery of the newborn occurs.

The Care Manager actor implementing the Vital Records option also interacts as a Form Filler with the Form Manager and Form Reciever actors. It supports the gathering and submission of vital statistics to the appropriate authorities for issuance of appropriate birth documentation, or for referral to social services if needed.

X.1.3 Order Placer

The Order Placer Actor represents the information system where the provider enters an order (e.g., CPOE). The Order Placer of this profile is composed of actors from the IHE Radiology, Laboratory and Patient Care Devices Technical Frameworks. The Order Placer of this profile implements all of the ordering specific transactions of the Structured Workflow (SWF) profile from the Radiology domain, the Laboratory Testing Workflow (LTW) profile from the Laboratory domain, and the Point of Care infusion verification (PIV) profile in the Patient Care Devices domain. Healthcare providers will need to order both imaging studies and laboratory tests during the care of the mother or newborn regardless of the healthcare setting.

Order Placers must be able to order tests from different locations. This profile requires that an Order Placer actor be able to order diagnostic tests from multiple locations. A typical obstetric setting may order lab tests from several laboratories depending upon the test, or several imaging centers depending upon the imaging study required.

X.1.4 Imaging Order Filler

The Imaging Order Filler Actor represents the information system that recieves and processes orders for imaging services. The Imaging Order Filler actors is a minor variation of Order Filler in the Structured Workflow (SWF) profile of the IHE Radiology Technical Framework. It supports the same ordering transactions as found in the SWF profile, but has one required and two optional transactions. From the perspective of the care providers in this profile an Imaging Order Filler is a single information system that manages orders and results for a given type of study. To avoid unnecessary complexity it is represented as a single actor in this profile even though the implementation may involve the coordination of several components on the Order Filler side.

The RAD-28 Structured Report Export transaction is used by the Imaging Order Filler to supply the report results to the Enterprise Report Repository. This transaction is the same one used by the SINR profile of the Radiology Technical Framework to supply imaging reports via an HL7 message.

The Imaging Order Filler implementing the Content Exchange option also supports the direct exchange of imaging reports via the PCC-0 Exchange Content transaction using the content specified in the XDS-SD profile. The Imaging Order Filler that implements the Imaging Data Exchange option supports direct exchange of imaging data and reports using the RAD-54 Provide and Register Imaging Document Set from the XDS-I profile.

X.1.5 Laboratory Order Filler

The Laboratory Order Filler Actor represent the information system that receives and processes orders for laboratory testing. The Laboratory Order Filler actors is a simplification² of the Order Filler in the Laboratory Testing Workflow (LTW) profile of the IHE Laboratory Technical Framework. It supports the same ordering transactions as found in the LTW profile, but has one optional transaction. The Laboratory Order Filler implementing the Content Exchange option also supports the direct exchange of laboratory reports via the PCC-0 Exchange Content transaction using the content specified in XD-LAB profile.

X.1.6 Enterprise Report Repository

The Enterprise Report Repository is able to share results with the Health Information Exchange by transforming them into the appropriate form (XD-LAB for laboratory results or XDS-SD for imaging results). This operation need not be automatic. It can be initiated by a user of the information system represented by the Enterprise Report Repository. It can also be performed automatically based on the business rules that are configured into that actor. For example, a laboratory result might be automatically shared if the patient has consented to sharing it, the provider has acknowledged its receipt, three days have elapsed since the report was acknowledged by the provider and the report does not contain certain restricted results (e.g., HIV status). Enterprise Report Repositories that support rule based exporting must also provide a mechanism whereby providers can share a document based upon their professional judgement.

X.1.7 Remove/Central Viewer

The Remove/Central Viewer actor accepts monitoring and alarm data from the Device Gateway actor and makes it available to healthcare providers.

X.1.8 Device Gateway

The Device Gateway actor coordinates communication between the Remove/Central Viewer and specialized monitoring (e.g., FHM) or treatment (e.g., Infusion Pump) devices.

X.1.9 Personal Health Record

The Personal Health Record actor represents the information system storing a patient's personal health data. This actor is responsible for supplying personal health data to the Care Manager actors through the PCC-0 Exchange Content transaction using the PHR Extract content specified in the Exchange of Personal Health Record Content profile.

² A complete implementation of the Order Filler Actor from LTW meets all requirements of the Laboratory Order Filler Actor of this profile.

X.1.10 Form Manager

The Form Manager is used to retrieve forms that need to be completed for administrative purposes during the process of birth and delivery. Such forms may be used to submit data to obtain a birth certificate for the newborn child, or to support referrals of the mother and newborn for social services. The Care Manager sends clinical information about the birth to the forms manager using the Maternal Child Health content specified in the Maternal Child Health Profile. The Form Manager responds with the appropriate forms for these administrative services which can then be filled out by the Care Manager actor acting as the Forms filler.

X.1.11 Form Reciever

Upon completion of these administrative forms, the Care Manager can submit them to the Form Reciever to initiate appropriate administrative actions, such as the submission of a birth certificate.

X.1.12 Clinical Decision Support Service

The Clinical Decision Support service may be used by the Care Manager actor to identify appropriate education, testing or treatment options for the mother or newborn.

All the Actors described above, the transactions they must support, and the options for each actor are described in more detail in the table and sections below. Table X.1-1 lists the transactions for each actor directly involved in the Perinatal Workflow (PW) Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions for the profile and each of the options it supports.

In the table below: The actors column identifies the actors and their requirements in subsequent columns. The “Option” column identifies the defined options that requires a specific transaction or IHE profile content. This column will contain “All” if the requirements of the subsequent columns apply to any implementation of the actor. Otherwise it will identify the named option for which it applies.

The “Transactions/Content” column identifies the transactions or content that is supported by actors implementing the given option. The “Req” column indicates whether ther transaction or content is required (labeled “R”) or is optional (labeled “O”). The last column provides a reference to the IHE publication and profile where the transaction was originally defined.

Table X.1-1. Perinatal Workflow (PW) Integration Profile - Actors and Transactions

Actors	Option	Transactions / Content	Req	Reference
Patient Registration	All	ITI-8 Patient Identity Feed	R	(PIX) ITI TF-2:3.8
		ITI-30 Patient Identity Management	R	(PAM) ITI TF-2:3.30
Personal Health Record	All	PCC-0 Exchange Content	R	(PW) PCC TF-2:3.0
		PHR Extract	R	(XPHR) PCC TF-2:6.3.1.5
		MDS Maternal Discharge Summary (as Consumer)	R	(APR) PCC APR:C
		NDS Newborn Discharge Summary (as Consumer)	R	(NDS) PCC NDS

Actors	Option	Transactions / Content	Req	Reference
Care Manager ¹	All	PCC-0 Exchange Content	R	(PW) PCC TF-2:3.0
		PHR Extract	R	(XPHR) PCC TF-2:6.3.1.5
		XDS-SD Scanned Documents	O	(XDS-SD) ITI TF-3:5.2
		XD-LAB Sharing Laboratory Reports	O	(XD-LAB) LAB TF-3:2
	Pt. Reg.	ITI-30 Patient Identity Management	R	(PAM) ITI TF-2:3.30
	CDS	PCC-12 Request for Clinical Guidance	R	(RCG) PCC TF-2:3.12
	Obstetric Option	APS Antepartum Summary	R	(APR) PCC APR:W
		APHP Antepartum H & P	R	(APR) PCC APR:X
		APE Antepartum Education	O	(APR) PCC APR:Y
		APL Antepartum Laboratory	O	(APR) PCC APR:Z
		PPVS Post Partum Visit Summary	R	(PPVS) PCC PPVS
	L&D Option	LDHP Labory and Delivery History and Physical	R	(LDR) PCC LDR:A
		LDS Labor and Delivery Summary	R	(LDR) PCC LDR:B
		MDS Maternal Discharge Summary	R	(LDR) PCC LDR:C
	New born	NDS Newborn Discharge Summary	R	(NDS) PCC NDS
	Admin Services	ITI-34 Retrieve Form (as Form Filler)	R	(RFD) ITI RFD-2:3.34
		ITI-35 Submit Form (as Form Filler)	R	(RFD) ITI RFD-2:3.35
		MCH Maternal Child Health	R	(MCH) QRPH MCH
Clinical Decision Support Service	All	PCC-12 Request for Clinical Guidance	R	(RGC) PCC TF-2:3.12
Order Placer	All	RAD-2 Placer Order Management	R	(SWF) RAD TF-2:4.2
		RAD-3 Filler Order Management	R	(SWF) RAD TF-2:4.3
		LAB-1 Placer Order Management	R	(LTW) LAB TF-2:4.1
		LAB-2 Filler Order Management	R	(LTW) LAB TF-2:4.2
		ITI-30 Patient Identity Management	R	(PAM) ITI TF-2:3.30
	Pt. Reg.	ITI-30 Patient Identity Management	R	(PAM) ITI TF-2:3.30
	L&D	PCD-03 Communicate Infusion Order	R	(PIV) PCD PIV
Imaging Order Filler	All	PCC-12 Request for Clinical Guidance	R	(RCG) PCC TF-2:3.12
		RAD-2 Placer Order Management	R	(SWF) RAD TF-2:4.2
		RAD-3 Filler Order Management	R	(SWF) RAD TF-2:4.3
		RAD-28 Structured Report Export	R	(SINR) RAD TF-2:4.28
	Img. Data	RAD-54 Provide and Register Imaging Document Set	R	(XDS-I) RAD TF-3:4.54
	Exch Option	PCC-0 Exchange Content	R	(PW) PCC TF-2:3.0
		XDS-SD Scanned Documents	R	(XDS-SD) ITI TF-3:5.2
Laboratory Order Filler	All	LAB-1 Placer Order Management	R	(LTW) LAB TF-2:4.1
		LAB-2 Filler Order Management	R	(LTW) LAB TF-2:4.2
		LAB-3 Order Results Management	R	(LTW) LAB TF-2:4.3
	Exch Option	PCC-0 Exchange Content	R	(PW) PCC TF-2:3.0
		XD-LAB Sharing Laboratory Reports	R	(XD-LAB) LAB TF-3:2
	New born	Newborn Hearing Screening	R	TBD
		Newborn Bloodspot Test	R	TBD
Enterprise Report Repository	All	RAD-28 Structured Report Export	R	(SWF) RAD TF-2:4.28
		LAB-3 Order Results Management	R	(LTW) LAB TF-2:4.3
		PCC-0 Exchange Content	R	(PW) PCC TF-2:3.0
		XD-LAB Sharing Laboratory Reports	R	(XD-LAB) LAB TF-3:2
		XDS-SD Scanned Documents	R	(XDS-SD) ITI TF-3:5.2

Actors	Option	Transactions / Content	Req	Reference
Remove/Central Viewer	All	PCD-01 Communicate Device Data	R	(DEC) PCD TF-2:3.1
		PCD-06 Disseminate Alarm	R	(ACM) PCD ACM
		PCD-07 Report Dissemination Status	R	(ACM) PCD ACM
Device Gateway	All	PCD-01 Communicate Device Data	R	(DEC) PCD TF-2:3.1
		PCD-03 Communicate Infusion Order	R	(PIV) PCD PIV
		PCD-06 Disseminate Alarm	R	(ACM) PCD ACM
		PCD-07 Report Dissemination Status	R	(ACM) PCD ACM
Form Manager	All	ITI-34 Retrieve Form	R	(RFD) ITI RFD-2:3.34
		MCH Maternal Child Health	R	(MCH) QRPH MCH
Form Reciever	All	ITI-35 Submit Form	R	(RFD) ITI RFD-2:3.35

Note 1: The Care Manager must support the View Option of Content Consumer for all content profiles listed.

X.2 Perinatal Workflow (PW) Integration Profile Options

Options that may be selected for this Integration Profile are listed in the table X.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table X.2-1 Perinatal Workflow (PW) - Actors and Options

Actor	Options	Vol & Section
Patient Registration	<i>No options defined</i>	- -
Care Manager	<i>Patient Registration Option</i>	X.2.1
	<i>Obstetrics Option¹</i>	X.2.2
	<i>Labor and Delivery Option¹</i>	X.2.3
	<i>Newborn Care Option¹</i>	X.2.4
	<i>Clinical Decision Support Option</i>	X.2.7
	<i>Administrative Services Option</i>	
Order Placer	<i>Patient Registration Option</i>	X.2.1
Imaging Order Filler	<i>Content Creator Option</i>	X.2.5
	<i>Imaging Data Option</i>	X.2.6
Laboratory Order Filler	<i>Content Creator Option</i>	X.2.5
Enterprise Report Repository	<i>No options defined</i>	- -

Note 1: At least one of these options shall be specified.

X.2.1 Patient Registration Option

An actor implementing the Patient Registration option must implement transaction ITI-30 Patient Identity Management. A system that passes the tests for the Patient Demographics Consumer Actor as described in the IHE ITI Patient Administration Management (PAM) profile has successfully demonstrated implementation of this option.

X.2.2 Obstetrics Option

A Care Manager actor that implements the Obstetrics Option is intended for use in that setting and is capable of creating the necessary content that is shared from an Ob/Gyn setting to a labor and delivery setting. A system that passes tests for the Content Creator Actors defined for the Antepartum Summary (APS) and Antepartum History and Physical (APHP) content profiles has successfully demonstrated implementation of this option.

X.2.3 Labor and Delivery Option

Actors that implement the Labor and Delivery Option are intended for use in that setting.

The Care Manager actor must also be capable of creating the necessary content that is shared from an labor and delivery setting to other providers. A Care Manager system that passes tests for the Content Creator Actors defined for the Labor and Delivery History and Physical (LDHP), Labor and Delivery Summary (LDS) and Maternal Discharge Summary (MDS) has successfully demonstrated implementation of this option.

Order Placer actors must demonstrate the ability to place orders to control an infusion pump, and so is required to implement the PCD-03 Communicate Infusion Order transaction.

X.2.4 Newborn Care Option

Actors that implement the Newborn Care Option are intended for use in settings that provide care for newborns.

Care Manager actors implementing this option support the creation of the Newborn Discharge Summary (NDS) specified in profile supplements issued this year. A system that passes tests for the Content Creator Actors defined for these profiles has demonstrated implementation of this option.

Laboratory Order Fillers that implement this option must implement the content creator actor of the Newborn Hearing Screening and Newborn Bloodspot Test results in the LAB-3 Order Results Management message in response to orders for those tests.

X.2.5 Content Creator Option

An order filler implementing the Content Creator option demonstrates that it can exchange the result of that order with other systems (e.g., through a Health Information Exchange).

A Laboratory Order Filler must share results (implement the content creator actor) using the XD-LAB Sharing Laboratory Results profile. An imaging order filler must share results (implement the content creator actor) using the XDS-SD Scanned Documents profile

X.2.6 Imaging Data Option

An Imaging Order Filler that implements the Imaging Data Option is required to implement transaction RAD-54 Provide and Register Imaging Document Set as described in the XDS-I profile. Actors supporting this option are able to support the exchange of images (e.g., ultrasounds).

X.2.7 Administrative Services Option

A Care Manager that implements the Vital Records option is able to submit vital records data to a vital records registry through the use of the ITI Request Form for Data Capture (RFD) profile and the QRPH Maternal Child Health (MCH) profile.

X.2.8 Clinical Decision Support

Actors that implement the Clinical Decision Support option are able to issue a PCC-12 Request for Clinical Guidance transaction prior to completing another transaction specified in this profile to ensure that appropriate care is being given.

X.3 Perinatal Workflow (PW) Process Flow

Figure X.3-1 below shows the basic flows expected in the Perinatal Workflow profile. The registration actor performs registration and updates of patient information. These updates can be sent to the Care Manager, Order Placer, or Health Information Exchange.

X.3.1 Registration

Registration of the patient can occur in the obstetric or labor and delivery setting or in the Health Information exchange prior to, or during the patient's first visit to the organization occurring providing perinatal care.

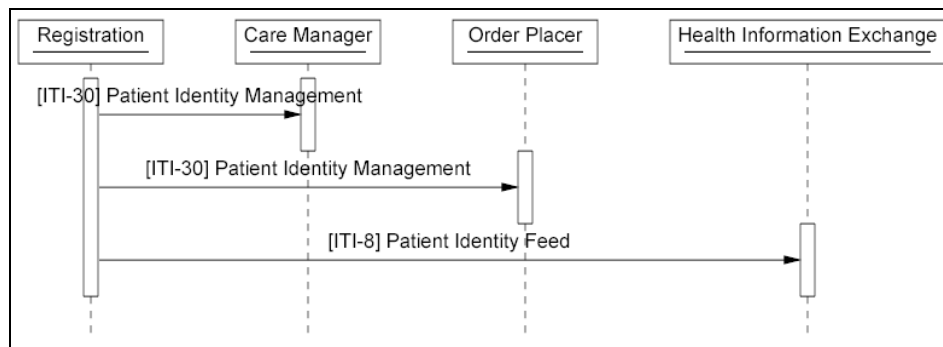


Figure X.3-1 Registration Process Flow

X.3.2 Initial Visit

During the initial obstetric visit the healthcare provider will examine the new mother, generating a history and physical. Information about the date of conception and last menstrual period is gathered to help in estimating the date of delivery, and this information may be supplemented by the patients personal health record.

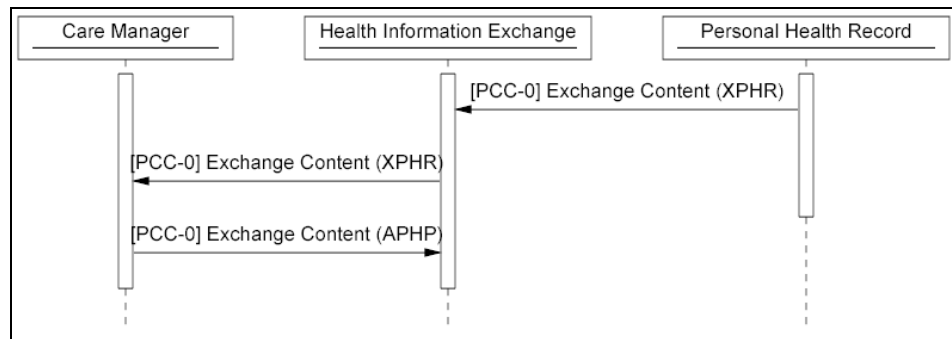


Figure X.3-2 Initial Visit H&P Process Flow

A blood test for pregnancy is ordered. When the results are returned, the provider will notify the mother of the result. The provider will share this lab result in the healthcare exchange and the new mother can look at the result online.

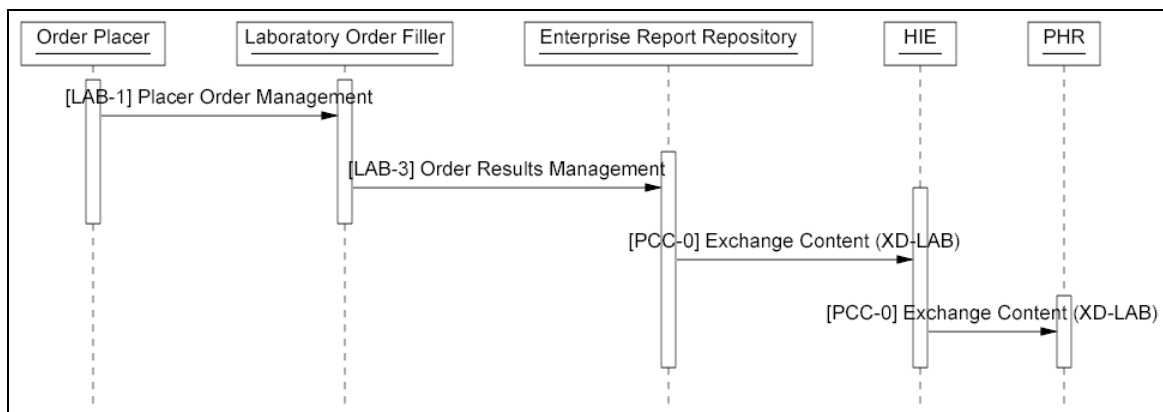
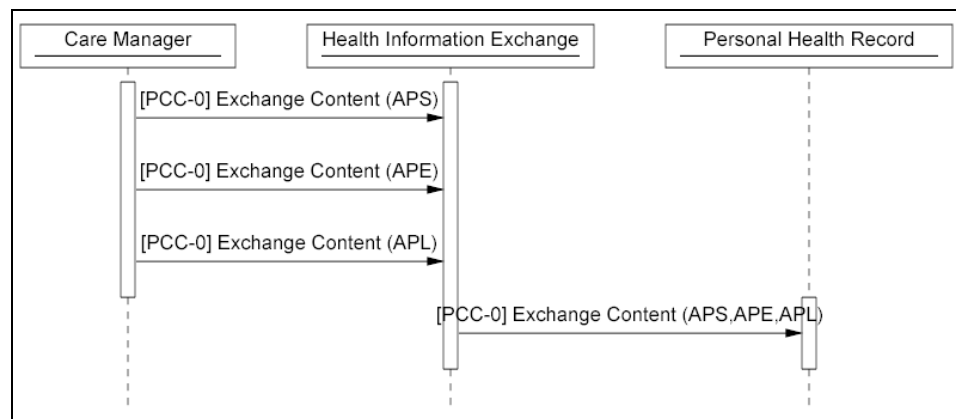


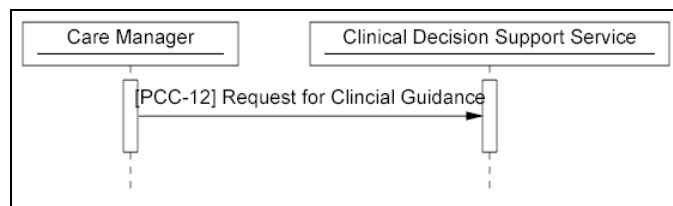
Figure X.3-3 Pregnancy Test Process Flow

X.3.3 Prenatal Care

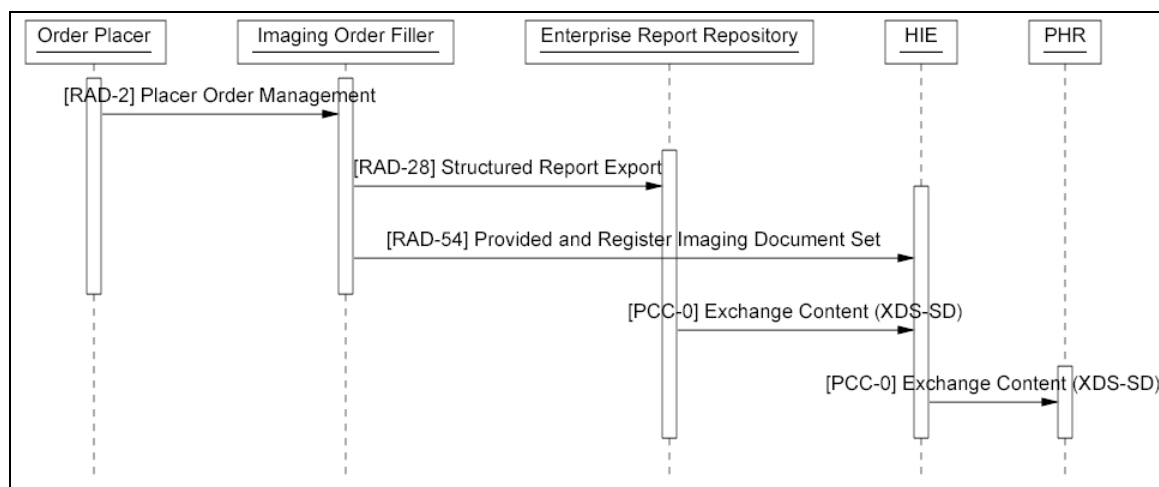
As the pregnancy progresses the mother will meet with a clinician in the obstetric providers office periodically to review the progress of the pregnancy. Additional laboratory tests will be ordered, and those results reported back to the obstetric provider and these results will also be added to the patient's antepartum summary and antepartum labs. The patient will be educated on birthing procedures and laboratory testing and results. The antepartum education report will also be produced.

**Figure X.3-4 Subsequent Visit Process Flow**

A clinical decision support system may be used to help in the evaluation results of some of these laboratory tests (e.g., in the case of genetic tests), or to identify specific immunizations that the expectant mother should receive based upon her past immunization history.

**Figure X.3-5 Clinical Decision Support Process Flow**

An ultrasound study will be ordered, and an updated date of delivery may be computed based on the results of that study. The images and results from this study can be shared for access by other providers, and also to the mothers personal health record. An image enabled PHR can let the mother actually see the ultrasound results through her PHR.

**Figure X.3-6 Ultrasound Process Flow**

As the patient nears the date of delivery, the antepartum summary, and the antepartum education, and lab results will be shared so that they may be accessed by the birthing center.

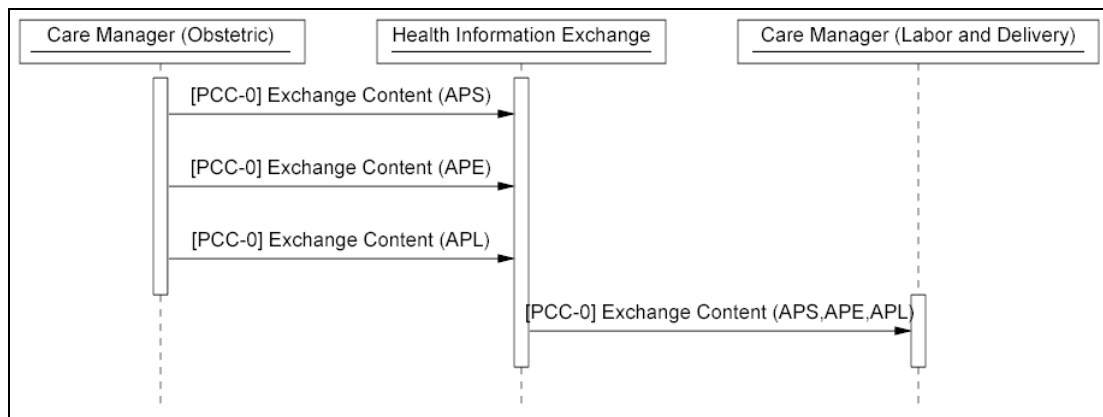


Figure X.3-7 Predelivery Process Flow

X.3.4 Labor and Delivery

When the patient begins labor, they will be treated by the birthing center, which will access the prior documents as well as information from the patient's personal health record. A copy of the mothers most recent antepartum summary will be copied over to her labor and delivery records. In many cases, another history and physical examination will be done at the time of admission.

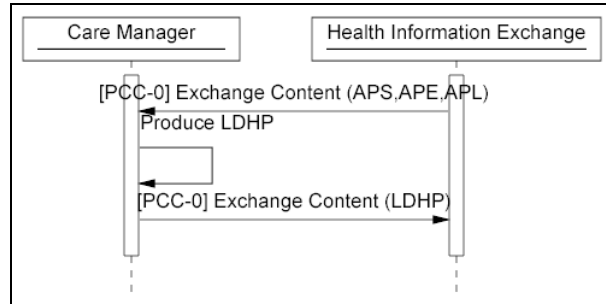


Figure X.3-7 Labor and Delivery Admission H&P Process Flow

As labor progresses, the mother will receive anesthesia, possible through a programmable infusion pump. This can be programmed by the order entry system.

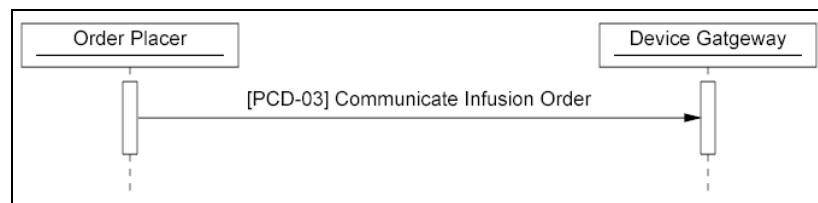


Figure X.3-8 Anesthesia Process Flow

The mother and newborn will be attached to monitors, and the monitoring data and any alarms that might be generated can also be routed to the central monitoring station in the hospital, or to pagers or other devices used to contact healthcare personell at the labor and delivery facility. Data is entered into the care management system as labor progresses.

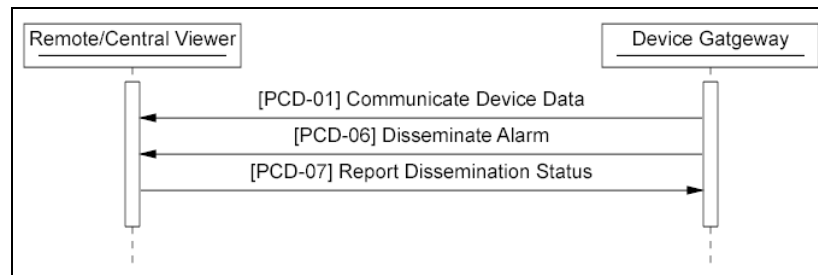


Figure X.3-9 Monitoring and Alarm Communication Process Flow

After successful delivery of the newborn, the labor and delivery summary is produced, and can be shared for subsequent access by the newborn’s pediatrician.

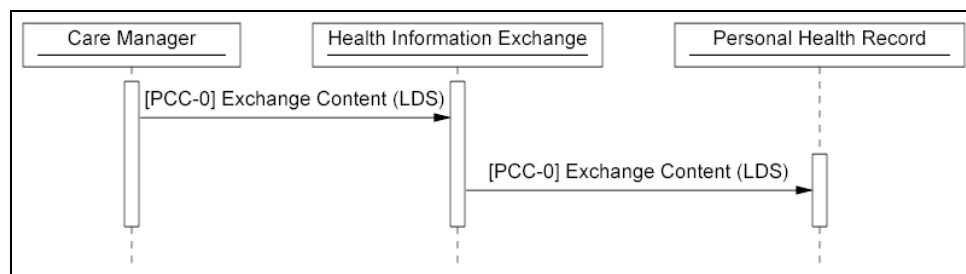


Figure X.3-10 Labor and Delivery Summary Process Flow

X.3.5 After Delivery

Per protocol, tests for the newborn hearing screening and a dried bloodspot test are ordered. The results of these tests are reported, and placed in the newborn’s pediatric care folder.

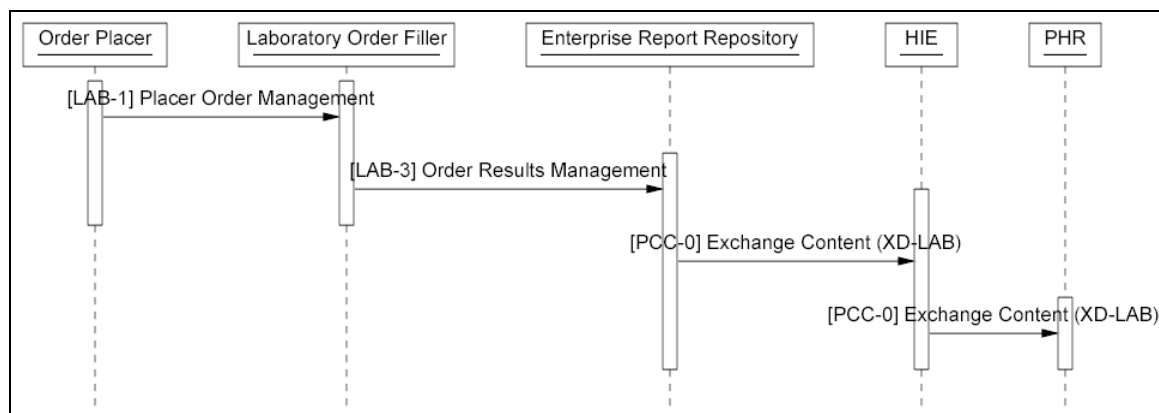


Figure X.3-11 Newborn Screening Process Flow

Information from the labor and delivery is communicated from the labor and delivery EHR to a vital records service which generates the appropriate form to be completed for submission of the birth certificate. When the mother is available (and has recovered) after delivery, she completes the necessary information not available from the EHR to obtain a birth certificate for her new baby. The form is submitted and a birth certificate is eventually mailed to the mother's home.

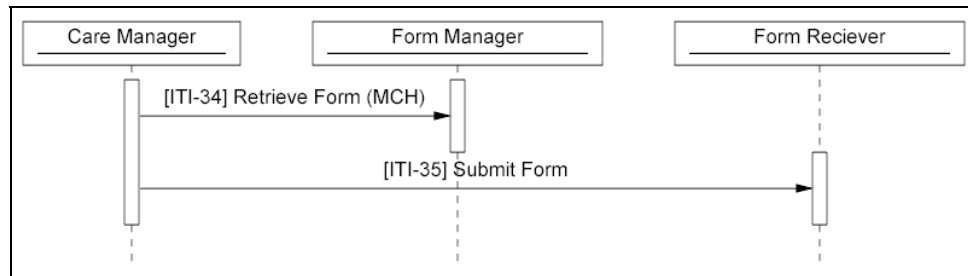


Figure X.3-12 Administrative Records Process Flow

After a day or two, the mother and baby are discharged from the hospital. A discharge summary is produced for both of them, and a copy of the mother's discharge summary is made in the post-partum care folder, and the baby's is made in the newborn's pediatric care folder.

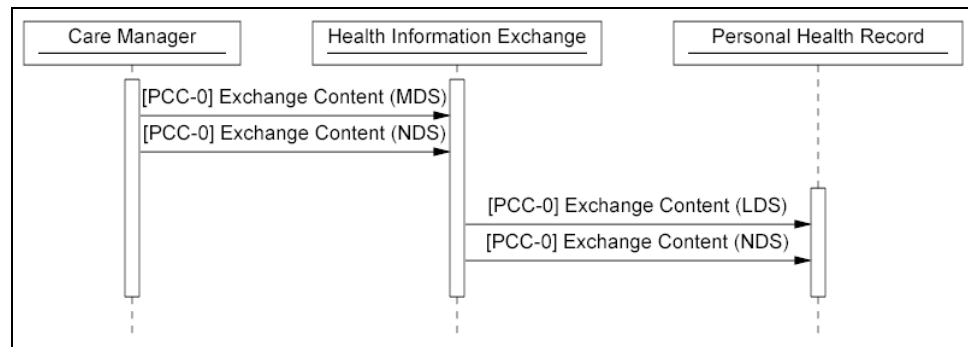


Figure X.3-13 Newborn and Mother Discharge Process Flow

X.3.6 Postpartum Care

After discharge, the mother follows up with her obstetric provider. Information from the delivery can be accessed by that provider through the health exchange. After the six-week, post partum visit, the mother's obstetric provider completes the post-partum visit summary.

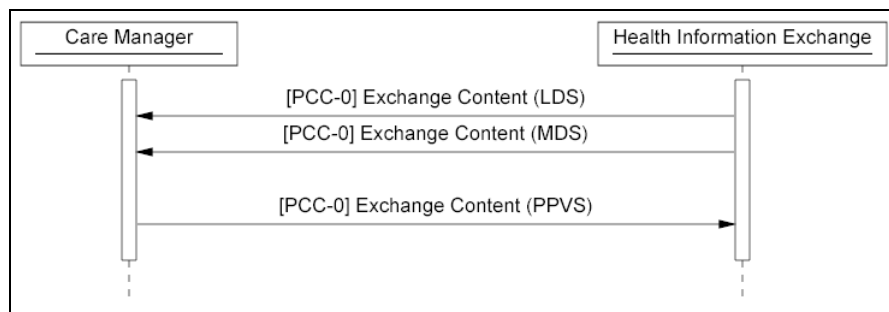


Figure X.3-14 Postpartum Process Flow

X.4 Perinatal Workflow (PW) Security Considerations

The Perinatal Workflow profile incorporates transactions and actors from previously existing IHE profiles. Security considerations appropriate to those actors and transactions are also relevant in this profile, as are some new considerations that arise from the combination of these actors and transactions.

X.4.1 Misidentified Patient

During patient registration, a patient may be misidentified as a result of insufficient differentiating demographics. This risk is present in any system that has a registration function and is not specific to this profile. It is potentially present in any system that uses the Patient Identity Cross Referencing (PIX), Patient Demographics Query (PDQ), or Patient Administration Management (PAM) profiles.

Patient misidentification can result in comingling of administrative and medical data for two patients. This may result in the loss of integrity of the health information for both patients, and could result in the use of inappropriate treatments for one or both patients. The transactions used in this profile for patient identity management support the inclusion of additional demographics which can be used to confirm the identity of a patient. Systems implementing this profile should ensure that appropriate details are incorporated into transactions communicating patient identity (e.g., addresses and other identifiers).

X.4.2 Malicious attempts to obtain patient information

Malicious attackers or users may attempt to gain patient identity information to perpetrate fraud (e.g., identity theft, insurance theft), or to obtain health information for other purposes (e.g., report a pregnancy of a well-known individual).

This is a general threat to any application which contains healthcare information, and is not specific to this profile.

To protect the information, the users of the applications providing access to it should be able to authenticate themselves to the application. When information is exchanged electronically, the communications channel should either be physically secured or encrypted or both. Finally, any

access to patient health data should be audited. Actors of this profile can be grouped with the IHE Enterprise User Authentication (EUA) profile to establish their credentials. They can also be grouped with the IHE ATNA profile to ensure that communications are encrypted, and access to patient health information is audited.

X.4.3 Accidental Release of Protected Health Information

Certain kinds of health information is often recognized by law or regulation as being more sensitive and requiring additional protection before exchange or disclosure. For example, information about sexual activity, AIDs, psychiatric records or participation in alcohol or substance abuse programs are protected by state and federal law in the US.

This is a general threat to any application which contains sensitive healthcare information, and is not specific to this profile.

Applications implementing this profile must ensure that appropriate access controls and permissions are applied to users. IHE Enterprise User Authentication (EUA) profile can be used to establish user credentials within an enterprise, or the Cross Enterprise User Authentication (XUA) profile can be used to communicate user information across enterprises. Data requiring an additional level of protection can be identified as has been specified in the IHE Basic Patient Privacy Consents (BPPC) profile.

X.4.4 Inability to Communicate Orders due to System Failure or Malicious Attack

The Order Placer Actor in this profile may not be able to communicate orders to a receiving system. The failure of this communication will become obvious to providers, and fallback mechanisms can be used to ensure orders are executed. Typical communication failures will be immediately obvious through application behaviors. Failures due to malicious attack would not be immediately obvious but would eventually be detected by lack of response to the order, and would be more rare. Orders described by this profile are for diagnostic tests rather than therapeutic treatments, which reduces risk somewhat that the failure to communicate the order would result in loss of life or quality of life issues. Implementors of this profile should ensure that appropriate responses to orders are monitored.

X.4.5 Inappropriate Communication of Mother / Child Identity in Adoption Cases

In cases of pregnancy where the child is subsequently put up for adoption by the mother, information about the mother or the child may be inappropriately communicated to the other through exchange of medical documents describing results affecting both patients (e.g., the labor and delivery summary). Applications implementing this profile should provide a mechanism to disable communication of the mother's data to the child's record and visa versa, or anonymize that data. Anonimization of the mother's and/or child's record is out of scope for this profile, but may be the subject of future work in the PCC or ITI domain.

X.4.6 Externally sourced data may be inaccurate or unreliable

One concern often expressed about the exchange of information between patients and providers, or even between two providers is that data coming from outside the organization may be inaccurate or unreliable. Because there are multiple data sources from which information can be gathered, there will rarely be a single source for a relevant piece of health information. The availability of multiple sources for health information enables providers a cross check for certain health information. In cases where there is a new finding, the provider would simply use the same mechanisms to verify the information as they would if it came to them through non-electronic means (as they already do today).

Information that comes from external sources through the XDS, XDM or XDR profiles use a message authentication code, so that providers can be assured that it has not been altered in transit. Furthermore, this information can also be digitally signed by the information source using the IHE Digital Signature profile (DSG). This assures the receiver of the information that it cannot be repudiated by the signer of the data. This does not address the reliability of the information source itself. Providers must use existing methods to verify information they receive from external sources (e.g., as are used with patient communicated histories, or paper copies of medical records).

Volume 2 - Transactions

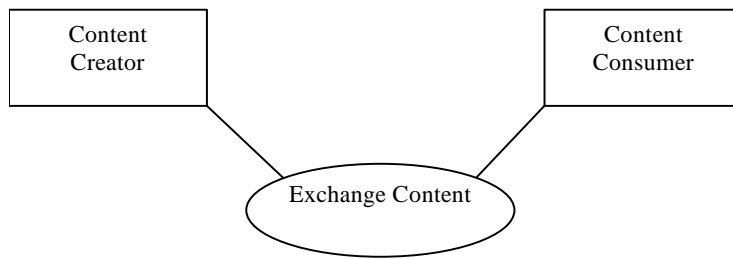
Add section 3.Y

3.0 Exchange Content

This section corresponds to Transaction 0 of the IHE PCC Technical Framework. Transaction 0 is used by the Content Creator and Content Consumer actors of various IHE Content profiles.

3.0.1 Scope

3.0.2 Use Case Roles



Actor: Content Creator

Role: Create Content

Actor: Content Consumer

Role: View or Import Content

3.0.3 Referenced Standard

IHE XDS, XDR or XDM profiles of ebXML RIM and Registry Services.

3.0.4 Interaction Diagram

Interactions for the PCC 0 Exchange Content transaction vary depending upon the infrastructure used for the health information exchange.

3.0.4.1 Exchange Content with Cross Enterprise Document Sharing

See IHE Cross Enterprise Document Sharing (XDS) in ITI TF-1: 10 and the related transactions in ITI TF-2a:18 and ITI TF-2b:41 and 42. The sequence of operations is as shown in Figure 3.0-1 below

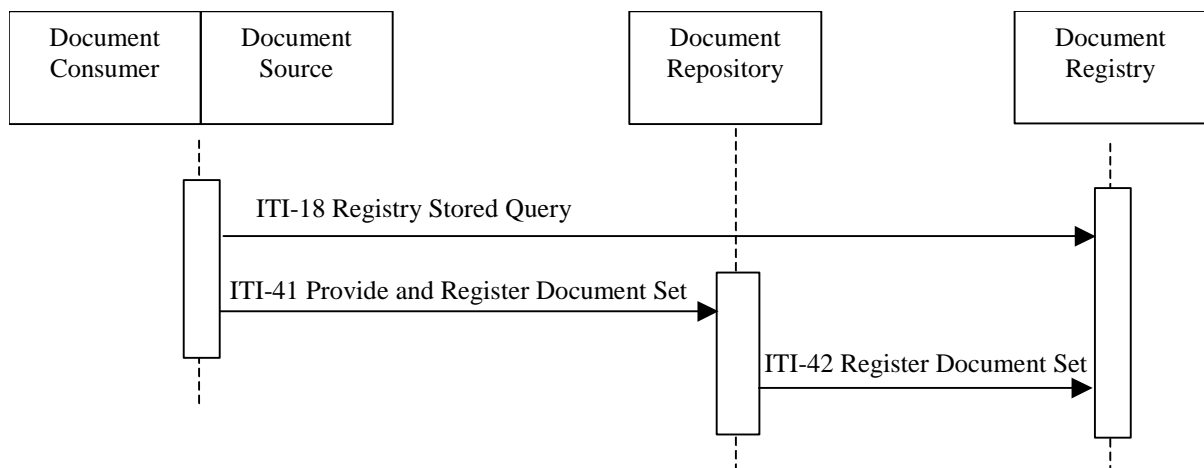


Figure 3.0-1 XDS Actors and Transactions for Exchange Content

3.0.4.1.1 ITI-18 Registry Stored Query

This interaction is optional in most cases. It may be required when a specific folder must be used in an exchange operation, and that folder must be discovered.

3.0.4.1.2 ITI-41 Provide and Register Document Set

The Provide and Register Document set interaction is required to communicate the contents of the exchange to the document repository. The repository is then required to communicate the registration information to the document registry.

3.0.4.2 Exchange Content with Cross Enterprise Document Reliable Interchange

See IHE Cross Enterprise Document Reliable Exchange (XDR) and the related transactions in ITI TF-2b:41. The sequence of operations is as shown in Figure 3.0-2 below

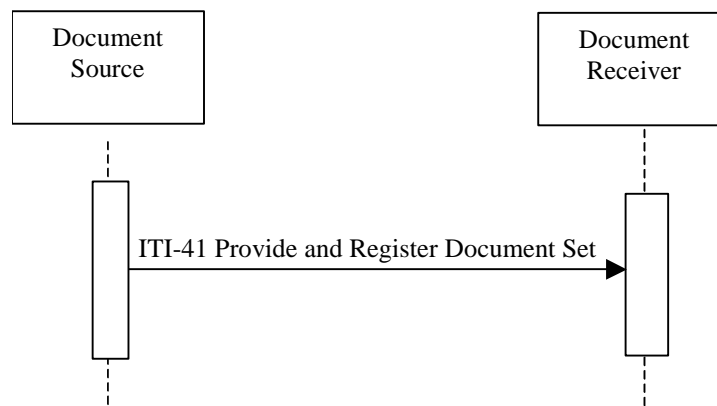


Figure 3.0-2 XDR Actors and Transactions for Exchange Content

3.0.4.2.1 ITI-41 Provide and Register Document Set

The Provide and Register Document set interaction is required to communicate the contents of the exchange to the document receiver. There is no mechanism to query for appropriate folders to place documents in when using the Provide and Register Document Set.

3.0.4.3 Exchange Content with Cross Enterprise Document Sharing on Media

See IHE Cross Enterprise Document Sharing on Media (XDM) and the related transaction in ITI TF-2b:32. The sequence of operations is as shown in Figure 3.0-3 below

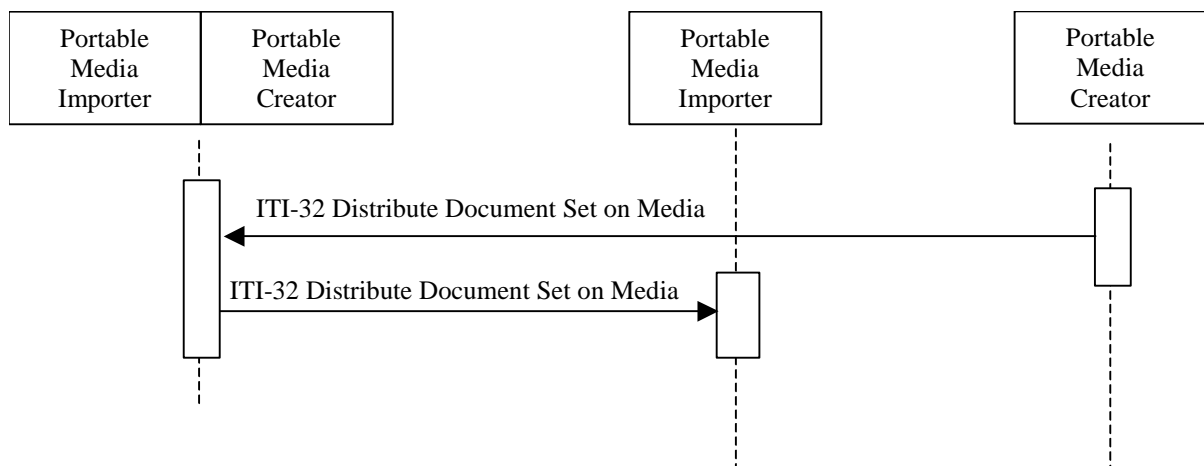


Figure 3.0-3 XDM Actors and Transactions for Exchange Content

3.0.4.3.1 ITI-32 Distributed Document Set on Media

The location of folders to use on the media can be determined by looking at existing media.

3.0.5 Security Considerations

Content Creator Actors are responsible for ensuring that only authorized users create content, that the author of this content is identified within the documents exchanged, and that communications are secured between the sender and receiver.

Content Consumer Actors are responsible for ensuring that only authorized users obtain access to content that is being retrieved and/or imported into the receiving system, and that communications are secured between it and the sender.

3.0.5.1 Security Audit Considerations

Appropriate audit messages must be generated according to the specifications for the transactions used from the ITI Technical Framework.

Insert section 6.2 below

6.2 Folder Specifications

Folders can be used for many purposes in information exchanges that support the XDS, XDR and XDM profiles. One such use is to gather information together for a single episode of care, where that episode has a defined starting and ending point. Folders that are used for this purpose are created based on a given trigger event that signals the start of an episode of care. Often this will be the creation of a particular kind of document that signals the new episode. Because it is hard to automate the determination of episode of care, applications using folders for this purpose should provide a mechanism to allow users to validate the folder where documents are being created. Figure 6-1 below shows an example of the metadata used with a Folder being used for this purpose.

```
<RegistryPackage id="Folder">
  <Name>
    <LocalizedString value="Labor and Delivery Records"/>
  </Name>
  <Description>
    <LocalizedString value="comments"/>
  </Description>
  <!-- Classify registry package Folder as being an XDSFolder -->
  <Classification>
    classificationNode="urn:uuid:d9d542f3-6cc4-48b6-8870-ea235fbc94c2"
    classifiedObject="Folder"/>
  <!-- Classify this Folder as being a collection of labor and delivery records -->
  <Classification>
    classificationScheme="urn:uuid:1ba97051-7806-41a8-a48b-8f6ce7af683c5"
    classifiedObject="Folder" nodeRepresentation="15508-5">
    <Name>
      <LocalizedString value="Labor and Delivery Records"/>
    </Name>
    <Slot name="codingScheme">
      <ValueList>
        <Value>LOINC</Value>
      </ValueList>
    </Slot>
    </Classification>
  <!-- Patient Identifier -->
  <ExternalIdentifier>
    identificationScheme="urn:uuid:f64ffdf0-4b97-4e06-b79f-a52b38ec2f8a"
    value="6578946^^^&1.3.6.1.4.1.21367.2005.3.7&ISO">
    <Name>
      <LocalizedString value="XDSFolder.patientId"/>
    </Name>
  </ExternalIdentifier>
  <!-- Folder Identifier -->
  <ExternalIdentifier>
    identificationScheme="urn:uuid:75df8f67-9973-4fbe-a900-df66cefecc5a"
    value="1.3.6.1.4.1.21367.2005.3.7.3670984664">
    <Name>
      <LocalizedString value="XDSFolder.uniqueId"/>
    </Name>
  </ExternalIdentifier>
</RegistryPackage>
```

Figure 6-1 Folder Metadata Example

6.2.A Antepartum Folder Specification

The Antepartum Folder contains information from the Antepartum Care period of a pregnancy.

This folder should be coded as required for the Region where it is used. A recommended code to use is X-Antepartum Records from LOINC. The Antepartum Folder contains a set of documents describing care given during the Antepartum period of a pregnancy. This period is defined as the period between determination of pregnancy and the beginning of the final labor of the pregnancy.

Under exceptional conditions a pregnancy can have multiple periods of labor and delivery which may also overlap the antepartum period. For example, a premature labor may occur which is successfully stopped. In these cases, a Labor and Delivery folder is created for each distinct Labor and Delivery period (see Labor and Delivery Folder below).

The Antepartum Folder is expected to contain documents conforming to the content specifications for the Antepartum History and Physical (APHP), Antepartum Education (APE), Antepartum Labs (APL) and Antepartum Summary (APS). In addition, it may contain other documents such as imaging studies (XDS-I), laboratory results (XD-LAB), or other content pertinent to the antepartum care of the patient.

When an APHP, APE, APL or APS document is shared, the Content Creator shall:

1. Determine the appropriate Antepartum Folder to use for sharing OR
2. Create an Antepartum Folder if an appropriate one does not already exist.

The first step is completed by:

1. Locating the most recently updated (XDSFolder.lastUpdate) Antepartum Folder for the patient (either on existing XDM media being updated, or in an XDS registry).
2. Verifying that this folder is correct. The reason for this step is that there may be multiple antepartum periods corresponding to different pregnancies that are less than nine months apart (e.g., in cases where a miscarriage occurs).

If an appropriate Antepartum Folder cannot be found it shall be created by:

1. Creating a new Folder using the X-Antepartum Records code from LOINC or the code required by the National Extension.
2. The folder should have a name identifying it as an Antepartum Folder, and should have an indication of which antepartum period it references so that it can be readily verified by a provider. For example, the date that the Antepartum Period started, or the number of this pregnancy (e.g, Antepartum Record starting 2/2/2010, or Antepartum Record for Pregnancy 1).

The APHP, APE, APL or APS documents are placed in the the folder that was found or created. Other documents known to be part of or relevant to Antepartum care may also follow this protocol. For example, documents describing fertility treatment leading to conception may also be included in the Antepartum folder.

6.2.L Labor and Delivery Folder Specification

The Labor and Delivery Folder contains information from the Labor and Delivery period of a pregnancy.

This folder should be coded as required for the Region where it is used. A recommended code to use is 15508-5 Labor and Delivery Records from LOINC. The Labor and Delivery Folder contains a set of documents describing care given during the Labor and Delivery period of a pregnancy. This period is defined as the period between onset of Labor and its completion or termination.

Under exceptional conditions a pregnancy can have multiple periods of labor and delivery which may also overlap the antepartum period. For example, a premature labor may occur which is successfully stopped. A separate Labor and Delivery Folder shall be created for each episode of labor experienced by the mother. The definition of episode of labor should be coordinated with regional or local policies where they exist. If no such policy exists, we recommend that two occurrences of labor in a 24 hour period be treated as a single episode of labor.

The Labor and Delivery Folder is expected to contain documents conforming to the content specifications for the Labor and Delivery History and Physical (LDHP), Labor and Delivery Summary (LDS), and Maternal Discharge Summary (MDS). In addition, it may contain other documents such as imaging studies (XDS-I), laboratory results (XD-LAB), or other content pertinent to the labor and delivery care of the patient.

When an LDHP, LDS or MDS document is shared, the Content Creator shall:

1. Determine the appropriate Labor and Delivery Folder to use for sharing OR
2. Create a Labor and Delivery Folder if an appropriate one does not already exist.

The first step is completed by:

1. Locating the most recently updated Labor and Delivery Folder for the patient (either on existing XDM media being updated, or in an XDS registry).
2. Verifying that this folder is correct. The reason for this step is that there may be multiple labor and delivery episodes for a single pregnancy as described above.

If an appropriate Labor and Delivery Folder cannot be found it shall be created by:

1. Creating a new Folder using the 15508-5 Labor and Delivery Records from LOINC or the code required by the National Extension.
2. The folder should have a name identifying it as a Labor and Delivery Folder, and should have an indication of which labor and delivery period it references so that it can be readily verified by a provider. For example, the date that the Labor started (Labor starting 2/2/2010).

Placing the newly submitted document(s) in that folder.

Other documents known to be part of Labor and Delivery care may also follow this protocol.

When the Labor and Delivery Folder is created, the submitter shall locate the most recent Antepartum Folder, verify that it is correct, locate the most recent Antepartum Summary in that folder, and ensure that document also appears in the newly created Labor and Delivery Folder.

There are additional requirements when a Maternal Discharge Summary (MDS) is shared, see Postpartum Folder below.

6.2.N Newborn Folder Specification

The Newborn Folder contains information about a newborn child.

This folder should be coded as required for the Region where it is used. A recommended code to use is X-Newborn Records from LOINC. The Newborn Folder contains a set of documents describing care given during the Newborn period of a child. This period is defined as the period between delivery and the beginning of the neonatal period (usually one month according to various regional policies).

The Newborn Folder is expected to contain documents conforming to the content specifications for the Labor and Delivery Summary (LDS), Newborn Discharge Summary (MDS) and Newborn Screening (NBS) profiles. In addition, it may contain other documents such as imaging studies (XDS-I), laboratory results (XD-LAB), or other content pertinent to care of the newborn.

When an NDS or NBS document is shared, the Content Creator shall:

1. Determine the appropriate Newborn Folder to use for sharing OR
2. Create a Newborn Folder if an appropriate one does not already exist.

The first step is completed by:

1. Locating the most recently updated Newborn Folder for the newborn (either on existing XDM media being updated, or in an XDS registry).
2. Verifying that this folder is correct.

If an appropriate Newborn Folder cannot be found it shall be created by:

1. Creating a new Folder using the X-Newborn Records from LOINC or the code required by the National Extension.
2. The folder should have a name identifying it as a Newborn Folder.

Placing the newly submitted document(s) in that folder.

Other documents known to be part of Newborn care may also follow this protocol.

When the Newborn Folder is created, the submitter shall locate the most recently updated Labor and Delivery Folder for the mother, verify that it is correct, locate the most recent Labor and Delivery Summary in that folder, and ensure that document also appears in the newly created Newborn Folder. This capability must be able to be overridden in certain scenarios where the

connection between the mother and newborn should not be made (e.g., in cases of a newborn being given up for adoption).

6.2.P Postpartum Folder Specification

The mother's Postpartum Folder contains information from the Postpartum period of a pregnancy.

This folder should be coded as required for the Region where it is used. A recommended code to use is X-Postpartum Records from LOINC. The Postpartum Folder contains a set of documents describing care given during the Postpartum period of a pregnancy. This period is defined as the period between Delivery and the final follow up visit with the provider of obstetric care.

The Postpartum Folder is expected to contain documents conforming to the content specifications for the Postpartum Visit Summary (PPVS), Labor and Delivery Summary (LDS), and Maternal Discharge Summary (MDS). In addition, it may contain other documents such as imaging studies (XDS-I), laboratory results (XD-LAB), or other content pertinent to the Postpartum care of the patient.

When an MDS or PPVS document is shared, the Content Creator shall:

1. Determine the appropriate Postpartum Folder to use for sharing OR
2. Create a Postpartum Folder if an appropriate one does not already exist.

The first step is completed by:

1. Locating the most recently updated Postpartum Folder for the patient (either on existing XDM media being updated, or in an XDS registry).
2. Verifying that this folder is correct.

If an appropriate Postpartum Folder cannot be found it shall be created by:

1. Creating a new Folder using the X-Postpartum Records from LOINC or the code required by the National Extension.
2. The folder should have a name identifying it as a Postpartum Folder

Placing the newly submitted document(s) in that folder.

Other documents known to be part of Newborn care may also follow this protocol.

When the Postpartum Folder is created, the submitter shall locate the most recent Labor and Delivery Folder, verify that it is correct, locate the most recent Maternal Discharge Summary in that folder, and ensure those documents also appear in the newly created Postpartum Folder.