Integrating the Healthcare Enterprise

IHE IT Infrastructure (ITI)

Technical Framework Supplement

Cross-Enterprise Document Workflow (XDW)

Draft for Public Comment

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Foreword

This is a supplement to the IHE IT Infrastructure Technical Framework 7.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is submitted for Public Comment between June 3, 2011 and July 3, 2011. Comments are invited and may be submitted at http://www.ihe.net/iti/iticomments.cfm. In order to be considered in development of the Trial Implementation version of the supplement comments must be received by July 3, 2011.

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:

Replace Section X.X by the following:

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

Information about the IHE IT Infrastructure can 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

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Introduction

The Cross-Enterprise Document Workflow (XDW) profile enables participants in a multi-organizational environment to track the steps related to patient-centric workflows as they coordinate their activities. It builds upon the sharing of health documents provided by other IHE profiles such as XDS, adding the means to associate documents to a patient-specific workflow. XDW provides a common interoperability infrastructure upon which a wide range a specific workflow "content" may be defined. It is designed to support the complexity of health services delivery with much flexibility to adapt as workflows evolve.

This profile defines a shared workflow tracking data structure, called a "workflow document" that records past steps of a workflow and maintains the references to health information input and output associated with each step. Such shared workflow state information allows the various participating systems to be aware of the history (past steps) of any of the workflows known for a patient, access the workflow current state and remain coordinated by updating this shared document with the new steps they have performed.

XDW is intended to offer a common, workflow-independent interoperability infrastructure that:

- Provides a platform upon which a wide range of specific workflows can be defined by "content specialization" with minimal specification and implementation efforts (e.g., Medical Referrals, Prescriptions, Home Care). These will be called XDW-Based Content Profiles
- Benefits many clinical and non-clinical domains by avoiding different competing approaches to interoperability.
- Increases the consistency of workflow interoperability, and enables the development of interoperable workflow management applications where workflow-specific customization is minimized.
- Facilitates the definition and evolution of workflows for and by health professionals, minimizing the technical skills needed.
- Facilitates the integration of multi-organizational workflows with the variety of existing organization workflow management systems.

More specifically XDW supports workflows that:

- Are patient-centric.
- Have a business/clinical specification which is defined "above" XDW. The business definition of the workflow is external to XDW. The business definition of the workflow on top of XDW needs to be known only by the participating systems, not by the XDW infrastructure. This workflow business definition is performed by specializing key coded data elements in the workflow document (value sets, step succession rules, referenced

types of documents, etc.). Such workflow definitions are simply referenced by a unique identifier.

- Need to be tracked in distributed environments, so that the workflow participants need to know the most recent step performed, and what was the history of past steps. Only "information about the workflow history so far" is shared, so no centralized workflow management system is needed for XDW.
- Keep a strict separation between XDW which tracks the workflow and the clinical or administrative information which is managed through pointers to documents shared in a traditional XDS manner.
- Leave the driving of the workflow to the health professional. Future steps are not managed in XDW, but left to the business layer above XDW where requests or expectations are considered integral to the outcome of previous steps (care plans, requests, etc.).

Open Issues and Questions

1. *Should we more specific in term of kinds of queries have to be supported or implemented by a Document Consumer in XDW ? Show all workflow for patient, show me all active workflow, I've a workflow document Id give me the approved one (walking through replace associations or with folder or how?)*
2. *A step may refer to another Workflow Document as input or output (created a new workflow). The capability to have a step refer to another specific step in the same WD as inputs or outputs has not been included. Is that OK?*
3. *XDW does not explain how to define a notification system about the change(replacement). Should an appendix be developed to discuss?*
4. *In a Workflow Document, the reference to an input or output document in a step is a documentID. Is it sufficient?*
5. *Appropriateness of the use of FolderID for referrencing other Workflow Documents. (To reference a workflow document inside an other workflow document benefits from the use of the FolerID of the workflow Document. This avoids referencing a specifc workflow document that may have been deprecated due to further steps been added.)*
6. *Appropriateness of the use of Folders for managing back links from documents to workflow documents. Should this back link be mandatory or optional? (A performance improvement mechanism to find the Workflow Documents referencing a specific clinical document has not been included. An approach to have any referenced documents placed in the same folder as the Workflow documents has been considered but not included. This Folder mechanism could have offered a simpler back-link within an XDS affinity domain. However it does not scale up to document that may be referenced in a multi-community environment (use of XCA) As it is expected that XDW would be extended in the future to mult-communities.)*

7. *Definition of the information that will be in the header: open/close, creator, uniqueID,….*
8. *Management of the closing of a workflow to avoid inactive workflow document being returned by queries. This introduce some form of state of the workflow. However, as XDW does not want to define a mechanisms to define overall workflow states (this may be done through the definition of specific steps by the workflow specific specifications built on top of XDW. To make that point clear, it is proposed to only introduce a "workflow active flag", which may be valued either as: "active" or "inactive" to make clear that such a mechanism is quite limited. It is proposed to place this "workflow active flag" in the document metadata "event code list". It is proposed to not duplicate this workflow active flag in the wokflow document header, but to simply introduce a copy of the flag indication in the workflow step data that resulted in modifying the "workflow active flag".*
9. *A framework for specifying XDW-Based Content Profiles is proposed. It does not allow the XDW Document Content specification to be changed in its structure (no new data elements may be added). It allows to constrain already defined data elements in the XDW Workflow Document such as defining: (1) a set of Step Name codes and display names allowed, (2) succesion rules/constraints between these steps, (3) the referenced input and output document content specifications (e.g. IHE PCC , Phamacy, Laboratory, QRPH Content profiles), (3) the ability to span "sub-workflows" by creating new workflow documents, etc. This approach enables the development of more generic XDW Workflow management applications.*
10. *This proposal use the CDA as formal structure of the Workflow Document. Is it appropriate? If not propose a detailed alternative.*
11. *This proposal does not yet specified templates, value set if any, codes, etc. these will be defined, please comment.*

Closed Issues

1. *Should there be any clinical information inside the Workflow Document? No, XDW as specified requires that all the Clinical information be included by reference to external documents. (Figure 1). This ensures that a generic workflow document structure is defined, with only a few attributes customized for the workflow specifics (e.g., workflow definition IDs, workflow description, step status codes, status step description, possible referenced documents specification, etc.).*

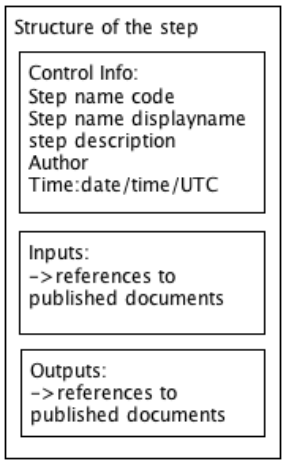

Figure 1: Schema of the Step

(introduce a block which has the information of the workflow document, such an header, with title, purpose, creator,UniqueID for workflow instance …) these datas has to be coded or not?

2. *It was decided to not include the management of the status of the steps that are "booked steps in the future". Steps are a record of past up the most recent steps that has been performed. Future activities should be introduced inside documents referenced as outputs (e.g. orders, requests, treatment plans, etc.). This reflect the reality that in a multi-organizational environment future steps are an "expectation" shared by one professional with others that will rely upon their medical judgment and the latest information to perform or not such expected activities".*
3. *The same document can be referenced in the input or output of one or more steps*
4. *This profile specifies no rules for controlling changes of status.*
5. *IHE-ITI specifies a classCode for XDW Workflow document.*

Volume 1 – Integration Profiles

1.7 History of Annual Changes

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

- Added the XDW Profile that enables participants in a multi-organizational environment to track the steps related patient-centric workflows as they coordinate their activities.

For the information of reviewers, the following permission is already part of the framework.

1.n Copyright Permission

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2.2.X Cross-Enterprise Document Workflow Content Profile

The Cross-Enterprise Document Workflow (XDW) profile enables participants in a multi-organizational environment to track the steps related to patient-centric workflows as they coordinate their activities. It builds upon the sharing of health documents provided by other IHE profiles such as XDS, adding the means to associate documents related to patient-specific workflows. XDW provides a common interoperability infrastructure upon which a wide range of specific workflow "content" may be defined. It is designed to reflect the complexity of health services delivery with flexibility to adapt as workflows evolve.

Add Section X

X Cross-Enterprise Document Workflow Content profile

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This profile defines a shared workflow tracking data structure, called a "workflow document" that records past steps of a workflow and maintains the references to health information input and output associated with each step. Such shared workflow state information allows the various

participating systems to be aware of the history (past steps) of any of the workflows known for a patient, access the workflow current state and remain coordinated by updating this shared document with the new steps they have performed.

XDW is intended to offer a common, workflow-independent interoperability infrastructure that:

- Provides a platform upon which a wide range of specific workflows can be defined by "content specialization" with minimal specification and implementation efforts (e.g., Medical Referrals, Prescriptions, Home Care). These will be called XDW-Based Content Profiles.
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- Need to be tracked in distributed environments, so that the workflow participants need to know the most recent step performed, and what was the history of past steps. Only "information about the workflow history so far" is shared, no centralized workflow management systems is needed for XDW.
- Keep a strict separation between XDW which tracks the workflow and the clinical or administrative information which is managed through pointers to documents shared in a traditional XDS manner.
- Leave the driving of the workflow to the health professional. Future steps are not managed in XDW, but left to the business layer above XDW where requests or expectations are considered integral to the outcome of previous steps (care plans, requests, etc.).

The XDW profile uses general purpose document sharing infrastructures such as those offered by the IHE XDS transactions. The XDW profile is defined as a Content Profile using document

sharing transactions and profiles a shared workflow tracking data structure called a "workflow document".

This profile defines the content of a workflow document that records past steps of a workflow and maintains the references to health information input and output associated with each step. Such shared workflow state information allows the various participating systems to be aware of the history (past steps) of any of the workflows known for a patient, access the workflow current state and remain coordinated by updating this shared document with the new steps they have performed.

X.1 Actors/ Transactions

The XDW Content profile is based on two actors, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, in PCC TF-2: 4.1. An XDW Content Creator shall be able to create new workflows (create a new XDW Workflow Document and place it into a new folder) as well as contribute to existing workflows (consume an existing Workflow Document and replace it with an updated XDW Workflow Document).

Figure X.1-1. XDW Actor Diagram

X.2 Cross-Enterprise Document Workflow Profile Options

Options that may be selected for this 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 XDW - Actors and Options

Actor	Options	Vol & Section
Content Creator	*No options defined*	- -
Content Consumer	*View Option*	ITI TF-1: X.2.2.1
	Document Import Option	ITI TF-1: X.2.2.2

X.2.1 Grouping

A XDW Content Creator or Content Consumer shall be grouped with appropriate actors from the XDS profile to exchange XDW workflow documents. The metadata sent in the document sharing or interchange has specific relationships or dependencies (which we call bindings) to the content of the clinical document – a XDW workflow document.

- A XDW Content Creator shall be grouped with:
  - An XDS.b Document Source with both the Document Replacement Option and the Folder Management Options
- A XDW Content Consumer shall be grouped with:
  - An XDS.b Document Consumer

X.2.2 XDW Content Profile Options

X.2.2.1 View Option

See PCC TF-1:3.4.1.1

See PCC TF-2:3.1.1

X.2.2.2 Document Import Option

See PCC TF-1:3.4.1.2

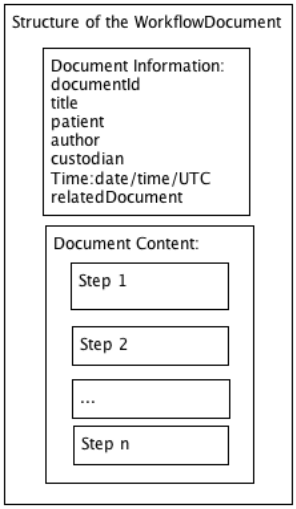
See PCC TF-2:3.1.2

X.3 XDW Document

The implementation of the XDW Content Profile is based on the management of a document, the XDW Workflow Document. This document is used to track the steps of the workflow which is followed, to manage the documents related to a clinical workflow and its changes as it evolves step after step. The Content Creator shall be able to create XDW Workflow Document as specified in ITI TF-3:5.3.

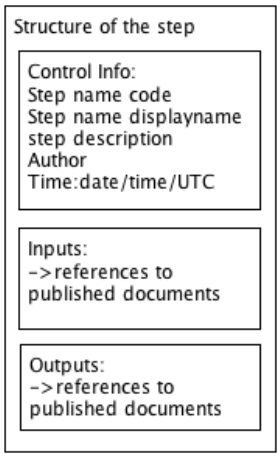
The XDW Workflow Document is a structured document which contains shared information about an instance of a workflow and more specifically, about the steps that have happened so far in the context of this workflow.

As shown in the Figure, the XDW Workflow Document is structured into two parts: a first part with general information about the document, and a second part with sections that describe the different steps.



Each step tracked by the XDW Workflow Document has the same structure based on three categories of information: step control information, the referenced document identified as input to the step and the referenced documents identified as output of the step.

- The **Control Information** describes the specific step and its author.
- The **Inputs** contains information needed to access documents used in performing this step. For example, this could contain a reference to a referral request.
- The **Outputs** contains information needed to access documents output as a result of performing this step. For example, this could contain a reference to a report written by a specialist.



At any time, if a participant chooses to advance the workflow for a specific patient, it shall create one (or more) new step by adding this step to the most recent instance of the workflow document. This new version of the workflow document is then published as a replacement. The technical description of the updating of the workflow document is specified in ITI TF-3:5.y.

All deprecated Workflow Documents, as well as the most recent (active) Workflow Document are placed in a "Folder" so that the folder uniqueId provides a stable reference to an instance of a workflow, while the workflow document uniqueId is different for each of the various past versions of the workflow. There is no requirement that all referenced documents (clinical documents referenced inside the Workflow Document) be placed by reference within this same folder.

It is up to each specification of the specific workflow to analyze the need and frequency to search for the list of workflows in which a specific document may be referenced. If such a "workflow back-link" is deemed necessary, it may be performed in an XDS environment by a various approaches, such as:

- Query for workflow documents based on their metadata atttributes (workflow active flag, date of service, document class, document type, documentformat, etc.) and by filtering the retrieved set of (non-deprecated) workflow documents for the referenced document Id across all steps within each workflow document.
- If all participants in a workflow are part of the same XDS Affinity Domain, by requiring that all documents referenced within a specific Workflow Document be placed within the folder that contains the Workflow Document.

X.4 XDW Use-Cases and Process Flow in an XDS Affinity Domain

A broad range of use cases may be supported by the XDW Content Profile.

The purpose of this section is to describe a typical usage of XDW Document Workflows with no intent to represent the breadth and flexibility of the applicability of XDW. A simple use case is decribed in this section to provide the necessary background to the reader in understanding the capabilities of XDW. To gain a deeper understanding of XDW, four more complex use cases are documented in Appendix XX. The approach used in Appendix XX is to describe four use cases that progress from the simplest use case to more complex ones to explain the different challenges addressed by this profile.

X.4.1 Use Case Simple Referral Workflow

X.4.1.1 Story Board

The use case is focused on managing the workflow of a physician referring a patient to another healthcare provider.

X.4.1.2 Process Flow

A patient attends a consultation with his GP for a health problem. The GP examines him and some of his reports in relation with his health problem. After the visit, the GP prescribes a consultation with a specialist, creating an eReferral document and referring to the results of the studies.

The specialist consults the eReferral and examines the patient on the basis of the documents of interest related (such as the eReferral and the reports that the GP has referenced) and proceeds with the exam. At the end of the exam, he generates the clinical report of the exam, references the clinical report inside the workflow document and updates it. This report can be notified to the referring GP and the e-Referral is completed.

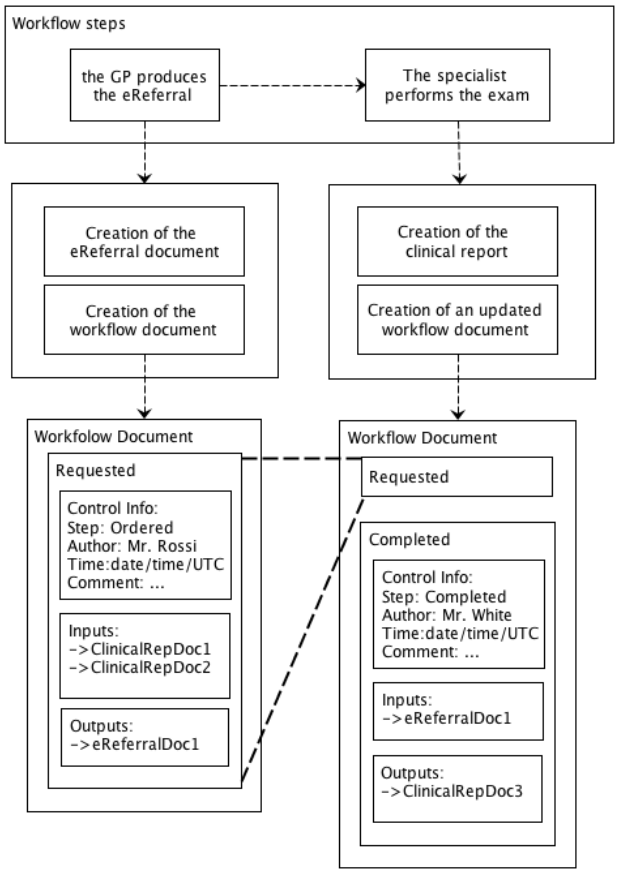
At any time, during this process, the GP may access related new document produced as a result of this execution of this workflow or any of its steps. This is accomplished possible through a simple query and retrieve by the GP's software to Registry and Repository.

Although not shown in this use case, it would also be possible to manage a system of subscription and notification to communicate the progress between the different steps through the use of the Document Metadata Subscription (DSUB) profile or the Notification of Document Availability (NAV) profile.

This use-case is a simplified since many other IHE profiles could be brought in to further automate and enrich. These are not shown so as to focus on the XDW content.

X.4.1.3 Composite Structure Diagram

The following diagram represents the UML diagram representing the the workflow steps of this use case. For any step of the workflow the Composite Structure Diagram represents a column in which there is a block which represent the technical actions related to that step and the structure and the content of the XDW Workflow Document at that time.



X.4.1.4 Sequence Diagram

435 The following diagram represents the sequence of data exchanged between “system actors” involved in this use case. This is an example of XDS application. In this case, the Content Creator is grouped with an XDS Document Source and the Content Consumer with an XDS Document Consumer. The Share Content between Content Creator and Content Consumer is implemented through the use of XDS transactions.

440 In the diagram both GP and Specilist labels represent a Content Creator and a Content Consumer embedded.

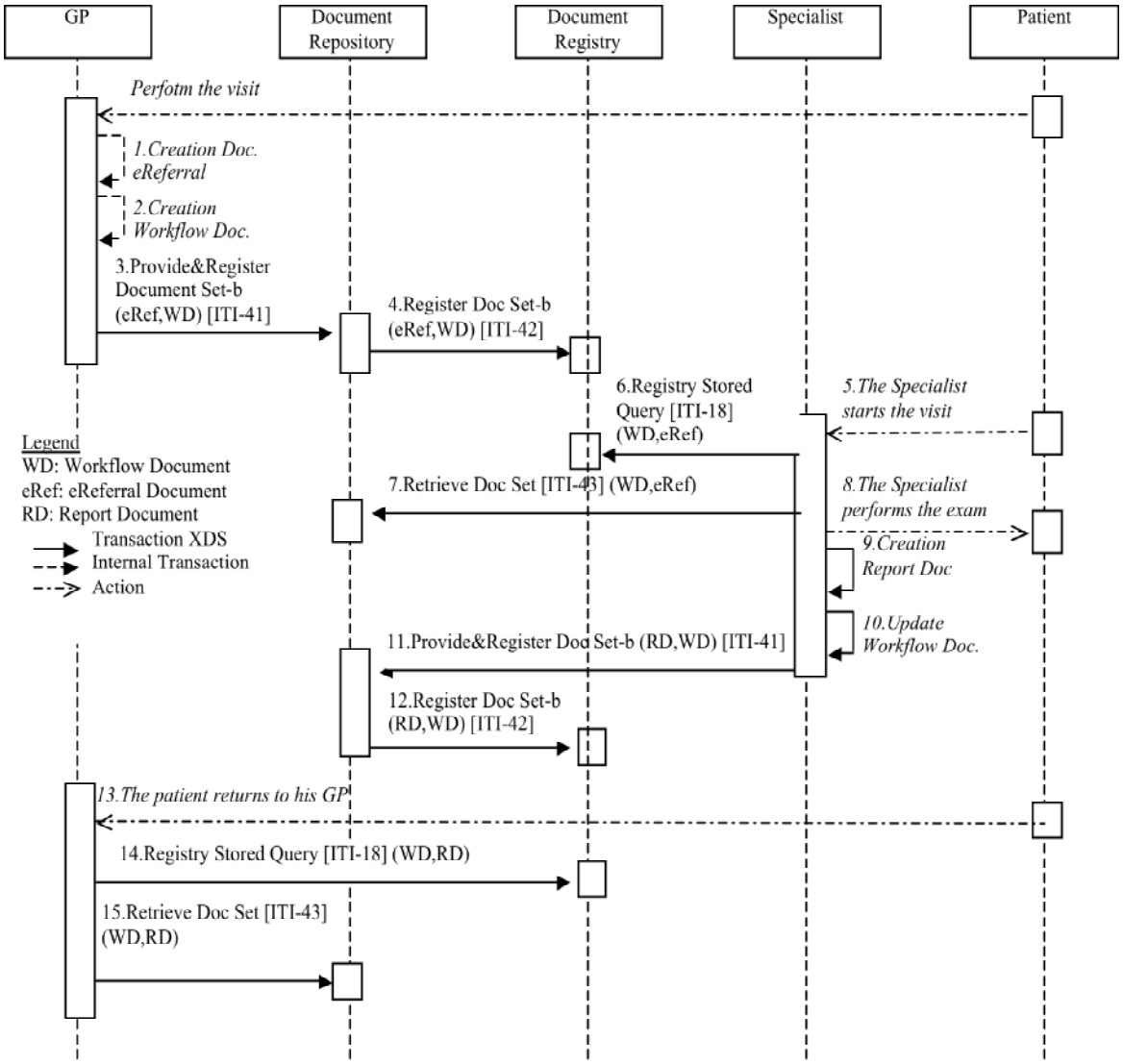


Figure X.4.1.4-1. Basic Process Flow in XDW Profile, Simple Referral use case

X.5 XDS Security Considerations

The XDW content profile does not include any mandatory security or privacy controls. The XDW content is an administrative document that should not include clinical information but administrative information can be just as sensitive as clinical information.

The XDW Workflow Document will be authored by many different organizations that are expected to replace the prior version. With clinical documents one does not expect different organizations to replace other organizations' documents. Generally a clinical document comes from one organization or individual. Thus there might be security rules in place that restrict the Replace operation to force both the Prior and New document to be authored by the same

organization. These rules would need to be relaxed in order to allow XDW to function. These changes should be controlled and audited; thus the transport for XDW should have grouping with ATNA and XUA.

This will result in additional security considerations beyond those for the usual clinical report.

Appendix XX XDW Use Cases

The purpose of this appendix is to describe typical use cases supported by the Cross Enterprise Document Workflow profile (XDW) with the intent to provide a sense of the breadth and flexibility of the applicability of XDW. The approach used in this Appendix is to describe four use cases, progressing from the simplest use case to more complex ones to explain the different challenges addressed by this profile.

The use cases described are examples of possible usage. However, many other use cases related to different domains could be addressed with this profile. The use cases described need to be regarded as possible examples and not as an exhaustive solution to the real life scenarios. These use case are not intended to constrain nor replace future profile development that other IHE Domain would perform.

The first use case is an e-Prescription Workflow. This scenario describes the solution to the problem of tracking of the workflow of a pharmaceutical prescription. In its life cycle the e-Prescription has different steps which characterize its availability and usability. This is the simplest use case analyzed because it is focused on the workflow of a single document, the e-Prescription document. Although the process of prescribing and dispensing medication can be complex this sample use-case describes a linear scenario with clear and defined steps.

The second use case is an e-Referral Workflow. This scenario describes the solution to the real life problem of tracking the workflow for a specialty exam request (e-Referral). It approaches the problem of tracking the different steps which characterize the availability and usability of the electronic referral request with the focus on the possibility of having some documents as inputs to a step of the workflow. In some scenarios, in fact, there is the need to provide some information as a background of the process to allow the professionals to make decisions and evaluate the steps to perform.

The third use case is a workflow related to a Tele-counseling Service for Neurosurgery. This use case approaches the problem of tracking a workflow which can have some cyclic steps and some decisional steps. The Tele-counseling Service for Neurosurgery is a service which is provided between two different healthcare providers and which can involve many clinical specialists. The XDW Profile is focused on the tracking of the different requests and responses for the tele-counseling services and on the follow-up of the patients through cycles of tele-counselling.

The fourth use case is a healthcare professional monitoring workflow. This scenario describes the workflow followed by a patient which is involved in a follow up at home of his health status. This use case is characterized by a sequence of visits at patient's home to check his clinical parameters with the possibility to trigger a new workflow of tele-counseling. This chapter is focused on the relation between different Workflow Documents and the clinical workflows that they tracks.

An increased complexity is presented in this appendix starting from the linear management of the workflow with a single document to the management of different workflow related together in scenarios with some decisional steps and some loops. The use cases that are presented in this

Appendix are only some examples needed to understand the use of the profile but they are not exhaustive in describing any possible workflow manageable with the XDW Content Profile.

XX.1 Use Case e-Prescription Workflow

XX.1.1 Story Board

The use case is focused on the workflow of a pharmaceutical prescription (e-Prescription). This use case approaches the problem of tracking the different steps which characterize the availability and usability of the electronic prescription. In a scenario in which there is a paper prescription, each step of workflow is tracked by the physical location of the prescription. When the doctor produces the prescription, he gives it to the patient and the patient can take it to the pharmacy of his choice; once he has used that prescription the pharmacist keeps the prescription so the patient has no possibility to use it again. In a scenario in which the prescription is electronic there is the problem of tracking the steps of the workflow. The main problem is that: once the doctor produces the e-Prescription and publishes it, it could be retrieved and so used many times. The XDW profile is focused on the management of these steps to guarantee the correct flow of the process.

This is the simplest use case analyzed because it is focused on the workflow of a single document, the e-Prescription document. Although the process of prescribing and dispensing medication can be complex this sample use-case describes a linear scenario with clear and defined steps. This use cases described need to be regarded as possible examples and not as an exhaustive solution to the real life scenarios. The use case are not intended to constrain nor replace future profile development that other IHE Domain would perform.

We present below the clinical story:

A patient attends a consultation to his GP for a health problem. After the visit, the doctor generates an e-Prescription containing two prescription items.

From this moment the prescription is available to a wide range of pharmacies and the patient can go to a pharmacy of his choice to buy the medications.

When the patient goes to the pharmacy, the pharmacist checks in which step the e-Prescription is and he may checks the potential interactions of the active substances prescribed. If interaction problems are not present, the pharmacist produces a Pharmaceutical Advice Document to validate the prescription items and from this moment the items prescribed can be dispensed.

When the pharmacist proceeds to dispense the items, he realizes that only one of the two medications is not available so he creates a Dispensed Document for the medication dispensed. After some days, the other medication is dispensed to the patient and a new Dispense Document is produced by the pharmacist. By this the prescription is closed.

XX.1.2 Process Flow

We present below the chronological steps with the technical actions, the numbers in brackets quoted in this description are the numeration used in the sequence diagram:

- A patient attends a consultation to his GP for an health problem.
- The GP examines the patient and generates an e-Prescription containing two prescription items.
- The GP's prescription placer software produces two objects: one e-Prescription (1) containing the two prescription items and one Workflow Document (2) to trace the clinical workflow of the e-Prescription. At this step, the Workflow Document has only one task which describes the first step: production of the e-Prescription. This task is characterized by three elements: a section of "inputs" where the author puts a set of information useful to understand the reason for the e-Precription (the references of the report of the visit, the references of reports of exams, etc.), a section of "control info" where the author tracks the specific information of the step (the author and date of the step and the description of the action made), and a section of "outputs" where all the documents produced in relation with the step and possible suggestions for the next step are tracked.
  - The Content Creator provides the e-Prescription Document and the Workflow Document to the Document Repository (3,4)
- From this moment the prescription is available to a wide range of pharmacies.
- The patient goes to a pharmacy of his choice to buy the medications.
- The pharmacist asks for patient health card in order to retrieve both the document containing the ordered medication (e-Prescription document) and the workflow document.
  - The Content Consumer query and retrieves the Workflow Document and the e-Prescription Document. (5,6)
- He checks in which step the e-Prescription is (using the Workflow Document) and he may checks the potential interactions of the active substances prescribed.
- Interaction problems are not present. The pharmacist produces a Pharmaceutical Advice Document (7) to validate the prescription items and replaces the Workflow Document with the updated one which contains all the information of the previous Workflow Document and also a new task to describe the current step (8). With this step the e-Prescription passes from the step "ordered" to the step "validated"and from this moment the medications prescribed can be dispensed.
  - The Content Creator provides the Pharmaceutical Advice Document and replaces the old Workflow Document with the updated one (9,10).
- When the pharmacist dispenses the items, he queries and retrieves the Workflow Document, the e-Prescription Document and the Pharmaceutical Advice Document of interest and if all the information are correct he can dispense the medications prescribed.

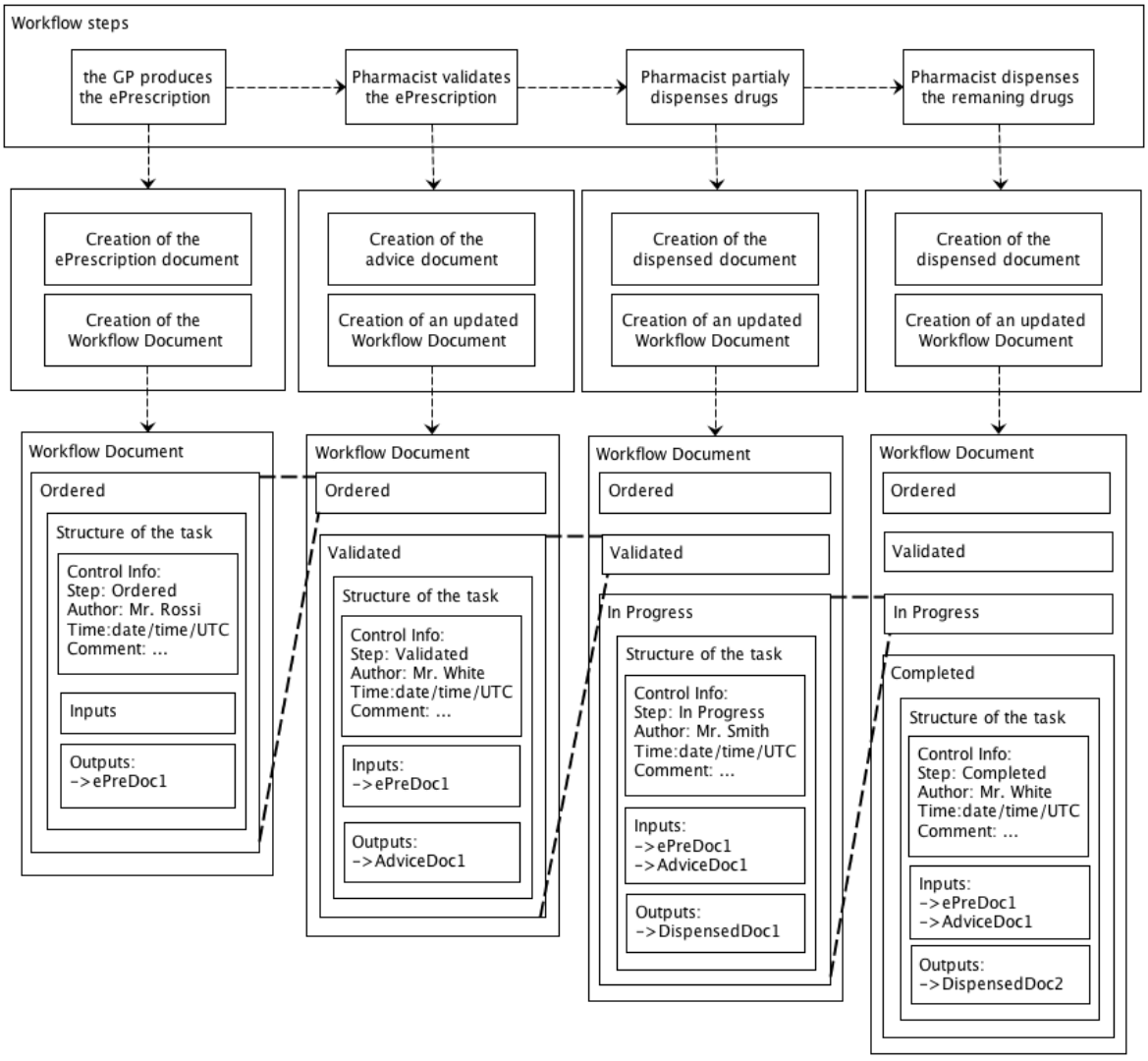
570 - The Content Consumer query and retrieves the Workflow Document, the e-Prescription Document and the Advice Document (11,12).

- The pharmacist realizes that only one of the two medications is available so only one Dispensed Document is created by the pharmacist (as indicated in the pharmacy domain) and will be linked and tracked in the workflow document (13). The Workflow Document
575 is replaced with a new version which contains all the information of the previous Workflow Document and also a new task to describe the current step (14). The e-Prescription passes from the step “ordered” to the step “in progress”. In this way no other pharmacy can take charge of that prescription.
    - The Content Creator provides the Dispensed Document and replaces the old
580 Workflow Document with the updated one (15,16).
- After some days, the other medication is dispensed to the patient. The existing Workflow Document is replaced with an updated one (14). The new Workflow Document contains all the information of the previous document and a new step to describe the passage of the e-Prescription to the step “completed”. At the same time a new Dispensed Document
585 is created and linked in the new step of the Workflow Document (13).
    - The Content Creator provides the Dispensed Document and replaces the old Workflow Document with the updated one (15,16).

At any time during the workflow the replacement of the workflow document can produce a notification to the GP. These notifications can be done through the use of the DSUB profile or
590 the NAV profile. The rules of the trigger events for the notification can be defined by the different scenarios.

XX.1.3 Composite Structure Diagram

The following diagram represents the UML diagram representing the the workflow steps of this use case. For any step of the workflow the Composite Structure Diagram represents a column in
595 which there are blocks which represent the technical actions related to that step and the structure and the content of the Workflow Document at that time.



XX.1.4 Sequence Diagram

600 The following diagram represents the sequence of data exchanged between “system actors” involved in this use case. This example uses an XDS application. In this case, the Content Creator is grouped with an XDS Document Source and the Content Consumer with an XDS Document Consumer. The Share Content between Content Creator and Content Consumer is implemented through the use of XDS transactions.

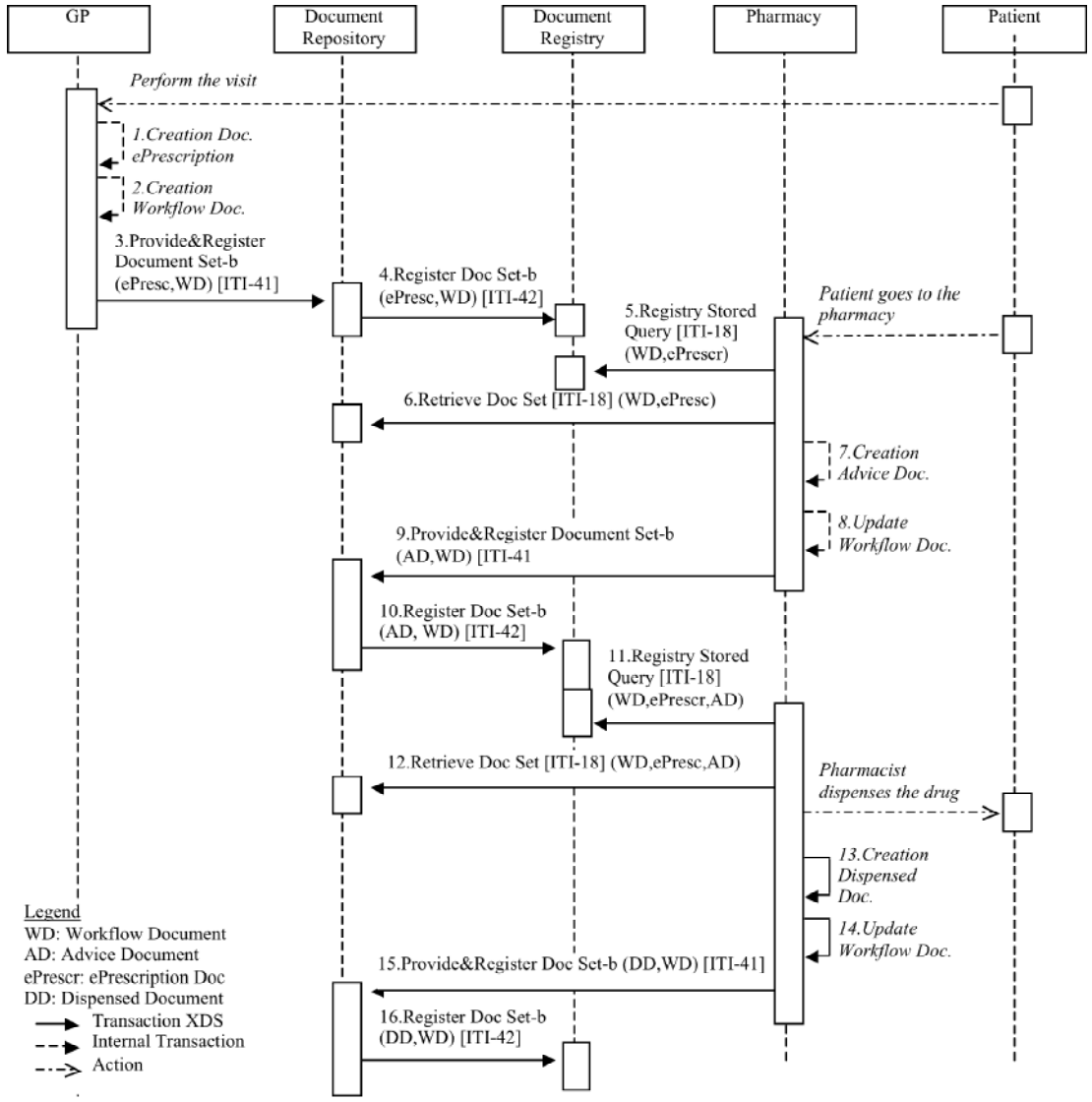


Figure XX.1.4-1. Basic Process Flow in XDW Profile, e-Prescription use case

XX.2 Use Case e-Referral Workflow

XX.2.1 Story Board

The use case is focused on the workflow of a specialist exam (e-Referral). This use case, in the same modality of the previous, approaches the problem of tracking the different steps which characterize the availability and usability of the electronic prescription. The problems are the same described in the previous use-case (how manage the tracking of the steps of the workflow). The different from the previous is that the e-Referral follow all workflow of the exam prescribed in object and in the workflow are involved more actors and more systems. This use case is focused on the possibility to have some documents as inputs of a workflow. In some scenarios, in fact, there is the necessity to provide some information as a background of the process to allow the professionals to take decisions and evaluate the steps to do.

This is one of the simplest use case analyzed because it is focused on the workflow of a document, the e-Referral document, which is linear with clear and defined steps. The only criticality additionally is the possibility to link other documents in the input data of a step

We present below the clinical story:

A patient attends a consultation to his GP for a health problem. The doctor examines him and some of his reports in relation with his health problem. After the visit, the doctor prescribe an exam.

From this moment the e-Referral is available to a wide range of care providers. The patient can call or go to a healthcare care provider of his choice to have the exam. The HCP checks the step in which the e-Referral is and he books the visit. After a few days the patient is admitted at the hospital, the HCP consults the e-Referral and the process for the visit starts. The exam takes place and the doctor can analyze all the documents of interest related (such as the e-Referral and the reports that the GP has related) and proceeds with the exam. At the end, he generates the clinical report of the exam with some images related. This report can be notified and the e-Referral is closed.

XX.2.2 Process Flow

We present below the chronological steps:

- A patient attends a consultation to his GP for a health problem.
- The doctor examines him and some of his reports in relation with his health problem. At the end of the visit the doctor generates a report for the visit and an e-Referral (1) where he orders an exam. To provide a good overview of the information needed to do the exam, the GP decides to link some of the reports analyzed inside the inputs element of the step of the Workflow Document (2). At this step, the Workflow Document has only one task which describes the first step: production of the e-Referral. This task is characterized by three elements: a section of “inputs” where the GP tracks the references

to the report of the visit and to a set of reports which can be useful to better understand the reasons to do the exam prescribed; a section of "control info" where there are the information of the step; a section of "outputs" where all the documents produced in relation with the step (such as the e-Referral document) and possible suggestions for the next step are tracked.

- GP's prescription placer software produce two objects: one e-Referral for the exam and one Workflow Document to trace the clinical workflow of the e-Referral; this two objects are referenced using the XDS Folder mechanism. The use of the XDS Folder mechanism is not binding but its use is suggested to collect all documents related to the same clinical event and tracked by the same Workflow Document.
  - The Content Creator provides a document folder to group all document produced and related at the same workflow document
  - The Content Creator provides the e-Referral Document and the Workflow Document to the Document Repository (3,4)
- From this moment the e-Referral is available to a wide range of care providers.
- The patient goes to a healthcare care provider of his choice to have the exam.
- The HCP asks for patient health card in order to retrieve both the documents containing the ordered exams and the associated workflow document.
  - The Content Consumer queries and retrieves the Workflow Document and the e-Referral Document
- The HCP checks the step in which the e-Referral is (using the Workflow Document) and he books the visit. Once he has booked the visit, he replaces the workflow document with an updated one including all the information of the previous Workflow Document and a new workflow step for the referral workflow (it passes from ordered to scheduled).
  - The Content Creator replaces the old Workflow Document with the updated one.
- When the patient is admitted at the hospital, the HCP consults the e-Referral document and the Workflow Document associated and checks if the e-Referral is still in the step placed and it has been booked by the same health care provider.
  - The Content Consumer queries and retrieves the Workflow Document and the e-Referral Document.
- If the e-Referral's step is correct and the exam can take place, the HCP replaces the Workflow Document with the updated one which contains all the information of the previous one and a new task to describe the current step. At this step the e-Referral passes from the step scheduled to the step in-progress and the exam can take place.
  - The Content Creator replaces the old Workflow Document with the updated one.
- The exam takes place, the doctor analyzes all the documents of interest related to this workflow (such as the reports that the GP has related in the inputs of the first step) and proceeds with the exam. At the end, he generates the clinical report of the exam, some

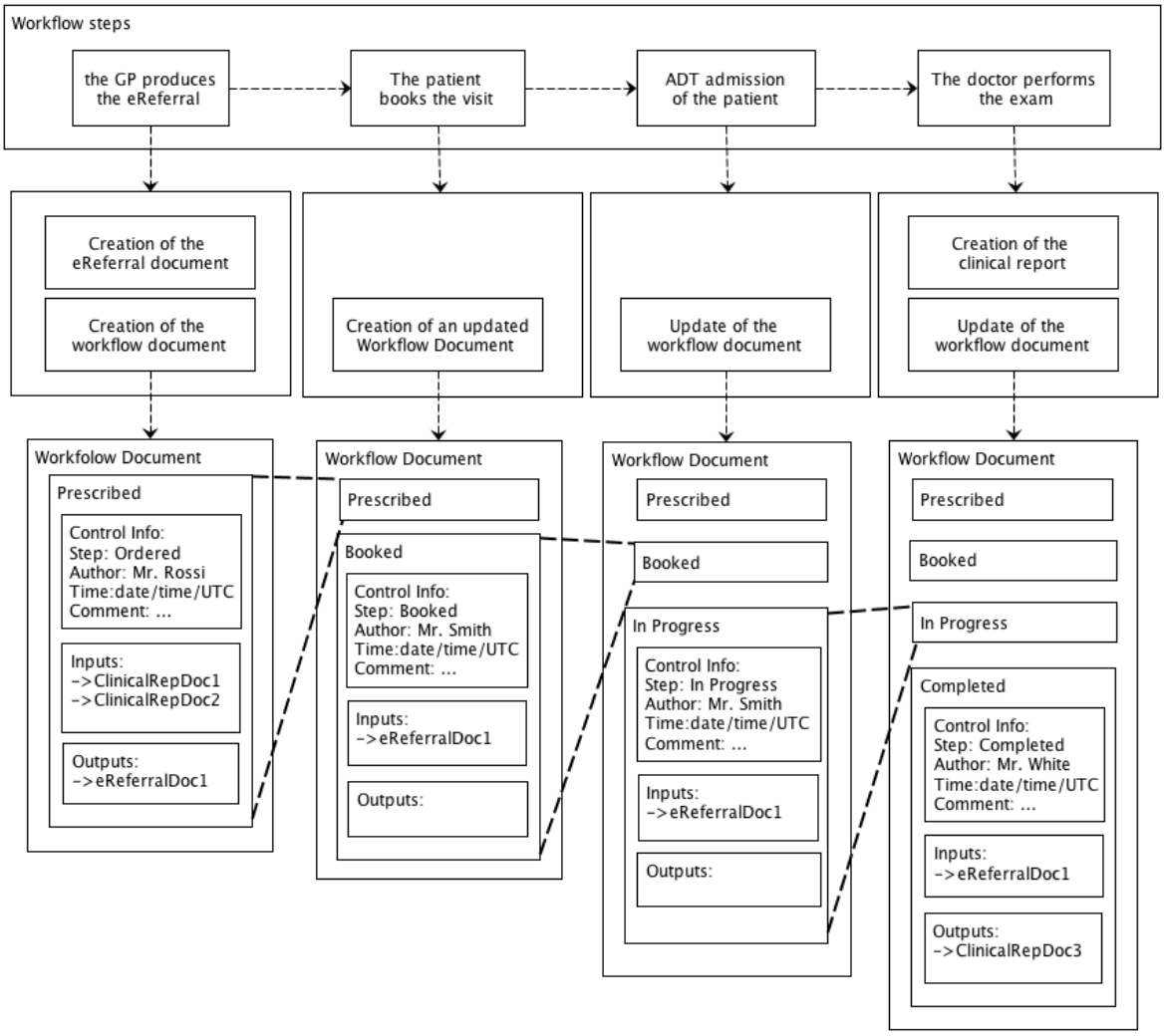
images and the workflow document is updated with a new step (it passes from scheduled to completed).

- The Content Consumer queries and retrieves the Workflow Document, the e-Referral Document and all document of interest related to this Workflow Document.
- The Content Creator replaces the old Workflow Document with the updated one.
- The Content Creator provides the report Documents.

At any time, during this process, in case the patient visits his GP to assess progress, the GP may consult the WD and access related new document produced as a result of this execution of this workflow or any of its steps. This process is possible through a simple query and retrieve by the GP's software to the Registry and Repository. It is also possible to manage a system of subscription and notification to communicate the progress between the different steps throw the use of the Document Metadata Subscription (DSUB) profile or the Notification of Document Availability (NAV) profile.

XX.2.3 Composite Structure Diagram

The following diagram represents the UML diagram representing the workflow steps of the use case on the top. For any step of the workflow the Composite Structure Diagram represents a column in which there are a blocks which represent the technical actions related to that step and the structure and the content of the Workflow Document at that time.



XX.2.4 Sequence Diagram

The following diagram represents the sequence of data exchanged between “system actors” involved in this use case. This is an example of XDS application. In this case, the Content Creator is grouped with an XDS Document Source and the Content Consumer with an XDS Document Consumer. The Share Content between Content Creator and Content Consumer is implemented trough the use of XDS transactions.

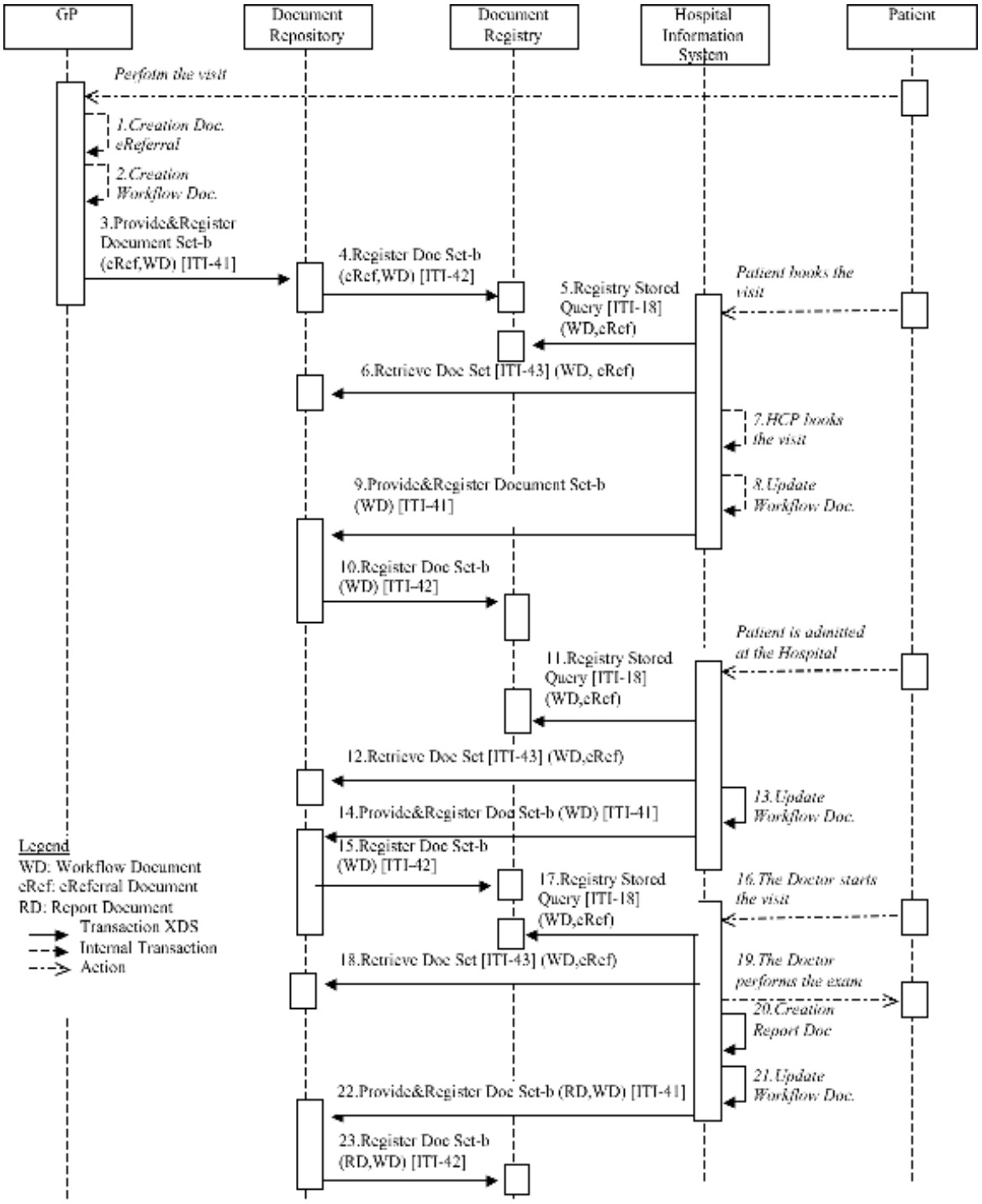


Figure XX.2.4-1. Basic Process Flow in XDW Profile, e-Referral use case

XX.3 Use Case Tele-counseling Service for Neurosurgery Workflow

XX.3.1 Story Board

The use case is focused on the workflow related to a Tele-Counseling Service for Neurosurgery. This use case approaches the problem of tracking a workflow which can have some cyclic steps.

The Tele-Counseling Service for Neurosurgery is a service which is provided between two different healthcare providers, one with high specialty unit (Hub Unit) and one peripheral hospital without neurosurgery ward (Spoke Unit). This use case involves patients who have a minor head injury and who are attended by a Spoke Unit which doesn't have a specialty unit to well evaluate them. The Spoke Unit needs to ask a Tele-Counseling to the specialized unit of reference, the Hub Unit, which can evaluate the clinical case and decide, which can be the right clinical treatment for that specific patient. The main treatment are two: the patient is moved to the Hub Unit for neurosurgical procedure or the patient starts a follow up process in the Spoke Unit characterized by a cycle of Tele-Counseling to follow the evolution of the clinical status. The XDW profile is focused on the tracking of the different requests and responses for the Tele-Counselings.

We present below the clinical story:

A patient is hospitalized for a minor head injury in a Spoke Structure. When the patient arrives at the hospital, the physician, who takes care of him, orders some exams such as a CT exam or MRI exam. Once the physician analyzes the reports produced and, in case he considers that the patient needs for neurosurgical procedure, he can ask for counseling to the Hub hospital of reference. At this step, the doctor starts the process of Tele-Counseling producing a Request Document and sending the links of the reports and the images of the exams to the Hub Unit. The doctor of the Hub analyzes the Request Document and the information related and at the end, he produces his diagnosis in a report and decides if it is necessary to transfer the patient or if it is possible to start a follow up process in the Spoke Unit.

In the first scenario, the patient is moved to the Hub Unit and the workflow for this use case is closed.

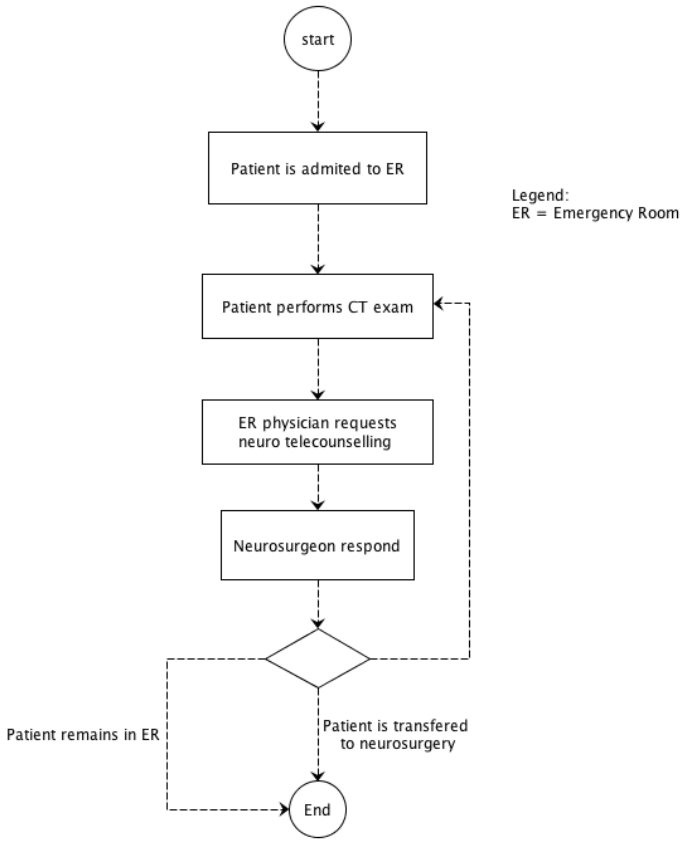
In the second one, instead, the patient remains in the Spoke unit and starts a process of follow up where, in the period he remains in the hospital, he has some exams (such as MRI, CT, RX or other exams which helps to understand the clinical status of the patient) and Tele-Counselings to check his state of health. Each time that the patient needs a Tele-Counseling a new Request Document is created and all the information needed to evaluate the clinical status of the patient are sent to the Hub Unit. This follow up ends when the physician, who takes care of the traumatized patient, or the physician of the Hub Unit, who provides the Tele-Counseling, decides that the patient is ready to be discharged or his clinical status is stable.

XX.3.2 Process Flow

We present below the chronological steps:

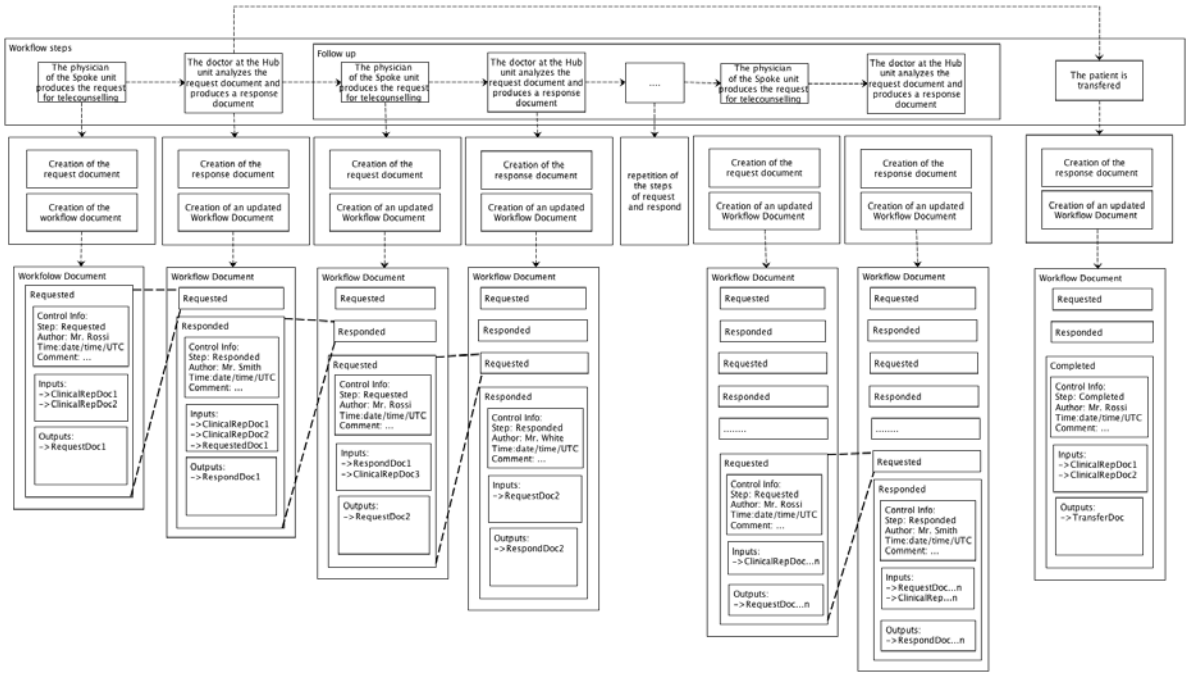
- A patient is hospitalized for a minor head injury in a Spoke Structure.
- The physician, who takes care of the traumatized patient, orders some exams for the patient
- The patient performs the exams (CT exam or MRI exam) and after the exams some reports are produced.
- The physician, who takes care of the traumatized patient, analyzes the reports produced and, in case he considers that the patient needs for neurosurgical procedure, he can ask for counseling to the Hub hospital of reference. At this step, the doctor starts the process of Tele-Counseling producing a Request Document and a Workflow Document which will truck all steps. In the Workflow Document, at this moment, there are only one task where: in the "input" section there are the links to Request Document, the reports of the exams and possible images are trucked and in the "control info" section there are the general information of the step.
  - The Content Creator provides a document folder to group all documents produced and related at the same Workflow Document.
  - The Content Creator provides a Workflow Document and a Request Documents for the neurosurgical Tele-Counseling. In the Workflow Document, there are now also the links to reports and images related to this workflow.
- The Hub receives the request for Tele-Counseling. This event can be supported with a system of notification (profiles DSUB or NAV) to alert the Hub that there is a request available.
  - The Content Consumer queries and retrieves the Workflow Document and the related Request Document
- The doctor of the Hub analyzes the Request Document and the documents and the images related; at the end, he produces his diagnosis in a report and decides if it is necessary to transfer the patient.
  - The Content Creator replaces the old Workflow Document with the updated one and provides the report of the counseling
- At this step the physician, who takes care of the traumatized patient in the Spoke Unit, receives the report and proceeds to transfer the patient or to start the process of follow up. In the first case, he updates the workflow document and starts the transfer. In this case, the workflow is closed. In the second case, he updates the workflow document and hospitalizes the patient. The new Workflow Document contains all the information of the previous Workflow Document and also a new task to describe the current step.
  - The Content Consumer queries and retrieves the Workflow Document and the related Reports
  - The Content Creator replaces the old Workflow Document with the updated one
- If the patient remains in the Spoke unit, he starts a process of follow up where, in the period he remains in the hospital, he has some exams (such as MRI, CT, RX or other exams which helps to understand the clinical status of the patient) and Tele-Counseling to

check his state of health. All the documents produced and all the steps of the process are tracked in the workflow document step by step. Each time that the patient needs a Tele-
790 Counseling a new Request Document has to be created and to be trucked in the same Workflow Document.



XX.3.3 Composite Structure Diagram

795 The following diagram represents the UML diagram representing the workflow steps of the use case on the top. For any step of the workflow the Composite Structure Diagram represents a column in which there are blocks which represent the technical actions related to that step and the structure and the content of the Workflow Document at that time.



XX.3.4 Sequence Diagram

The following diagram represents the sequence of data exchanged between "system actors" involved in this use case. This is an example of XDS application. In this case, the Content Creator is grouped with an XDS Document Source and the Content Consumer with an XDS Document Consumer. The Share Content between Content Creator and Content Consumer is implemented though the use of XDS transactions.

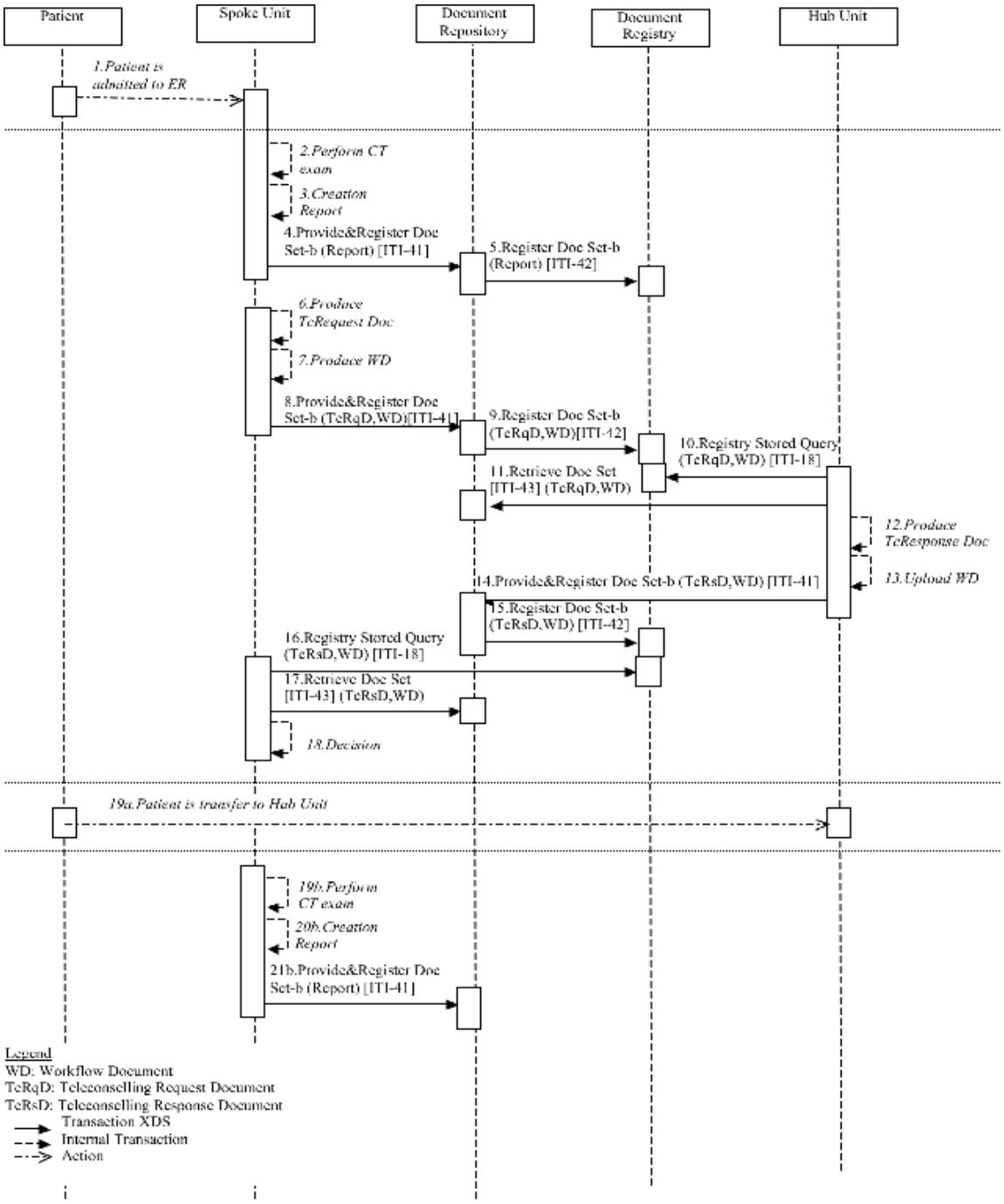


Figure XX.3.4-1. Basic Process Flow in XDW Profile, Tele-counseling Service for Neurosurgery Workflow use case

XX.4 Healthcare professional Monitoring Workflow

The use case is focused on the healthcare professional monitoring and possible Tele-Counseling related together. This scenario involves two different workflows, the monitoring one and the Tele-Counseling one, which are related and depended. In this specific use case, the first workflow, in one of its step, generates the second one. During the developing of the second workflow until its finish, the first one is blocked. This solution is specific for this use case but in other scenarios there could be the possibility to have two different workflows related and independend in their progress.

This scenario describes the workflow followed by a patient which is involved in a follow up at home of his health status. This use case is characterized by a sequence of visits at patient's home to check his clinical parameters with the possibility to trigger a new workflow of Tele-Counseling. So this chapter is focused on the relation between different Workflow Documents and the clinical workflows that they track.

We present below the clinical story:

A patient is hospitalized for a specific health problem and, after a period in the hospital, the doctor decides to discharge the patient and controls him with a program of follow up at home.

The doctor requests the approval by the service of competence for the follow up program and if the request is approved he discharges the patient.

The Homecare service schedules a program of assistances. At any time that a visit takes place, the caregiver produces a report for the visit and in relation with the results he can confirm the next visit scheduled, modify the agenda of the visits or, in case of problems, request a Tele-Counseling. In this last case, a new workflow for the Tele-Counseling is opened and related to the previous workflow.

The specialist who performs the Tele-Counseling can decide if the patient has to be hospitalized or he can remain in the homecare program. If the patient is hospitalized, in any case after his discharge he can return in the homecare program.

XX.4.1 Process Flow

We present below the chronological steps:

- A patient is hospitalized for a specific health problem.
- After a period in the hospital the doctor decides to discharge the patient through a program of follow up at home.
- The doctor of the hospital provides a Request Document for the follow up of the patient and a Workflow Document to track the steps of the follow up. In the Workflow Document, at this moment, there are only one task where: in the "input" section there are the links of the reports of the exams and possible images that can be useful to evaluate the possibility of follow up at home; in the "control info" section there are the general

information of the step and in the "output" section there is the link to the Request Document produced.

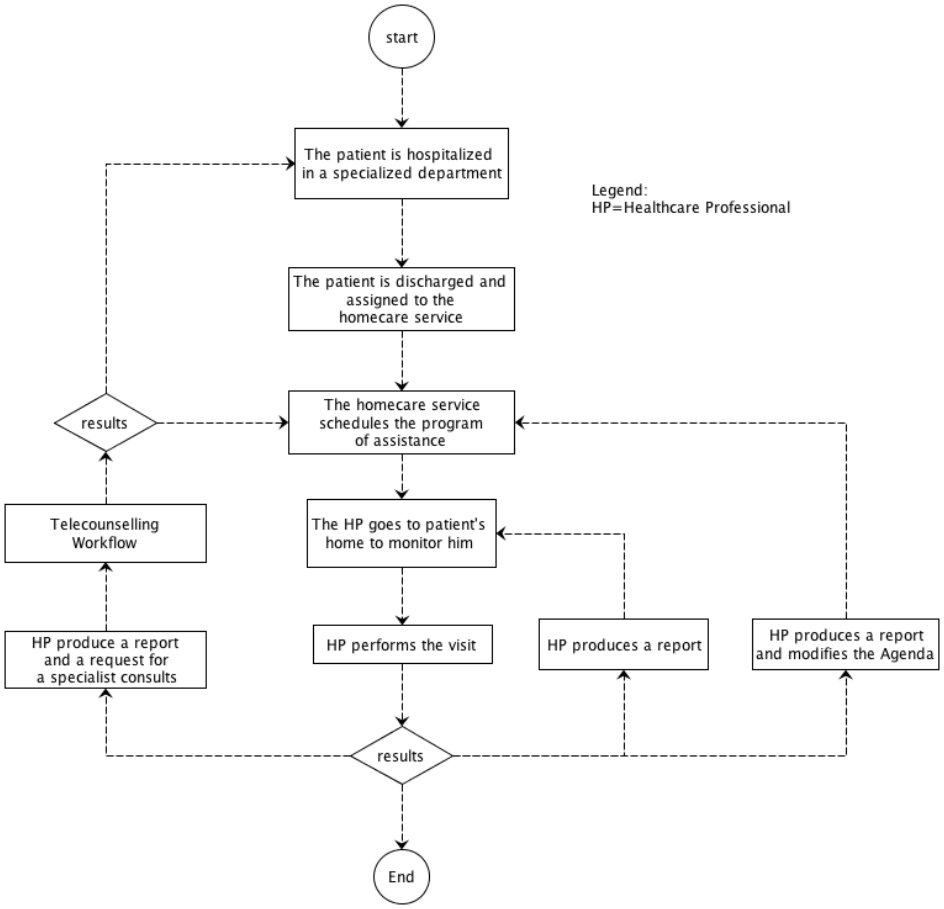
- The Content Creator provides a document folder to group all documents produced and related at the same Workflow Document. The XDS Folder mechanism is not binding but its use is suggested to collect all documents related to the same clinical event and tracked by the same Workflow Document
- The Content Creator provides the Request Document and the Workflow Document to the Document Repository

- The Homecare Service, structure responsible for the follow up of patients in their homes, evaluates the Request Document and decides if allows it
  - The Content Consumer queries and retrieves the Workflow Document and the Request Document
- Once the Homecare Service evaluates the request, it provides a Respond Document with the response and updates the workflow document. The updated Workflow Document has the same information of the previous one and also a new task which describes the current step and the decision taken ("accepted" or "rejected"). This task has three elements: in the "input" section there could be the link of the Request Document; in the "control info" section there are the general information of the step and in the "output" section there is the link to the Respond Document produced.
  - The Content Creator replaces the old Workflow Document with the updated one and provides the Advice Document
- The software of the department in which the patient is hospitalized queries and retrieves the documents related to patient connected to that department. At the moment in which the Respond Document and the Workflow Document is published by the Health District there is the possibility to manage a system of notification, such as with the profile DSUB, which allows an increase of the performance of the system and a reduction of the loss of time waiting the response.
  - The Content Consumer queries and retrieves the Workflow Document and the Respond Document
- When the Homecare Service accepts the requests with a Respond document, the patient is discharged and a discharged letter is published. At the same time the Workflow Document is updated with a new step and the reference to the discharged letter is tracked in the outputs element of this step.
  - The Content Creator replaces the old Workflow Document with the updated one and provides the discharged letter document
- When the patient is discharged, the Homecare Service schedules a program of assistance for the patient and produces a document of it. At the same time, the Workflow Document is updated with a new step and the reference to the discharged letter is tracked in the inputs element of the step and the program of assistance document in the outputs element.

- The Content Consumer queries and retrieves the Workflow Document and the discharged letter
- The Content Creator replaces the old Workflow Document with the updated one and provides the program of assistance document produced

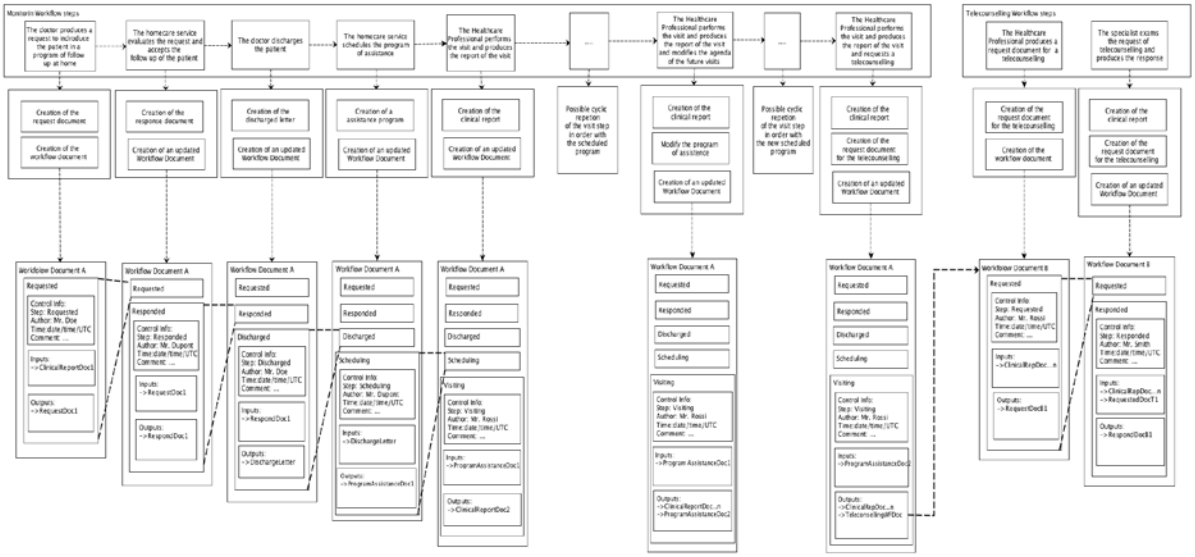
- When the visit takes place, the Healthcare Professional goes at patient's home, checks the workflow step in the Workflow Document and, after some tests, he produces a report of the visit which contains the data of the tests, the diagnosis and comments. If the status of the patient is stable, the Healthcare Professional books the next visit; if the status of the patient is getting worse, he can change the agenda of the visits and provide a new program of assistance which follows the patient with an increased frequency; else, if the status of the patient suggests some alerts, the Healthcare Professional can decide to request a specialist Tele-Counseling. In the first case, the Healthcare Professional provides the report of the visit and updates the Workflow Document with a new step, step which has the references of the program of assistance document in the inputs element and the references of the report of the visit in the outputs element. In the second case, the Healthcare Professional provides the report of the visit and a new program of assistance document and updates the Workflow Document with a new step with the references of the old program of assistance document in the inputs element of the step and the references of the report of the visit and of the new program of assistance document in the output element. In the third case, where there is the need of a specialist Tele-Counseling and so a new workflow to track it starts, the Healthcare Professional provides the report of the visit and updates the Workflow Document with a new step with the references of the program of assistance document in the inputs element of the step and, in the output element, the references of the report of the visit and of a new workflow document to track the workflow of the Tele-Counseling. For details on the management of the workflow for the Tele-Counseling service we refer to the chapter "Use Case Tele-Counseling Service for Neurosurgery Workflow". From this step there are so two different Workflow Documents which are related together: one which tracks the healthcare professional monitoring and one which tracks the specialist consult.
  - The Content Consumer queries and retrieves the Workflow Document
  - If the patient is stable, the Content Creator replaces the old Workflow Document with the updated one, provides the Report of the visit.
  - If the status of the patient is getting worse, the Content Creator replaces the old Workflow Document with the updated one, provides the Report of the visit and the new program of assistance document.
  - If the status of the patient suggests some alerts, the Content Creator replaces the old Workflow Document with the updated one, provides the Report of the visit and the new workflow document for the Tele-Counseling.

This workflow is characterized by a cycle of some steps of checks-up and possible specialist consults. The last step can be repeated as many times as necessary and the workflow ends when the patient doesn't need to be monitored by an healthcare professional.



XX.4.2 Composite Structure Diagram

The following diagram represents the UML diagram representing the workflow steps of the use case on the top. For any step of the workflow the Composite Structure Diagram represents a column in which there are a blocks which represent the technical actions related to that step and the structure and the content of the Workflow Document at that time.



935

Glossary

Add the following terms to the Glossary:

Volume 3 – Cross-Transaction Specifications and Content Specification

Add section 5.Y

5.Y Cross-Enterprise Document Workflow Module

This section describes the the content of the XDW Workflow Document and the requirements of the Cross-Enterprise Document Workflow (XDW) Content profile. The main structure of the document and some elements related to its metadata and the management of its lifecycle need to be fixed and independent by the domain or the scenario in which it is used. The different IHE domains and the different scenarios, in which the Cross-Enterprise Document Workflow Content profile is applied, have to define the specific rules of the workflows. The structure of the Workflow Document and the general rules defined by the ITI domain remain fixed; the different domains and Affinity Domains can contestualize only the different steps of the workflow and their content (e.g.: name and codes).

The use of a defined structure for the workflow document, of a common set of metadata and of their values and a common management for the workflow document is necessary to guarantee the interoperability cross-enterprise.

5.Y.1 Referenced Standard

HL7 CDA Release 2.0

5.Y.2 Content Module of the XDW Workflow Document

The XDW Content Profile is based on the rules specified on “Patient Care Coordination Technical Framework“ about how organizes content modules categorically by the base standard. XDW uses one base standard, CDA Release 2.0. So For CDA Release 2.0 the modules are organized by document, section, entry, and header elements.

A CDA document is wrapped by the <ClinicalDocument> element, and contains a header (see 5.3.6.1) and a body (see 5.3.6.2). The header lies between the <ClinicalDocument> and the <StructuredBody> elements, and identifies and classifies the document and provides information on authentication, the encounter, the patient, and the involved providers.

The body contains the content information and the body of a Workflow Document is comprised of structured markup. The figure shows a structured body, which is wrapped by the <StructuredBody> element, and which is divided up into recursively nestable document sections. In a CDA Workflow Document the structure structure follows a pattern composed of:

- HEADER
- BODY: the Body present a mother section for each step of the workflow

- Each mother section is divided in 3 parts:
  - The first part with the control information about author and data that performed the step
  - Two subsection child: one for the INPUT documents and one for the OUTPUT documents

```
<ClinicalDocument>

<!-- Header -->

        <component>
                <structuredBody>
                  <!-- TASK 1 -->
                        <component>
                                <section>
                                        <code/>
                                        <!-- CONTROL INFORMATION -->
                                        <author>
                                                <time/>
                                                <assignedAuthor/>
                                                        <!-- info about data time and author of the
step-->
                                                </assignedAuthor>
                                        </author>
                                        <!-- INPUT -->
                                        <component>
                                                <section>
                                                        <code/>
                                                        <title/>
                                                        <text/>
                                                        <entry>
                                                                <!-- including the references at
the published document -->
                                                        </entry>
                                                </section>
                                        </component>
                                        <!-- OUTPUT -->
                                        <component>
                                                <section>
                                                        <code/>
                                                        <title/>
                                                        <text/>
                                                        <entry>
                                                         <!-- including the references at the
```

```
published documents -->
                                                </entry>
                                        </section>
                                </component>
                        </section>
                </component>
                <!-- TASK 2 -->
                <component>
                        <section>
                                <code/>
                                <!-- CONTROL INFORMATION -->
                                <author>
                                        <time/>
                                        <assignedAuthor/>
                                                <!-- info about data time and author of the
step-->
                                        </assignedAuthor>
                                </author>
                                <!-- INPUT -->
                                <component>
                                        <section>
                                                <code/>
                                                <title/>
                                                <text/>
                                                <entry>
                                                        <!-- including the references at
the published document -->
                                                </entry>
                                        </section>
                                </component>
                                <!-- OUTPUT -->
                                <component>
                                        <section>
                                                <code/>
                                                <title/>
                                                <text/>
                                                <entry>
                                                 <!-- including the references at the
published document -->
                                                </entry>
                                        </section>
                                </component>
                        </section>
                </component>
        </structuredBody>
```



```
        </component>
</ClinicalDocument>
```

5.Y.2.1 Header

The purpose of the CDA header is to enable document exchange across and within clinical institutions and facilitate document management; the header of a workflow document contains all the necessary informationins to identify the document it self, workflow type the first author and organizasion involved.

5.Y.2.1.1 CDA Header Attributes

This section describes attributes of the root ClinicalDocument class.

ClinicalDocument.id
ClinicalDocument.code
ClinicalDocument.title
ClinicalDocument.realmCode
ClinicalDocument.typeId
ClinicalDocument.templateId
ClinicalDocument.effectiveTime
ClinicalDocument.confidentialityCode
ClinicalDocument.languageCode
ClinicalDocument.setId
ClinicalDocument.versionNumber

```
<!-- DOCUMENT DATA -->
        <!-- Definition of validity context -->
        <realmCode code=" "/>
        <!-- Identification CDA R2 -->
        <typeId root=" " extension=" "/>
        <!-- templateID: Definition of the template to define the ties on the content of the document -->
        <templateId root=" " extention=" "/>
        <!-- id: documentID -->
        <id extension=" " root=" " displayable=" " assigningAuthorityName=" "/>
        <!-- code: Defining the type of CDA document (typecode metadata in XDS) -->
        <code code=" " displayName=" " codeSystem=" " codeSystemName=" " codeSystemVersion=" "/>
        <!-- Title optional but required when it is rendered by style-sheet -->
        <title> Workflow Document</title>
        <!-- Date and time of CDA document creation -->
        <effectiveTime value="20110501112000+0100"/>
        <!-- Confidentiality Code (N,R,V) -->
        <confidentialityCode code=" " codeSystem=" " codeSystemName=" " displayName=" "/>
        <!-- Language Code describe the lenguage in which the documnt is written -->
        <languageCode code=" "/>
        <!-- SetId rappresents the same identification for all the version of the document -->
        <setId root=" " extension=" " assigningAuthorityName=" "/>
        <!-- Version Number describes the version of the document -->
        <versionNumber value=" "/>
```

5.Y.2.1.2 CDA Header Participants

This section describes classes related to the root ClinicalDocument class via a Participation.

Several CDA Header participations can be played by the same person. In such cases, the person should be identified as the player for each appropriate participation. For instance, if a person is both the author and the authenticator of a document, the CDA Header should identify that person as both the author participant and the authenticator participant.

On other occasions, CDA Header participants are played by different people.

- **recordTarget** — The recordTarget class represents the medical record that this document belongs to. The WD has exactly one recordTarget participant: the PatientRole with all attributes to identify the patient (id, addr, telecom, and print data as name, birth time, birth place)
- **author** — Represents the humans and/or machines that authored the document (the human and/or machine which provides the last version of the document). The two principal attributes are:
  - **time** that specific data and time of document creation
  - **assignedAuthor** that contains all attributes associated with the author of the document (id, assigedAuthoring device in case of a machine, represented organization, addr, telecom)
- **custodian**— Represents the organization from which the document originates and that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian (the custodian can change in the different versions of the Workflow Document and it is the steward of the last version document). The custodian participation satisfies the CDA definition of Stewardship (A clinical document is maintained by an organization entrusted with its care). Because CDA is an exchange standard and may not represent the original form of the authenticated document, the custodian represents the steward of the original source document.

```
<!-- PATIENT DATA -->
        <recordTarget>
                <patientRole>
                        <!-- the main patient ID (the same of the XDS patientId) -->
                        <id root=" " extension=" " assigningAuthorityName=" "/>
                        <!-- root is the official ID of other Authority -->
                        <id root=" " extension=" " assigningAuthorityName=" "/>
                        <!-- addr: Adress is optional (HP:primary home, H:home, TMP:temporary adress)--
>
                        <addr use=" ">
                                <streetName>--</streetName>
                                <houseNumber>--</houseNumber>
                                <postalCode>--</postalCode>
                                <city>--</city>
```



```
                        <country>--</country>
                    </addr>
                    <!-- telecom: phone number is optional (HP:home phone, WP:work phone,
MC:mobile cellular)-->
                    <telecom value=" " use="WP"/>
                    <telecom value=" " use="HP"/>
                    <!-- -->
                    <patient>
                        <name>
                            <given>--</given>
                            <family>--</family>
                            <suffix>--</suffix>
                        </name>
                        <administrativeGenderCode code=" " displayName=" " codeSystem=" "
codeSystemName=" "/>
                        <birthTime value="19841106"/>
                        <birthPlace>
                            <place>
                                <addr>
                                    <country>--</country>
                                    <city>--</city>
                                </addr>
                            </place>
                        </birthPlace>
                        <!-- optional is guardian is who rappresents the patient (cases of minors or
of not able patients) -->
                        <!-- <guardian> </guardian> -->
                    </patient>
                </patientRole>
            </recordTarget>
```

```
<!-- AUTHOR DATA -->
            <author>
                <!-- Date and time of document creation -->
                <time value="20110501112000+0100"/>
                <assignedAuthor>
                    <id  root=" " extension=" " displayable=" " assigningAuthorityName=" "/>
                    <id  root=" " extension=" " displayable=" " assigningAuthorityName=" "/>
                    <assignedAuthoringDevice>
                        <softwareName>--</softwareName>
                    </assignedAuthoringDevice>
                    <representedOrganization>
                        <id root=" "/>
                    </representedOrganization>
                    <!-- Adress is optional (HP:primary home, H:home, TMP:temporary adress)-->
                    <addr use="H">
                        <streetName>--</streetName>
                        <houseNumber>--</houseNumber>
                        <postalCode>--</postalCode>
                        <city>--</city>
                        <country>--</country>
```

```
                    </addr>
                    <!-- Phone Number is optional (HP:home phone, WP:work phone, MC:mobile
cellular)-->
                    <telecom value=" " use="WP"/>
                    <telecom value=" " use="HP"/>
                    <!-- -->
                </assignedAuthor>
            </author>
```

```
<!-- CUSTODIAN DATA: Custodian of the document is (who or what)responsible for the storage of the
document -->
            <custodian>
                <assignedCustodian>
                    <representedCustodianOrganization>
                        <id root=" " extension="" assigningAuthorityName=""/>
                        <name>--</name>
                        <telecom>--</telecom>
                        <addr>--</addr>
                    </representedCustodianOrganization>
                </assignedCustodian>
            </custodian>
```

5.Y.2.1.3 CDA Header Relationships

This section describes classes related to the root ClinicalDocument class via an ActRelationship.

ParentDocument — The ParentDocument represents the source of a document revision, addenda, or transformation. ParentDocument.text is modeled as an ED data type - allowing for the expression of the MIME type of the parent document. It is not to be used to embed the related document, and thus ParentDocument.text.BIN is precluded from use.

Allowable values for the intervening relatedDocument.typeCode are shown in the following table.

Code	Definition
APND (append)	The current document is an addendum to the ParentDocument.
RPLC (replace)	The current document is a replacement of the ParentDocument.
XFRM (transform)	The current document is a transformation of the ParentDocument.

A conformant CDA document can have a single relatedDocument with typeCode "APND"; a single relatedDocument with typeCode "RPLC"; a single relatedDocument with typeCode "XFRM"; or a combination of two relatedDocuments with typeCodes "XFRM" and "RPLC".

Document Identification, Revisions, and Addenda

A replacement document is a new version of the parent document. The parent document is considered superseded, but a system may retain it for historical or auditing purposes. The parent document being replaced is referenced via act relationship relatedDocument, where

relatedDocument.typeCode is set to equal "RPLC" (for "replaces"). An example is a report found to contain an error that is subsequently replaced by the corrected report.

An addendum is a separate document that references the parent document, and may extend or alter the observations in the prior document. The parent document remains a current component of the patient record, and the addendum and its parent are both read by report recipients. The parent report (represented by the ParentDocument class) being appended is referenced via act relationship relatedDocument, where relatedDocument.typeCode is set to equal "APND" (for "appends").

The ParentDocument attributes:

- **ID**= Every CDA document must have a unique ClinicalDocument.id, and thus the replacement or addendum documents each have ClinicalDocument.id that is different from that of the parent document.
- **SETID**= CDA documents may also contain a ClinicalDocument.setId and a ClinicalDocument.versionNumber, which together support a document identification and versioning scheme used in some document management systems. In this scheme, all documents in a chain of replacements have the same ClinicalDocument.setId and are distinguished by an incrementing ClinicalDocument.versionNumber.
- **VERSION NUMBER**= The initial version of a document gets, in addition to a new unique value for ClinicalDocument.id, a new value for ClinicalDocument.setId, and has the value of ClinicalDocument.versionNumber set to equal "1". A replacement document gets a new globally unique ClinicalDocument.id value, and uses the same value for ClinicalDocument.setId as the parent report being replaced, and increments the value of ClinicalDocument.versionNumber by 1. (Note that version number must be incremented by one when a report is replaced, but can also be incremented more often to meet local requirements.)

```
<!-- RELATED DOCUMENT DATA-->
        <relatedDocument typeCode=" ">
                <parentDocument>
                        <id root=" " extension=" " assigningAuthorityName=" "/>
                        <setId root=" " extension="" assigningAuthorityName=" "/>
            <versionNumber value=" "/>
                </parentDocument>
        </relatedDocument>
        <!-- inFulfillmentOf because the WD is not necessary created in respost of another document, it can be valorizated in the case of a WD generated by another WD -->
```

5.Y.2.2 Body

The section body of the document is structured in sections. Each section of the document describes a single step of the workflow tracked. Each section has a first part which describes the step itself and the author which perform the step and two sub-section needed to relate the external documents involved in the step as inputs of the step or as outputs.

The CDA WD is comprised of structured markup. The StructuredBody class represents a CDA document body that is comprised of one or more document sections. Document sections is nested, can override context propagated from the header, and can contain CDA entries.

5.Y.2.2.1 Control Info

The elements inside the section describes the information needed to identify the step of the workflow and the author of that. In these elements there is a code which identify the step and an element with a set of attribute to describe the author which performed the step.

```
!-- STEPCODE of the task. -->
<code code=" " displayName="task name" codeSystem=" " codeSystemName=" "/>
<!-- CONTROL INFORMATION -->
<author>
        <!-- Date and time of document creation -->
        <time value="20110501112000+010"/>
        <!-- the author of the task -->
        <assignedAuthor>
                <id  root=" " extension=" " displayable=" " assigningAuthorityName=" "/>
                <id  root=" " extension=" " displayable=" " assigningAuthorityName=" "/>
                <assignedAuthoringDevice>
                        <softwareName>--</softwareName>
                </assignedAuthoringDevice>
                <representedOrganization>
                        <id root=" "/>
                </representedOrganization>
                <!-- optional (HP:primary home, H:home, TMP:temporary adress)-->
                <addr use="H">
                        <streetName>--</streetName>
                        <houseNumber>--</houseNumber>
                        <postalCode>--</postalCode>
                        <city>--</city>
                        <country>--</country>
                </addr>
                <!-- optional (HP:home phone, WP:work phone, MC:mobile cellular)-->
                <telecom value=" " use="WP"/>
                <telecom value=" " use="HP"/>
        </assignedAuthor>
</author>
```

5.Y.2.2.1 Input Section

The section of Input is a sub-section of the task. It is structured with a part human readable and a part machine processable. In the part human readable there is the list of the external documents related as inputs of the step, in the part machine processable there are the information needed to find the documents related. Inside this section could be related from zero to n external documents.


```
<component>
	<section>
		<!-- code of the section INPUT [1..1] -->
		<code code="…" displayName="INPUT" codeSystem="..." codeSystemName="..."
		codeSystemVersion=".."/>
		<title>Section INPUT</title>
		<text>
			<list id="..">
				<caption>Input Documents</caption>
				<item>
					<content ID="docIN_1">Input Document 1</content>
				</item>
				<item>
					<content ID="docIN_2">Input Document 2</content>
				</item>
			</list>
		</text>
		<!-- ENTRY Machine Processable-->
		<entry>
			<act classCode="ACT" moodCode=" ">
				<code code=".." displayName="INPUT" codeSystem=".."
				codeSystemName=".."/>
				<!-- data of the external document referenced -->
				<reference typeCode="REFR">
					<originalText>
						<reference value="docIN_1"/>
					</originalText>
					<externalDocument classCode="DOC" moodCode=" ">
						<id extension=" " root=" "/> <!-- documentId -->
						<code code=" " displayName=" " codeSystem=" "
						codeSystemName=" "/>
					</externalDocument>
				</reference>
				<!-- data of the external document referenced -->
				<reference typeCode="REFR">
					<originalText>
						<reference value="docIN_2"/>
					</originalText>
					<externalDocument classCode="DOC" moodCode=" ">
						<id extension=" " root=" "/> <!-- documentId -->
						<code code=" " displayName=" " codeSystem=" "
						codeSystemName=" "/>
					</externalDocument>
				</reference>
			</act>
		</entry>
	</section>
</component>
```

5.Y.2.2.1 Output Section

The section of Input is a sub-section of the task. It is structured with a part human readable and a part machine processable. In the part human readable there is the list of the external documents related as outputs of the step, in the part machine processable there are the information needed to find the external documents related. Inside this section could be related from zero to an external documents.

```
<component>
	<section>
		<!-- code of the section OUTPUT [1..1] -->
		<code code="…" displayName="OUTPUT" codeSystem="..." codeSystemName="..."
		codeSystemVersion=".."/>
		<title>Section OUTPUT</title>
		<text>
			<list id="..">
				<caption>Output Documents</caption>
				<item>
					<content ID="docOUT_1">Output Document 1</content>
				</item>
			</list>
		</text>
		<!-- ENTRY Machine Processable-->
		<entry>
			<act classCode="ACT" moodCode=" ">
				<code code=".." displayName="OUTPUT" codeSystem=".."
				codeSystemName=".."/>
				<!-- data of the external document referenced -->
				<reference typeCode="REFR">
					<originalText>
						<reference value="docOUT_1"/>
					</originalText>
					<externalDocument classCode="DOC" moodCode=" ">
						<id extension=" " root=" "/> <!-- documentId -->
						<code code=" " displayName=" " codeSystem=" "
						codeSystemName=" "/>
					</externalDocument>
				</reference>
			</act>
		</entry>
	</section>
</component>
```


5.Y.3 XDS Metadata

5.Y.3.1 Document Metadata

The following metadata elements shall be used to describe the Workflow Document in an XDS Affinity Domain. The XDW profile does not introduce new metadata and all the metadata elements used are the common XDS document metadata specified in ITI TF-3: 4.1.5.

XDSDocumentEntry Attribute	Definition
author	Represents the humans and/or machines that authored the document. In the Workflow Document the Author is the human and/or machine which update that version of the Workflow Document. This means that when a Workflow Document is updated by a different person or machine, the author changes.
authorInstitution (sub-attribute of author)	No special requirements for Workflow Document
authorPerson (sub-attribute of author)	No special requirements for Workflow Document
authorRole (sub-attribute of author)	No special requirements for Workflow Document
authorSpecialty (sub-attribute of author)	No special requirements for Workflow Document
availabilityStatus	No special requirements for Workflow Document
classCode	The class code shall be XDW_Workflow_Document *Comment: This code will be requested from LOINC and will be inserted when provided*
classCode DisplayName	No special requirements for Workflow Document
comments	No special requirements for Workflow Document
confidentialityCode	No special requirements for Workflow Document
creationTime	No special requirements for Workflow Document
entryUUID	No special requirements for Workflow Document
eventCodeList	This list of codes represents the main clinical acts. For a Workflow Document, two unique codes are defined: Workflow Active and Workflow Inactive. Each version of the Workflow Document (as defined through document replacement) shall have in its eventCodeList either Workflow Active or Workflow Inactive indicating its overall status. This use of codes enables the use of query to locate active or inactive workflows with certain other properties. When a new workflow is created and its Workflow Document is published the code is set to “Workflow Active”. When the workflow is completed, the eventCodeList shall be set to “Workflow Inactive”. These codes are provided to be used as “key words” for queries to distinguish between workflow still open and workflow already close without the need to open the Workflow Document to check that.
eventCodeListDisplay	No special requirements for Workflow Document

XDSDocumentEntry Attribute	Definition
Name	
formatCode	urn:ihe:iti:xdw:2011 codesystem: 1.3.6.1.4.1.19376.1.2.3
hash	No special requirements for Workflow Document
healthcareFacility TypeCode	No special requirements for Workflow Document
healthcareFacility TypeCodeDisplay Name	No special requirements for Workflow Document
homeCommunityId	No special requirements for Workflow Document
languageCode	No special requirements for Workflow Document
legalAuthenticator	No special requirements for Workflow Document
mimeType	No special requirements for Workflow Document
patientId	No special requirements for Workflow Document
practiceSettingCode	No special requirements for Workflow Document
practiceSettingCode DisplayName	No special requirements for Workflow Document
repositoryUniqueId	No special requirements for Workflow Document
serviceStartTime	Shall be the start time the service being documented took place (clinically significant, but not necessarily when the document was produced or approved). For the Workflow Document the serviceStartTime is the time in which the workflow starts. If present, shall have a single value.
serviceStopTime	Shall be the stop time the service being documented took place (clinically significant, but not necessarily when the document was produced or approved).
size	No special requirements for Workflow Document
sourcePatientId	No special requirements for Workflow Document
sourcePatientInfo	No special requirements for Workflow Document
title	No special requirements for Workflow Document
typeCode	Shall be assigned codes from the value set specifying the precise kind of document (e.g. Pulmonary History and Physical, Discharge Summary, Ultrasound Report). The different IHE domains and/or XDS Affinity Domains will define a value set to define the kind of workflow that is tracked.
typeCodeDisplay Name	No special requirements for Workflow Document
uniqueId	No special requirements for Workflow Document
URI	No special requirements for Workflow Document

5.Y.3.2 XDS SubmissionSet Metadata

No additional constraints. See ITI TF-3: 4.1.8

5.Y.3.3 XDS Folder Metadata

The metadata elements shall be used to describe the XDS Folder that contains all versions of the Workflow Document (and/or possibly clinical documents related to it). The XDW profile does not introduce new metadata and all the metadata elements used are the common XDS folder metadata specified in ITI TF-3: 4.1.9. At the level of the XDS Affinity Domain is necessary to define some specific codes to identify the type of the Folder used.

XDSFolder Attribute	Definition
availabilityStatus	No special requirements for Workflow Document
codeList	Contains the set of codes specifying the type of clinical activity that resulted in placing XDS Document in this XDSFolder. The value shall be “XDW Workflow Context Folder”.
codeListDisplayName	No special requirements for Workflow Document
comments	No special requirements for Workflow Document
entryUUID	No special requirements for Workflow Document
homeCommunityId	No special requirements for Workflow Document
lastUpdateTime	No special requirements for Workflow Document
patientId	No special requirements for Workflow Document
title	No special requirements for Workflow Document
uniqueId	No special requirements for Workflow Document

5.Y.4 Discussion on Associations Types

The tasks within a Workflow Document can reference many clinical documents related to the workflow tracked. The Workflow Document contains the ids (XDSDocumentEntry.uniqueId) of the clinical documents and so, when the Workflow Document is known, all the clinical documents referenced can be retrieved using these ids.

Each clinical document can be referenced by many Workflow Documents in different steps and for different reasons. However, when a workflow document is known the related clinical documents are always reached through the ids tracked inside the different steps, in the sections “input” or “output”, inside the workflow documents.

In some use cases, however, it is useful to have a fixed id to identify the whole workflow. Since the Workflow Document will be replaced many times (it is replaced at each step), its uid/id is not useful for maintaining a fixed reference. Placing all versions of the same Workflow Document into a same folder allows to use the FolderId as the fixed link to the workflow.

Any Workflow Content Folder shall contain no more than one approved Workflow Document (labeled with specific XDSDocumentEntry.classCode value).

The use of a folder guarantees:

- When a Workflow Document is replaced the new version of the Workflow Document is automatically placed inside the same folder so the relationship with the clinical documents already published connected to that workflow is guaranteed.
- If a workflow generates a child workflow there will be two different folders, one for each Workflow Document. The relationship between the different workflows is always guaranteed inside the Workflow Documents using the folder's uniqueId as input or output of the step.

A good name/label for the folder would be Workflow Context Folder. A workflow context folder should be labeled so it can be differentiated from other folders; XDSFolder.codeList is the metadata that should be used.

5.Y.5 Workflow Document Lifecycle Management

The Cross-Enterprise Document Workflow profile specifies both the content of the Workflow Document and also the lifecycle management of the Workflow Document. The XDW Content Profile relies on XDS operations for management of the Workflow Document. The XDW Content Creator is grouped with an XDS Document Source and an XDW Content Consumer is grouped with an XDS Content Consumer.

As an overview, after the first step of the workflow, a Workflow Document is created and submitted in a Folder. At each subsequent step of the workflow, an updated version of the Workflow Document replaces the previous version. At the end of the workflow there will be a set of Workflow Documents deprecated and only the last one in approved status.

This section describes the standard operations needed to ensure that:

- The Workflow Document contains information for all completed steps in the workflow.
- The clinical documents associated with the Workflow Document are available (the relation from the Workflow Document to the clinical document is inside the Workflow Document by the use of uids inside the steps).

5.Y.5.1 Create workflow

When the first step of a new workflow is completed, the XDW Content Creator shall create the first version of the Workflow Document and the grouped XDS Document Source shal submit it to the Document Repository. The Document Source puts the Workflow Document in a new Workflow Context Folder.

5.Y.5.2 Update workflow document

For each subsequent step in the Workflow, an XDW Content Creator updates the content in the Workflow Document (e.g., by adding a new step) and then the grouped Document Source replaces the Workflow Document with its new version. This new version is automatically added to the correct Workflow Context Folder by normal XDS rules for document replacement in the context of a folder.

The process for updating the document is:

- Open the existing workflow document
  - Add or update workflow steps
  - Re-register (update) the workflow document by performing a document replace

5.Y.5.3 Add clinical document to workflow

Whenever a Workflow Document is added to a Workflow Context Folder, or a Workflow Document is replaced when a new step is complete, if there are clinical documents related to the new step, the Content Creator puts references to these documents inside the input and/or output sections of the step.

5.Y.5.4 Get a clinical document referenced by workflow

The most recent version Workflow Document may be retrieved at any point during the workflow.

The last version of the Workflow Document, with an approved status, contains all information on the workflow and its steps. So an XDW Content Consumer needs to analyze only the approved version to know all the information. However, the deprecated workflow documents are always available if someone needs to analyze the different versions updated step by step throught the workfllow

The Workflow Document contains details of each step as well as the DocumentEntry.uniqueId of all the referenced clinical documents, so a single stored query is adequate to get all the clinical document metadata. The query is needed because the workflow document contains only references to the clinical documents.

