Integrating the Healthcare Enterprise

IHE Radiology
Technical Framework Supplement

Imaging Diagnostic Report
(IDR)

Revision 1.0 – Draft for Public Comment

For review and comment only.

DO NOT implement this public comment version.

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

Foreword

This is a supplement to the IHE Radiology Technical Framework V21.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on May 9, 2024 for Public Comment. Comments are invited and can be submitted at https://www.ihe.net/Radiology_Public_Comments. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by May 31, 2024.

This supplement describes changes to the existing technical framework documents.

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

Amend section X.X by the following:

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

General information about IHE can be found at IHE.net.

Information about the IHE Radiology domain can be found at IHE Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at Profiles and IHE Process

The current version of the Radiology Technical Framework can be found at Radiology Technical Framework.

CONTENTS

Introduction to this Supplement

This supplement may or may not reach the status of a Trial Implementation profile this cycle. If it does, the first normative material will be the content definition (see Section 6.Z).

This profile describes a machine-readable format for reports on diagnostic procedures of common radiology specialties using common modalities. It defines a FHIR-based encoding of report content, specifically addressing common imaging report sections, including order, history, procedure/technique, comparison, findings/observations, impression/conclusion, recommendation, signatures, and addenda. Specific attention is given to the impression and recommendation sections as being of primary interest to most report consumers. Full coverage of the complexity of the Findings section are deferred to future work (See discussion in Section 6.Z.3.6).

The profile is intended to be suitable for Radiology, Cardiology, OB/Gyn, Oncology, Pathology and Optometry, but does not mandate any specialty-specific details.

In principle, this work could also apply to other imaging procedures such as pathology, or interventional and combined interventional and diagnostic procedures; however, details specific to those applications would potentially introduce variations and complexities that would exceed available committee bandwidth. The intention is to address such additional areas in future cycles, and doing so may require some data structure variants.

During Public Comment, the concepts and common profile details will be presented in this document. A companion IDR FHIR IG (Implementation Guide) contains the specification of the profiled FHIR Resources (ImagingDiagnosticReport, etc.). For Trial Implementation, this profile document may be folded into the IG pages.

The profile will not map out or provide examples of all the fine-grained patterns and practices that appear in imaging reports, and in particular does not claim to address idiosyncratic patterns in various specialties. This profile is intended to provide a common starting point and based on initial experiences and feedback, the profile may be expanded, or focused options or sister profiles may be created. Such follow-on work would likely benefit from collaborating with corresponding specialty society groups.

This profile focuses on content NOT workflow. Incorporation of the report into the EHR/medical record is discussed; however, adjacent workflows are not. Specifically, reporting workflow and the process of composing the information that ultimately ends up in the resulting report is not addressed, although this is an area of keen interest and will likely be addressed in subsequent work. Such an Imaging Report Composition Profile could address facets such as the incorporation of AI results into the report, the generation of proposed impressions based on the findings and indications, and the generation of proposed recommendations based on the impressions, guidelines, findings, and indications. Specifically, it would delve into the composition and coding of complex collections of Observations in the Findings section of the report which was largely deferred here.

Similarly, imaging acquisition workflow in a FHIR environment using ServiceRequest and Procedure resources is also a topic of interest but is out of scope for this profile.

Open Issues

1. Are the query patterns in Section X.4.2.2.1 adequate for clinical use? Should any be mandated?

   Which patterns are most common/important? Note that the query patterns cover "server-side filtering" where the server returns a list tightly tailored to the client's needs. Clients can also do "client-side" filtering, where they query for a tractably-sized list of responses, then examine the metadata of the returned list in more detail to do further filtering (that might be difficult to communicate to the server, or more difficult for the server to perform).

2. Should Report Readers have display requirements (like for primitives in AI Results)?

   If so, what should they be? The easiest thing will be for Readers to render the PDF, text, and/or HTML in the .presentedForm.

   FHIR provides some guidance here:
   https://www.hl7.org/fhir/R4B/documents.html
   https://www.hl7.org/fhir/narrative.html
   https://hl7.org/fhir/domainresource.html#resource

3. Should more coding be mandated at this time?

   This draft of the profile has chosen to target getting basic reports into FHIR representations (see discussion in Section 6.Z.3.6), and initiate downstream automations (see Section X.4.2.4) by requiring at least one coded Impression (see Section 6.Z.3.7). Greater coding is permitted but not required. More detailed guidance on coding Findings will be developed in concert with greater AI result integration in a subsequent profile. Should this profile be delayed in order to set a higher bar for the first step?
   A first step for Findings (either here or in the next profile) would be to take the "primitives" approach in AIR, and profile the creation of a basic measurement, a classification, a CDE Element, a CDE Set, etc.

4. Do practices in Europe and Asia use different report content & sections from what is described in Section X.4.1.2.1?

5. Should we mirror IMR Options for PDF Report and HL7 Text Report?

   It is currently permitted to include PDF and HL7 text versions of the report in .presentedForm, but there are no corresponding named options for sites to specifically require such support. Should there be?
   https://profiles.ihe.net/RAD/IMR/volume-1.html#15221-pdf-report-option
   https://profiles.ihe.net/RAD/IMR/volume-1.html#15222-hl7-text-report-option

6. Should we include/prefer .bodyStructure everywhere we use .bodySite?

   The post-coordination in bodyStructure may align better with search patterns. For example, one could search for cysts in the kidney, without having to expand the search to search the left kidney and the right kidney. The structure might also allow more nuanced anatomy references without excessive expansion of pre-coordinated codes. Related questions about heterogeneous coding and possible use of SCT expressions are discussed here https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2605270/

   What are current FHIR preferences and guidance on laterality, bodyStructure, etc.?

7. Should we incorporate SNOMED "polycode expressions"?

   Post-coordination is a useful method for coding complex semantics without having very large sets of pre-coordinated codes. DICOM SR, FHIR, and other formats often provide post-coordination data structures for common patterns (e.g. an attribute for anatomic location, with a second associated attribute for laterality). SNOMED defines an expression syntax to compose a compound code for use in a single attribute without requiring a multi-attribute data structure. See also https://confluence.ihtsdotools.org/display/DOCSTART/7.+SNOMED+CT+Expressions

   FHIR does permit such expressions. From https://hl7.org/fhir/R4/datatypes.html#Coding "If present, the code SHALL be a syntactically correct symbol as defined by the system. In some code systems such as SNOMED CT, the symbol may be an expression composed of other predefined symbol (e.g. post-coordination). Note that codes are case sensitive unless specified otherwise by the code system. The display is a text representation of the code defined by the system and is used to display the meaning of the code by an application that is not aware of the system."

   Past experience with allowing creators to freely compose post-coordinated expressions from codes of different pre-coordinated granularity has overwhelmed consumers with unpredictably large numbers of ways to express the same or similar information, and made it very challenging to determine if two expressions are in some sense the same.

8. Should we profile a specific code set for impression likelihood?

   There seems to be a reasonable basis for a 5- or 6-point scale with corresponding language mappings.
   See https://www.ajronline.org/doi/full/10.2214/AJR.15.15895
   https://rad.bwh.harvard.edu/diagnostic-certainty-scale/

9. Would FHIR List Resource be a better way to organize Impression references?

   Conventionally, imaging clinicians often order the items in the impression section to bring the more important ones to the beginning. (See Impression discussion in Section

X.4.1.2.1 Sections). List seems like it might be appropriate, but it's not clear how to incorporate it. Some reports number the list of impressions which can facilitate verbal referencing during communications. Also, impression "entries" in the narrative report often group several related items together in one entry. Conversely, sometimes "unrelated" items are grouped together because the dictating clinician was "lazy" and didn't call out a new "bullet", or because the clinician could be more verbally succinct by combining them.

10. Should some of the FHIR code attributes use CodeableConcept instead?

    Instead of a single code, it appears to allow for a set of equivalent codes which could help with code mapping, but that might be better handled with a code mapping service rather than putting it into each data object. Does it have other benefits? Oddly, the CodeableConcept example shows the .text incorporating not just the meaning of the Codeable Concept, but also semantics from the context in which the CodeableConcept is invoked which would seem to bend some data modelling rules.

11. What code set should be recommended for DiagnosticReport.code?

    FHIR references is LOINC Diagnostic Report Codes, but it is not clear exactly what the list includes for imaging. Radlex Playbook is good for including key elements like modality and body part, but also gets into usage of contrast which is of less interest to people searching the medical record for a particular (type of) report.

12. Should Report Creator be required to create ImagingStudy resource if none exists?

    Probably this should be handled between the Image Manager / Image Archive and the EMR in a different profile. Report Creator is not the best choice, but would it be useful to profile/permit it as a stop-gap? Note, when profiling ImagingStudy, note that .partOf references the Procedure resource, and .procedure holds one or more procedure codes.

13. How should negative findings and impressions be encoded?

    Structures are fairly clear for positive findings and impressions. But, an important part of many radiology reports is a definitive statement that a given pathology is not present. Will need to support negation of broad pathology/anatomy ("no disease in the chest", "no bleed in the GI tract"), negation of similar specificity to positive findings ("no tearing of the left Acetabular labrum"), and points on the spectrum in between. Also list-based statements ("No pathology A, B, or C seen in anatomy X", or "No pathology A present in anatomy X, Y, or Z").

14. What profiling of the Bundle Resource is needed?

    The scope of the current profile is for diagnostic reports used internal to the healthcare facility so the resources are, in principle, created on local FHIR servers to which other enterprise systems have access. Addressing the communication of reports across

enterprise boundaries is a logical next step. It is expected such transfers will use Bundles to group all the relevant resources to have a "functional" report at the other end without needing access to the originating facilities servers. What sort of profiling do we need to do, e.g., about what referenced resources are required to be included in a Bundle and to what degree of completeness? And what are some good examples to follow?

15. What profiling of the Addendum is needed?

    Beyond identifying the "amended" status of the DiagnosticReport resource, do we need to mandate whether the new DiagnosticReport artifact is a "delta" or a replacement report (that contains the "unedited" original as well as the addendum)? Should we specify display and archiving behaviors?

FHIRQ Questions

For these questions FHIR policy/architecture people may be able to provide background and any discussions/insights they've had.

1. Which version of FHIR should the profile be based on?
   A: This Public Comment draft used R5.
   (TC Revisit this during TI planning/prep based on the FHIR R* landscapes)

   WG20A – Makes sense. R6 balloting begins around June, and is mostly in line with R5. Implementation community might be targeting R6 at that time, so be ready to "migrate/revise" spec to R6 (which per Ana is likely pretty close to our R5). Some of our extensions might be folded into R6. Plan to harmonize with OO and PC for extensions – **Submit a JIRA Ticket and find the timing of their calls to discuss. (Kinson?+Kevin) (May Working Group meeting – 18-24 May Dallas) (Ticket # for .recommendations) https://jira.hl7.org/browse/FHIR-45131 https://jira.hl7.org/browse/FHIR-45290 - MIPS Reporting on Breast recommendations also required data on followup of recommendations.**

   When we get IDR closer to TI we will check R6 and decide how we document.
   R4 has achieved some stability and there may be some commercial implementation momentum. We could consider writing everything as R4+extension rather than R5 if the base libraries aren't updated but R5 is a big jump from R4 wrt many of our resources. R5 has also been made normative and there is hope that it too will achieve stability and commercial adoption. Specifically, R5 introduces ImageSelection (which is not available in R4), which is a key Resource for imaging reports. Integrated Reporting Applications (IRA) is based on R5.
   R6 is predicted to make Normative a large number of additional resources and may include several features that would be helpful for reporting. Progress toward R6 will be monitored and a decision on whether to migrate this profile to R6 may be considered during Trial Implementation.

2. Should referenced resources be bundled with the report?
(For US implementations, the Report is required to be exchanged and Brian will find out how that is handled) https://build.fhir.org/ig/HL7/US-Core/uscdi.html
https://build.fhir.org/ig/HL7/US-Core/StructureDefinition-us-core-diagnosticreport-note.html

   This may be more of an issue with cross-enterprise cases, but if a report references a Patient resource as the .subject, the receiver needs to be able to resolve all the references and have access permissions to retrieve them. The presentedForm likely provides some fallback for human consumption, but machine-readability could be hindered. See also Bundle Resource open issue.

3. Should referenced resources be versioned? WG20 comments?

   Resources like Patient or FamilyMemberHistory will be regularly updated over time. For medicolegal reasons, it may be important that the reference in the report reflect what was known to the radiologist at reporting time, not what is known now. FHIR has the concepts of .versionId and _history as optional features.
(ITI might have looked at this. Or try **Zulip Implementation thread** https://chat.fhir.org/#narrow/stream/179166-implementers and mention Lloyd and Grahame to get them on radar – also ask about .supportingInfo policy)(Query is also not straightforward to get history, you get latest by default)

4. Should resource timepoint-snapshots/summaries/extracts be specified? WG20 comments?

   E.g., the Patient resource is comprehensive, but a limited set of elements: name, MRN for identification; age, gender are referenced for clinical context. Order, History, Procedure, and Comparison are similarly selective of relevant details. Do we bundle copies of those resources with only relevant "key value" elements. The primary copy could be accessed if more is needed (e.g. for medicolegal). This also addresses the "at the time of this report" issue. The subset is also visible in the .text or .presentedForm.

5. How do we avoid incompatible imaging implementations based on .media.

6. How is DiagnosticReport.note intended to be used?
Who would populate it? Who reads it, for what purpose? Is it intended to be mandatory for systems to present the notes alongside the report? For imaging reports, the stated examples go in the body of the report itself. Maybe it was intended for narrative commentary for lab reports that imaging reports put in the body?

7. Given the .performer (Practice) and .resultsInterpreter (Practitioner) split hard coded into the DR, maybe we should constrain Interpreter? Better choice to deprecate .performer or just do the single "publishing practice", and then interpreter is PractitionerRole so if there are multiple (and multiple practices), then it is paired/clear.

8. Provenance – Seems to meet our needs but (someone) needs to finish vetting that it can handle the image reading workflow patterns (resident, attending, overreads, addendums,

etc.). That will likely be in the context of a workflow profile. This one is mostly concerned with capturing the signature of the "final" release. If we have time, we may get into it a bit beyond the current reference pointer.

O&O Questions

What is the purpose/distinction of bodysite and bodystructure given that bodysite is bound to Body Structure codes? [LATER rewrite to highlight bodystructure as the "better new way"]

1. Is body site commonly pre-coordinated in observation.code, or post-coordinated in observation.bodysite, or varied idiosyncratically between the two?
2. Is there a convention for recording "Anatomy X is unremarkable"? Also, "Pathology Y is not present"
3. When something that could be a measurement (organ diameter) is not measured but is visually assessed, and found to be normal or enlarged, how do we capture that? Do we encode .interpretation without encoding .value?

Closed Issues

1. Should we specify Export Options for FHIR R4, HL7 V2 ORU, etc.?
   A. No

   Section X.4.1.6 includes some discussion of hybrid environments and describes some strategies and guidance on how a "lossy downgrade" of a DiagnosticReport to an R4 Resource or an HL7 V2 ORU payload might be performed. While this is lossy, a receiving system that is only capable of handling ORU messages is likely unable to make productive use of the advanced codings that would be lost in the downgrade anyway.

   In any case, an arbitrary rendering of content into unformatted text is no worse than what is common today, so aren't hurting anything. If this profile is adopted we can do subsequent work to pave the onramps and offramps by formally describing the mappings and adding normative requirements.
2. What scope of exchange should be addressed?
   A. Inside a single enterprise

   The work done here on FHIR profiling will likely be fully applicable to different enterprises, but staying inside a single enterprise allows us to ignore issues that are not specific to reporting, like id and code mapping, and resolution of FHIR references to other enterprises. Leaving that to future work helps us focus and stay closer to our bandwidth constraints for this cycle, and let FHIR and ITI finish documenting general solutions we can follow.
3. Should we make new transactions or modify IMR transactions?
   A. New

IMR has Store/Find/Retrieve Multimedia Report with constraints on content and presentation behaviors, but multimedia is not required here (but is permitted). We can copy/paste to keep them aligned, and tailor for IDR usage. We can refactor later to either remove text from IMR, reference IDR and then keep additional constraints, or to merge the IMR pieces as profile-triggered extensions inside the IDR transactions. But it will be simpler to figure this out later. In the end, avoid duplicating large amounts of spec, because it is a pain to maintain and hard for implementers to confirm equivalence.

4. How much do we address Addendum handling?
   A. Encoding. No workflow

   Specify how to record/see if something reflects an addendum in the encoding. Describe the existence of report states like addenda, final and preliminary, but do NOT get into the workflow and the sequencing of the transactions to do signatures and prelims and addendum. There MAY be a new transaction added when we get around to doing that.

5. Include report flag for Radiologist to request outcome information (like RD Profile)?
   A: No

   FHIR CommunicationRequest resource is likely the appropriate mechanism for this. The reporting system can create both a DiagnosticReport and a CommunicationRequest for a given study. Avoid unnecessarily embedding workflow mechanics in result storage.

6. Should we put all our new references into DiagnosticReport.supportingInfo?
   A: No.

   Most of our additions are about supporting specific semantics for standard sections of imaging reports. They are not just "supporting information", they are formal parts of the standard report with specific roles to play. .supportingInfo is described as "Placer observations not explicitly requested by the filler to provide context or supporting information". Not a clear match for radiology history. Especially since the history will appear in report text, while "supportingInfo" was likely not intended to be in the presentedForm. NTE Segment may have this today

   Also not clear how one would construct a search to match values in the patient history, or family history, or comparison studies, or clinical questions, etc, if all those are put in the supportingInfo data bag.

IHE Technical Frameworks General Introduction

The IHE Technical Frameworks General Introduction is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

9 Copyright Licenses

IHE technical documents refer to, and make use of, a number of standards developed and published by several standards development organizations. Please refer to the IHE Technical Frameworks General Introduction, Section 9 – Copyright Licenses for copyright license information for frequently referenced base standards. Information pertaining to the use of IHE International copyrighted materials is also available there.

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IHE Technical Frameworks General Introduction Appendices

The IHE Technical Framework General Introduction Appendices are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

Appendix A – Actors

*Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:*

New (or modified) Actor Name	Description
Report Creator	~~**A system that**~~ generates and transmits preliminary, final, or amended diagnostic results (i.e., reports).
Report Consumer	~~**A system that**~~ receives ~~**imaging results (i.e.,**~~ reports~~)~~ **and associated results**.
Report Reader	~~**A part of a system that can**~~ access**es** reports ~~**through network query/retrieve or reading interchange media**~~ and ~~**allow the user to view reports**~~ present**s them to user**~~**sed as DICOM Structured Report Objects**~~.
Report Repository	~~**A system that**~~ provides long-term storage of reports and their retrieval ~~**as DICOM Structured Reporting Objects**~~.

Appendix B – Transactions

*Add the following **new or modified** transactions to the IHE Technical Frameworks General Introduction Appendix B:*

New (or modified) Transaction Name and Number	Definition
Store Imaging Diagnostic Report [RAD-Y1]	**A Sender sends an Imaging Diagnostic Report to a Receiver.**
Query Imaging Diagnostic Report [RAD-Y2]	**A Requester queries a Responder for Imaging Diagnostic Reports that match a filter.**
Retrieve Imaging Diagnostic Report [RAD-Y3]	**A Requester requests return of an Imaging Diagnostic Report from a Responder.**

Appendix D – Glossary

*Add the following **new or modified** glossary terms to the IHE Technical Frameworks General Introduction Appendix D:*

New (or modified) Glossary Term	Definition	Synonyms	Acronym/ Abbreviation
No new terms	LATER		

Volume 1 – Profiles

Domain-specific additions

None.

Add new profile Section

X Imaging Diagnostic Report (IDR) Profile

This profile (*See "Introduction to This Supplement" above*)

X.1 IDR Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at https://profiles.ihe.net/GeneralIntro/index.html.

Figure X.1-1 shows the actors directly involved in the IDR Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a required grouping (if any), are shown in conjoined boxes (see Section X.3).

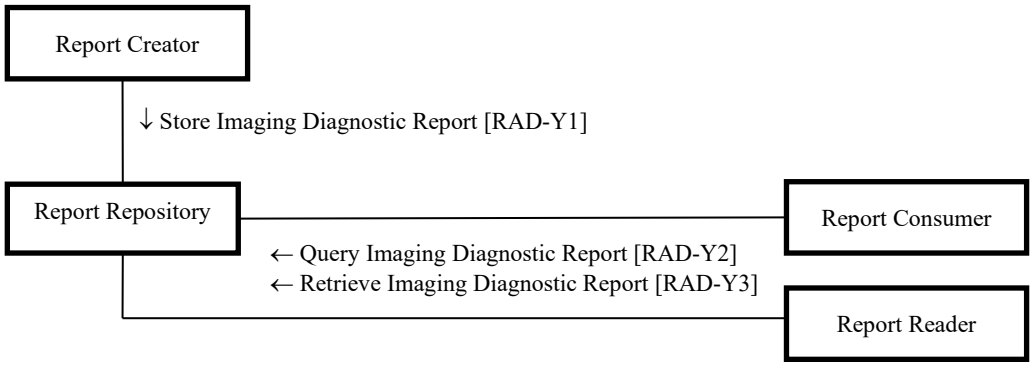

Figure X.1-1: IDR Actor Diagram

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

Table X.1-1: IDR Profile – Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Report Creator	Store Imaging Diagnostic Report [RAD-Y1]	Initiator	R	RAD TF-2: 4.Y1
Report Repository	Store Imaging Diagnostic Report [RAD-Y1]	Responder	R	RAD TF-2: 4.Y1
	Query Imaging Diagnostic Report [RAD-Y2]	Responder	R	RAD TF-2: 4.Y2
	Retrieve Imaging Diagnostic Report [RAD-Y3]	Responder	R	RAD TF-2: 4.Y3
Report Reader	Query Imaging Diagnostic Report [RAD-Y2]	Initiator	R	RAD TF-2: 4.Y2
	Retrieve Imaging Diagnostic Report [RAD-Y3]	Initiator	R	RAD TF-2: 4.Y3
Report Consumer	Query Imaging Diagnostic Report [RAD-Y2]	Initiator	R	RAD TF-2: 4.Y2
	Retrieve Imaging Diagnostic Report [RAD-Y3]	Initiator	R	RAD TF-2: 4.Y3

Note: The Send Imaging Result [RAD-128] transaction is defined in the Result Distribution (RD) Supplement. Notify of Procedural Observation [RAD-132] is defined in the Encounter-Based Imaging Workflow (EBIW) Supplement.

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in RAD TF-2: Transactions. This section documents any additional requirements on profile's actors.

X.1.1.1 Report Creator

A Report Creator coordinates the composition of the content of an imaging diagnostic report.

A Report Creator encodes diagnostic reports using FHIR DiagnosticReport resources. Systems that might implement this actor include traditional reporting products. It is also conceivable that a broker product might be able to take reports in some other format and compose an equivalent report encoded according to this profile.

Each resulting DiagnosticReport resource also includes at least one rendered report in HTML format in the same DiagnosticReport resource, either as base64 encoded binary, or by reference using a URL.

X.1.1.2 Report Repository

A Report Repository stores reports received from Report Creators and makes the reports available for other consumers through query/retrieve.

A Report Repository may modify how referenced resources are made available for subsequent access by systems that retrieve the report. This may be done to improve accessibility to consumer systems outside the local network, or may be done to improve efficiency of retrieval. For example, a Report Repository may adjust an internal URL to an externally accessible URL, or it may retrieve the rendered report referenced by a URL and embed it directly, base64 encoded, in the DiagnosticReport resource in a query response.

X.1.1.3 Report Reader

A Report Reader accesses reports from the Report Repository for presentation to a user. The capabilities to display those reports is not otherwise constrained here. Report Readers may render coded content from the report, or present pre-rendered versions contained or referenced in the .presentedForm, or some combination of that.

Systems that might implement this actor include EMRs, enterprise viewers, and patient portals. A reporting workstation might also implement this actor to access and present prior reports, in whole or in part, to the imaging clinician.

X.1.1.4 Report Consumer

A Report Consumer accesses reports from the Report Repository for processing. The capabilities to process those reports is not otherwise constrained here. Systems that might implement this actor include clinical decision support (CDS) systems, workflow automation tools, and clinical registries. A reporting workstation might also implement this actor to access and incorporate content from prior reports into the current report.

X.2 IDR Actor Options

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

Table X.2-1: Imaging Diagnostic Report – Actors and Options

Actor	Option Name	Reference
Report Creator	No options defined	--
Report Repository	No options defined	--
Report Reader	No options defined	--
Report Consumer	No options defined	--

X.2.1 (Options Placeholder - LATER)

X.3 IDR Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile ***in addition to <u>all</u>*** of the requirements for the grouped actor (Column 2) (Column 3 in alternative 2).

Section X.5 describes some optional groupings that may be of interest for security considerations and Section X.6 describes some optional groupings in other related profiles.

Table X.3-1: Imaging Diagnostic Report – Required Actor Groupings

IDR Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
Report Creator	ITI CT / Time Client	ITI TF-1: 7.1	--
Report Repository	None	--	--
Report Reader	None	--	--
Report Consumer	None	--	--

X.4 IDR Overview

X.4.1 Concepts

This section presents concepts and considerations that may be helpful to better understand, implement, and deploy this profile. This material is informative; there are no conformance requirements in this section.

For brevity, this section will sometimes refer to imaging diagnostic reports simply as "reports".

X.4.1.1 Report Formats: ORU, PDF, SR, CDA, FHIR

The proposed FHIR DiagnosticReport format would take its place among a number of existing report formats in use, to varying degrees, in existing hospital systems. This profile does not mandate specific transcoding capabilities, but since that will likely be part of successful product implementations, some guidance is provided here.

HL7 V2 ORU messages containing formatted or unformatted text are, as of the early 2020's, still a very common format for distributing reports. The primary advantage of this approach is its compatibility with the large install base of V2 systems, in particular when including the report in HL7 V2-driven electronic medical record systems. While the inclusion of OBX segments in the ORU message can provide some coded information, this is still poorly adopted and not well standardized. As a result, the machine-readability is quite low and the underlying mechanisms are not well suited to significant improvement of that.

Transcoding between ORU messages and DiagnosticReport will likely make use of the DiagnosticReport.presentedForm, and potentially some of the .text attributes on various resources in the encoding.

PDF renderings of full reports are also popular due to being able to capture and reproduce well-formatted human-readable presentations of the content. However, PDF documents lack machine-readable coding of the content which undercuts the ability to support functions like clinical decision support, workflow automation, and clinical databases.

Transcoding PDF renderings can make direct use of the ability to include PDF documents in the DiagnosticReport.presentedForm. Report Creators that provide PDFs in created DiagnosticReports will facilitate consumption by simpler downstream systems.

DICOM Structured Report (SR) introduced mechanisms for fully coded clinical information contained in persistent documents with robust management. In practice this encoding has been

predominantly used for objects created within the imaging department to capture measurements (echocardiography, fetal ultrasound, CT/MR oncology, etc.), radiation dose (x-ray RDSR, radiopharmaceutical RRDSR), contrast administration, computer-aided detection and diagnosis (CAD) results (mammography, chest radiography, etc.), and general procedure logs. While the SR format was also designed to support coded diagnostic reports, lack of format support where the reports are viewed, outside the imaging department, was an obstacle. When HL7 CDA was subsequently introduced, DICOM prepared a mapping and guidance for the use of CDA-based imaging diagnostic reports (See DICOM PS3.20).

Transcoding SR components, such as individual measurements and observations, addressed in part by activities in the joint DICOM WG-20/HL7 II Working Group. That work is directly relevant to coding SR components into the Findings section of a FHIR report. (See WG20 IG). Some of that guidance is relevant here, but it should be noted that this IDR Profile is scoped to first address the distribution and basic clinical consumption of imaging diagnostic reports and is thus focused most strongly on the Conclusions and Recommendations sections. Important subsequent IHE work will address the report creation process and more advanced consumption, which will delve deeper into the encoding of the Findings section, integration of AI inputs, research, incorporation of prior findings, etc., and make more use of the WG20 work.

HL7 Clinical Document Architecture (CDA) defines XML encodings for persistent clinical documents that can contain coded and uncoded content. CDA defines three levels of semantic interoperability (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC130066/):

- Level 1 – xml-wrapped text
- Level 2 – xml-wrapped text with section headers
- Level 3 – xml-wrapped text with section headers and structured and coded data

Where “Level 3” data constructs (called “entries”) enable individual structured and coded results. When adopted, CDA usage is often closely associated with the IHE XD* family of profiles, however cross-enterprise sharing of machine-readable data is still limited.

Transcoding CDA diagnostic reports will benefit from much of the information in DICOM PS3.20 as described above.

Since CDA and FHIR are both HL7 defined encodings, several pieces of work within FHIR provide guidance on transcoding between CDA and FHIR resources in general:

- https://www.hl7.org/fhir/comparison-cda.html
- https://build.fhir.org/ig/HL7/ccda-on-fhir/mappingGuidance.html

The IHE Results Distribution (RD) Profile also provides relevant guidance on best practices when using ORU, PDF, SR and CDA for distributing imaging diagnostic report content.

HL7 FHIR DiagnosticReport Resources have the potential to permit sophisticated levels of machine-readable data while also providing human-friendly presentations of the report, all within a FHIR-based HIT environment. Those are some of the key motivations for this profile. Details

on encoding imaging diagnostic reports based on the FHIR DiagnosticReport resource are provided in RAD TF-3:6.Z Imaging Diagnostic Report Content.

X.4.1.2 Purpose and Structure

The imaging diagnostic report is the definitive documentation of the results of an imaging examination or procedure. Importantly, it is intended to include medical interpretation and summarization of findings and other clinical context and information from outside the imaging procedure, not just the underlying observations, measurements, and findings themselves.

The report becomes part of the medical record of the patient. It is intended to be used by the referring physician and specialists to understand the patient's condition as part of diagnosis and treatment planning. The report often includes recommendations and advice from the interpreting clinician to the referring clinician about possible diagnoses, and further investigation, or patient management. Specifically, the report should respond to any clinical questions posed by the referring physician in the order. The report is also made available to the patient to help them understand their situation and support informed consent for subsequent procedures. Later, the report may be used during subsequent imaging procedures as a prior for comparison.

Machine-based consumers of reports will often be interested in specific individual data elements, such as a recommendation, a primary conclusion, or an actionable incidental finding (See subcases in Section X.4.2.4 Use Case #4: Report Processing). Human readers of reports may be interested in the report as a whole, or may also focus on specific elements (See Section X.4.2.3 Report Presentation). Presentation features involving hyperlinked report elements are addressed in the IHE Interactive Multimedia Report (IMR) Profile.

X.4.1.2.1 Sections

An important feature of imaging diagnostic reports is the organization of the content into sections intended to more efficiently and effectively communicate the information. The semantics of the sections are important. The same observation has different implications when present in the order, in the patient history, in the family history, or in the findings section of the report. "Flatlisting" into an undifferentiated collection of items can make the information more difficult to work with.

The American College of Radiology provides specific guidance in the ACR Practice Parameter for Communication of Diagnostic Imaging Findings on recommended report sections and content. While the titles may vary and the section groupings may differ slightly from practice to practice and from country to country, the approach of medical imaging clinicians to organizing report content is broadly consistent.

Note: **Words are bolded** to call attention to key details.

- **Patient** information such as **name**, age, gender, birthdate, and **medical record number** is typically provided first.
- **Order** information such as the **accession#**, the identity of the referring physician or organization, the indication for examination, and, ideally, additional patient context and

specific **clinical questions** provided by the referring physician. Clinical questions are sometimes of the form "Follow-up X", where X is an existing known finding (perhaps from a previous exam), or "Rule out X", where X is a condition for which imaging input is requested on whether or not it is present. **Indications** are also, hopefully, provided to provide important clinical context to the imaging clinician, and to support assessment of the appropriateness of the order and/or billing. If indications are not present, they are sometimes sought out by imaging staff.

Note: "Rule out X", while somewhat helpful for the imaging clinician, can be problematic for billing since it implies, but does not capture, symptoms that suggest the possible presence of the condition and establish the medical necessity of the imaging exam.

The Patient and Order information are often presented at the top of the report in a pre-defined "header" section with formatted fields for a number of the key details. Typically, this information is populated automatically, and not dictated by the imaging clinician.

- **History:** This section includes patient history and other prior clinical details deemed relevant to the imaging study by the imaging clinician. Some information may be provided by the referring physician in the order, and more is extracted from the medical record by imaging staff, automated tools, or by the radiologist themselves. This information provides background for the imaging clinician, context for the contents of the report, and is sometimes relevant to billing and clinical guidelines. Potential sources include impressions or summaries of the clinical notes from the encounter where the imaging order was placed.

- **Procedure and Materials:** This section contains information such as the **procedure type**, the anatomy imaged, the **date** and time of the imaging examination, and the facility that performed it.

  Also called Imaging **technique**, this section may describe the parameters that were used, details of any **contrast** media and/or radiopharmaceuticals administered, including concentration, volume, and route of administration, and any medications, and catheters or devices used.

  The section can also describe preparation of the **data produced** by the procedure: Views, image sets, recons, reformats and post processing.

  Radiation dose may also be described here; the text content and metrics may be constrained/formatted to meet local regulations.

  The information in this section is typically more detailed than what is listed as the Order, and in fact may differ from the ordered exam based on the needs of the patient and the judgment of the imaging clinician.

  Any deficiencies of the study may also be described here, such as whether the imaging was incomplete or if there were quality issues that prevented interpretation of some part of the study or otherwise compromise the sensitivity and specificity of the examination. In the event that a patient was unable to undergo imaging, for example due to

claustrophobia or a seizure, a report might still be produced and this section would note that the exam was not performed and provide a reason.

While the actual instructions given to the patient are not typically listed in the report, some mention the fact that instructions were given, and perhaps that risks were discussed and consent obtained. Procedure notes from the technologist are typically captured elsewhere, but significant details such as adverse patient reactions, or things that may affect the quality of the study, may be included here.

Procedure details that may be required for billing are sometimes included here as well.

- **Comparison:** This section is a list of other studies that were considered relevant by the imaging clinician. They are typically identified by type (**modality,** anatomy, exam type) and **date**. Findings from these studies and comparisons with the current study are typically woven into the next section (e.g. indicating no change, differentiating descriptions and/or measurements), although some of these studies may not be specifically mentioned in the findings. It is typically presumed that both the images and the report for each comparison study were available to the imaging clinician, however in some cases, such as for external priors, only the report or only the images were available, in which case that may be noted here.

- **Findings**: This section provides a detailed description of the findings on the imaging examination. The findings should be described in a clear and concise manner, using standardized anatomic, pathologic, and radiologic terminology whenever possible.

  When there are significant numbers of findings, the imaging clinician will typically organize them into groups, typically by anatomy. Reporting templates for particular procedure types (such as those at radreport.org) will also often organize the findings.

  An important distinction between Findings and Impressions is that Findings capture what the imaging clinician saw in the image, while Impressions capture what they inferred/concluded. The findings might record a radiolucency, while the impression records a fracture. There are some cases where the two overlap, but generally imaging clinicians try to capture in the Findings what the significant image features are, and strive in the Impressions to communicate to the referring physician what they think those represent in clinical terms.

- **Impression**, sometimes also called Conclusion or Diagnosis, provides the radiologist's **overall interpretation** of the findings, a specific diagnosis and/or differential diagnosis (when possible), **responses to any clinical questions** posed by the referring physician, and any **recommendations** for further management and/or confirmation, as appropriate.

  Recommendations most often cover subsequent diagnostic imaging or other diagnostic procedures such as biopsies or lab tests. They may also include suggestions to correlate the imaging result with other clinical information to improve the confidence of the diagnosis, referrals to specialists, or less commonly, therapeutic procedures. The recommendations may cite specific guidelines applied, particularly when the referring physician might be less familiar with the current guidelines for certain findings than the

imaging clinician. The imaging clinician may take into account the expertise of the referring physician when composing recommendations; for an unusual cancer, a family physician might find follow-up recommendations more helpful than an oncology specialist would.

Since referring physicians may specifically focus their attention on this section, the imaging clinician may choose particularly important details such as key findings or any adverse events, to re-iterate and summarize here.

The order of items in the impression is often significant, in that imaging clinicians frequently put the most critical, most actionable, most significant items first in the impression section to minimize the chance of them being overlooked. Impression items may also be numbered to facilitate verbal referencing, or linking to communications.

Some items in the impression may be clinically significant, but were not associated with the indications or reason for exam; for example, a lung nodule deemed to be suspicious on a chest exam for trauma. These are often referred to as "incidental findings".

Some items in the impression may be considered actionable, in that some follow-up action or communication is advisable. The recommendations may or may not include a specific corresponding follow-up action. A corresponding communication to relevant persons may or may not have taken place during the reporting process and be noted in the report.

Some items in the impression may be critical, in that they represent the potential for severe negative clinical impact to the patient if appropriate action is not taken promptly. The presence of such items almost always results in a communication with care staff and/or the patient.

There is strong interest in tooling to facilitate communicating critical results clearly and rapidly with the appropriate people, confirming that follow-up of actionable findings takes place, and making sure that incidental findings do not "fall through the cracks".

- **Communications** are records in the report about attempted and/or successful communications of some content of the report to the referring physician, the patient, or other appropriate person. Communication is not listed as a separate section in the ACR guidance, but codes for a communication section do exist. It is common practice to present communication records at the bottom of the report, just below the impressions, since they are often driven by specific items in the impression and occur at the end of the report creation process.

  The communication entry typically records the date, time, and method of communication, the person/organization contacted, and may summarize the content communicated.

- **Signature**, makes clear the identity and credentials of the author of the report and records their approval of the semantic content of the report as written.

- **Addendum**, contains report information recorded subsequent to the report being distributed as final. Addenda may contain corrections, such as typographical or

transcription errors, new findings that have come to the attention of the imaging clinician, additional procedure details needed to support billing or QA, additional observations requested by the referring physician, or re-interpretation of findings in light of additional clinical context.

There may be multiple addenda to a given report. Addenda can be authored by clinicians other than the original author of the report.

An addendum may contain just the supplementary information. Some systems present the addendum in a corresponding text box next to the original report. Based on local policies and practices, the addendum may also contain a complete "replacement" report. In either case, the original final report is always retained for medicolegal purposes. It can also serve as an effective way to resolve references.

It is important for addenda to be distributed promptly to all systems that received the original final report.

Note that ACR implies that for a brief report, some sections might not be specifically called out.

In general, it is left to the Report Creator implementers to address issues like interleaving content that is automatically generated and content provided by clinician dictation or input, or avoiding duplication of the same content in different sections, or ensuring the full content of the report is approved by the imaging clinician.

The Royal College of Radiologists (RCR) also provides guidance on communication with the referrer in Standards for interpretation and reporting of imaging investigations.

The purpose of the report is to provide a timely answer to the clinical questions posed, together with a holistic assessment of all the images for relevant and/or unexpected findings. The written report should be clear, and written in a way appropriate to the referrer's expected level of familiarity with the imaging abnormalities detected, the implications for the patient and the referrer's access to requesting further investigations. The wording of the report is likely to differ when it is written to a general practitioner (GP) who may be unfamiliar with a relatively rare condition, compared with a specialist in that particular field.

The report should be actionable and should therefore convey a knowledgeable and reasoned assessment of the examination and its contribution to the overall management of the patient.

The Key Performance Indicators identified by the RCR are:

- The report should answer the clinical question: target 100%.
- When an abnormality is described a tentative or differential diagnosis should be provided: target 100%
- Not all reports will have advice on the next step. However, where advice is given, the advice should be appropriate: target 100%.

X.4.1.3 Codes and Codesets

While this profile does not mandate the use of particular codesets for many of the details that are coded, agreeing within the local site or organization on common codesets will be a key prerequisite of effective deployment of this profile. This is necessary to facilitate automated functions such as those described in Section X.4.2.4.1. Further, since reports are typically circulated to other organizations, the use of codes from widely adopted standards will be particularly important to realize the full potential of coded reports. Many of the examples in this profile demonstrate the use of SNOMED codes (indicated by an SCT coding system value). SNOMED has agreements with DICOM and FHIR that identify a very large set of codes which can be used free of charge in DICOM and FHIR implementations anywhere in the world, independent of national licensing. This profile permits implementations to use alternate coding systems, for example if they need to use codes outside of the aforementioned sets in countries that do not have SNOMED licensing agreements.

LOINC has a significant collection of codes for measurements that could be of significant value in coding Findings. LOINC is also the source of the sections codes in RAD TF-3: 6.Z.3.0.1, which were drawn from the two panels defined in (81220-6, LN, Diagnostic imaging report – recommended C-CDA R2.0 and R2.1 sections) and (87416-4, LN, Diagnostic imaging report - recommended DICOM PS3.20 sections).

X.4.1.3 Relevant FHIR Resources

This section briefly introduces FHIR resources relevant to imaging diagnostic reports, and outlines their intended purpose, usage, and main details. The **maturity level** is shown in (parentheses).

Guidance on using these for encoding reports is provided in RAD TF-3: 6.Z (Imaging Diagnostic Report Content)

Note: Some of the relationships between these Resources are described in the Diagnostic Medicine Module.

The **Patient** Resource (N) encodes demographics and administrative information about an individual or animal receiving care. The resource appears fully adequate for imaging purposes and no need for imaging-specific modifications has been identified.

The **ServiceRequest** Resource (4) encodes an order for, in our case, a diagnostic imaging procedure. More profiling may be necessary to fully satisfy the workflow and record-keeping requirements of imaging procedures, but that is out of scope for this profile. The basic usage of the ServiceRequest within the context of the DiagnosticReport can be specified now and will likely not change significantly.

The **Encounter** Resource (4) describes an interaction between a patient and healthcare provider(s). Encounters can reference each other in a hierarchical structure; for example, an encounter with the imaging department might be a child of an encounter representing a hospital admission. Modelling and profiling encounters to represent imaging scenarios such as interventional procedures, outpatient imaging, pre-imaging preparation such as radiopharmaceutical injection, multi-stage imaging, etc. is out of scope for this profile.

Note: Resources that represent the basic information about a patient and a clinical encounter can be found in the Administration Module.

The **Procedure** Resource (4) encodes an action that was performed on a patient, such as a diagnostic imaging procedure, in our case in response to a ServiceRequest. The imaging Procedure is performed in the context of an imaging Encounter. Like ServiceRequest, more profiling of this resource may be required to fully satisfy the workflow and record-keeping requirements of imaging procedures.

The **ImagingStudy** Resource (4) represents the content produced in a DICOM imaging study. This is the primary output of one or more diagnostic imaging Procedures, typically in response to an imaging ServiceRequest.

The **DiagnosticReport** Resource (3) encodes findings and interpretation of diagnostic tests performed, in our case, on patients. The resource contains information about the test and the subject. It references a variety of other resources, including the ServiceRequest, Procedure, ImagingStudy, and atomic observations. In R5, it may contain conclusions as a single block of markdown and/or a set of codes.

Note: FHIR notes that DiagnosticReport "is not intended to support cumulative result presentation (tabular presentation of past and present results in the resource)." This profile does not rule out the inclusion of prior results, such as measurements for oncology, cardiology, or obstetrics, which might usefully be presented in a table format; however, it is acknowledged that the "source of truth" of those prior measurements is the prior report, not the current one.

The DiagnosticReport resource has also been profiled by the IHE IMR Profile.

The **ImagingSelection** Resource (2) encodes a selection of a specific portion of an imaging study to permit linkage to Observation and other resources that describe such a specific subset. The selection starts at the level of specific DICOM SOP instances and/or frames within a single Study and Series. It may include additional specifics such as an image region, an Observation UID or a Segmentation Number. One of its intended applications is to support encoding the spatial details of findings and impressions in diagnostic imaging reports.

The **Observation** Resource (N) encodes individual observed details such as those that appear in the findings and impressions of imaging diagnostic reports. Observation supports nesting and other relationship mechanisms to capture groups of associated observations.

The **Bundle** Resource (N) is a container for a set of related resources. It can be used for a variety of purposes related to data organization, storage, and messaging. In this profile, it is used to collect the set of resources that together comprise an imaging diagnostic report.

The **Composition** Resource (4) represents a document by encoding a specific presentation of a specific collection of resources. Additional metadata captures the subject (patient), document type, author, title, creation date, status (prelim, final), and confidentiality. A composition can be signed/attested. Like instances, they are intended to be immutable once created. Changes require a new "version". In some ways, Composition is a presentation-oriented alternative to DiagnosticReport. It supports sections with labels as a way to organize clinical and operational content. Each section has a title (text and coded) and can contain narrative (.text) and/or one or more .entry that reference other resources for supporting coded data. Using it inside a DiagnosticReport involves referencing the Composition which then references components

inside the DiagnosticReport to indicate which section semantics apply, thus providing a somewhat indirect way of organizing the coded information. It also somewhat duplicates the role of presentedForm. Some open questions remain on how report signatures are managed when a Composition is used to dynamically create a bundle.

Notes: 1. The FHIR Breast Radiology IG in R4 opted to use Composition instead of DiagnosticReport, reportedly in the belief that DiagnosticReport would be dropped. US Core opted to use DiagnosticReport instead of Composition. FHIR advises "If you have a highly structured report, then use DiagnosticReport – it has data and workflow support.", which is the approach taken in this profile.

2. FHIR says "Composition may also be used to organize observations and diagnostic reports, but that is only for purpose of readability, not to record critical relationships for interpretations."

The **DocumentReference** Resource (4) is basically a pointer to a document, such as a diagnostic report, serving as an index entry and possibly providing access path information. It replicates organizational metadata like the document type, format (Composition, PDF, CDA, SR), creation date, author, status, and signatures. The resource apparently may also include the document as inline base64 encoded data rather than providing a reference pointer (which raises a variety of implications).

Notes: 1. FHIR says "a DocumentReference typically reflects a non-FHIR object that is not a FHIR Document (e.g., an existing C-CDA document, a scan of a driver's license, or narrative note)."

2. FHIR also says "This resource is able to contain medical images in a DICOM format." while also noting that ImagingStudy and WADO-RS are the preferred method for indexing and accessing images. It will be left to future profiling work to determine whether this use of DocumentReference is introducing potential interoperability issues with how images are managed, indexed, exchanged, and presented in different scenarios.

X.4.1.4 Preliminary Reports, Final Reports, and Addendums

This profile does not address the workflow involved in arriving at a final report (which can be quite complex and involve interactions between multiple clinicians and staff including attending, resident, and overreading physicians), but it does address the metadata inside a published report that identifies the "state" of the encoded content.

This profile describes the content and encoding of a report that has reached the point of being suitable for "publishing" for use in patient care. While the relevant resources may exist in a partially populated form during the preceding report composition process, that is not addressed here.

Publishable reports may be preliminary, meaning that they are accessible to clinicians who may need initial information urgently, but at least one review and approval remains before the report is considered final.

Publishable reports will typically become final, meaning that they are have been approved and signed, and should be distributed according to local practices.

Once made final, any amendments to the report are handled as an addendum. See RAD TF-3: 6.Z.3.12 Addendum.

Once a final report is published, preliminary reports are typically sequestered, or removed from the medical record. In the case of an addendum, however, the corresponding final report is always retained for medicolegal reasons.

Since multiple instances of a given report may exist over time reflecting the above states, systems that handle imaging reports should, thus, expect to encounter multiple "copies" of a report that differ, or to encounter a retrieved current report that has different content than when retrieved previously. The metadata described in RAD TF-3: 6.Z.3 Imaging Diagnostic Report Encodings will help systems understand and deal with such situations.

X.4.1.5 Narrative vs Encoded Content and Structure

Historically, reports have been entirely narrative with a small amount of coded metadata for management. For example, when communicated in an HL7 V2 ORU message, the narrative may be prefixed by just the encoded patient name, MRN, Accession #, and date/time of the exam.

Providing report details as coded content makes that information machine-readable which opens the door to automated and semi-automated functions in systems that receive and process the diagnostic reports. The focus then shifts to considering what automated functions are of interest, and what report details they need in coded form to be able to operate effectively. Given that coding the entire content of the diagnostic report will be an enormous piece of work, identifying the functions that would provide the most value and utility also helps prioritize which parts of the report we should consider coding first. For additional discussion, see Section X.4.2.4.1 Report Processing Use Case.

The target of this profile is to capture todays narrative text reports in a FHIR encoding that includes metadata for intelligent handling, and initiates coding of certain pieces of content, such as the impressions and recommendations, to facilitate automated workflows. This is intended to facilitate starting the transition to FHIR-based reports. Subsequent profiles will tackle coding increasing amounts of the semantic content of the reports, especially findings, to support additional use cases.

Some principles (that are expected to evolve over time):

- All elements present in the report in coded form are also visible in the presentedForm.
- Some data generated for/during reporting goes into the study, not into the report. i.e., Report is not the transport for additional data that isn't "in the report"
    - E.g., AI analysis data underlying the summary conclusion that was included
- Some elements in the report are there to support billing and administrative processes, not clinical processes.
- Someday, all (or at least more) semantics visible in the presentedForm will be present in the report in coded form.
- It will help, when adding more coding specs, to be use case driven

X.4.1.6 Environmental Assumptions

Hybrid environments (mixing FHIR and HL7 V2 messaging) are inevitable. If FHIR is the primary stored representation of the report, it will inevitably need to be sent to a text/V2 based environment. This will be an important part of making deployment practical in existing hospitals.

HL7 is working on general guidance for conversion of content that is encoded in HL7 v2 Messages into roughly equivalent FHIR resources (https://build.fhir.org/ig/HL7/v2-to-fhir/)

Future drafts of this document might provide guidance specific to imaging diagnostic reports and related resources.

X.4.2 Use Cases

X.4.2.1 Use Case #1: Report Creation

A Report Creator encodes the report content.

X.4.2.1.1 Report Creation Use Case Description

The focus here is on encoding the collection of information at the end of the interpretation process into a DiagnosticReport-based format.

Marshalling the constellation of input data and interacting with that data during the interpretation process and assembling the report content is briefly discussed and shown here for context, but is not addressed by this specification.

Note: Other profiles that touch on that area (See Section X.6 Cross Profile Considerations) include:

- Integrated Reporting Applications (IRA)
- AI Results (AIR)
- Remote Radiology Reporting Workflow (RRR-WF)
- Management of Radiology Reporting Templates (MRRT)

The Report Creator receives report content from multiple sources. Traditionally, the bulk of the content comes directly from the interpreting clinician via a dictation system. Some content, such as procedure, technique, and dose information, may be automatically extracted from the study instances and/or HL7 order artifacts. Additional content may be generated by clinical software (conventional or AI-based) in the form of proposed measurements, segmentations, image features, and other data analysis. The methods used by the Report Creator to arrive at encoded content that is approved by the reporting clinician is not constrained by this profile. For example, the Report Creator might use a Large Language Model (LLM) to extract coded elements from the dictated narrative, or it might provide an interface for the clinician to quickly select coded elements. The Report Creator might have the referring clinician approve the entire report content at the end, or might get piecewise approval during composition.

A report may be circulated when it is created in a preliminary state and again later when it has been signed and updated to a final state, and potentially again if it is updated again with an addendum to the report. That status is captured in the encoding (See RAD TF-3: 6.Z.3.0) but managing that transition and handling of multiple versions of the report is left to subsequent reporting workflow profile work.

The created report is expected to include both narrative and coded content. See Section X.4.1.5 for a discussion of the balance and overlap between the two.

X.4.2.1.2 Report Creation Process Flow

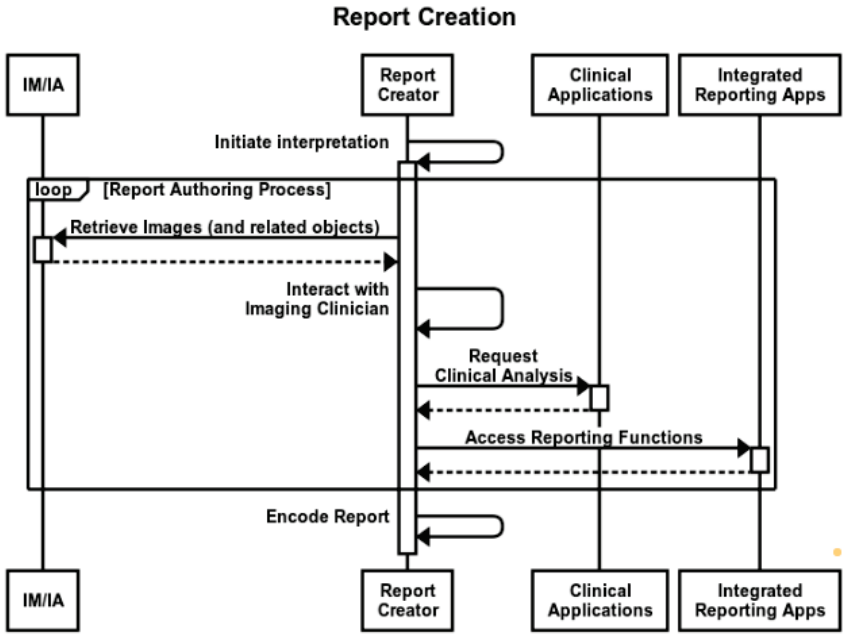

Figure X.4.2.1.2-1: Report Creation Process Flow

The text in Figure X.4.2.1.2-2 was used to generate the diagram in Figure X.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title Report Creation

participant IM/IA as IM
participant Report\nCreator as RC
participant Clinical\nApplications as CA
participant Integrated\nReporting Apps as IRA

RC->+RC: Initiate interpretation
loop Report Authoring Process
RC->+IM: Retrieve Images (and related objects)
IM-->-RC:
RC->RC: Interact with\nImaging Clinician
RC->+CA: Request\nClinical Analysis
CA-->-RC:
RC->+IRA: Access Reporting Functions
IRA-->-RC:
end
RC->RC: Encode Report
```

Figure X.4.2.1.2-2: Diagram Pseudocode for Report Creation Process Flow

X.4.2.2 Use Case #2: Report Storage & Distribution

A Report Creator provides encoded reports to a Repository (push), which then makes the reports (and the associated component resources) available for routing and/or retrieval (pull).

X.4.2.2.1 Report Storage & Distribution Use Case Description

This diagram shows the Report Creator sending the report directly to the Report Repository that serves as the storage server for subsequent query and retrieve transactions. Alternatively, the Report Creator might send the report to a Report Manager which handles short term workflows and dataflows and later migrates the report to the Report Repository for archiving.

This diagram shows the Report Consumer querying the Report Repository to identify a report of interest. Alternatively, the Report Consumer might be Report Reader in an EMR terminal where the referring physician has found a reference to the report (perhaps in the patient's folder or perhaps attached to recently placed orders) which allows a retrieval based on that reference, skipping the query.

It is also important to note that some Report Consumers may do resource-level queries on some of the components of the report, e.g., the Observations, Conditions, and Service Requests that make up the Findings, Impressions, and Recommendations. For more detail, see Section X.4.2.4 Report Processing.

Not shown in the diagram, some sites may configure Report Creators and/or Report Repositories and/or a special report router to push copies of all/most reports to additional destinations, such as a regional health information exchange, or patient portal system. The use case where specific reports are routed to particular destinations based on certain conditions and particular metadata values is framed as a report processing use case and is discussed in Section X.4.2.4.1.5 Smart Routing of Reports.

The EMR (Electronic Medical Record), in the role of either Report Reader or Report Repository, will likely index reports for browsing, in addition to using the query/retrieve model. The imaging study would appear as an entry in the medical record with an associated datetime, body part, and modality or exam type. The report may appear in a list of patient documents, also with an associated datetime, body part, and modality or exam type. The originating order will appear in the medical record, but references go from the DiagnosticReport and ImagingStudy resources to the ServiceRequest resource, not the other way around. So going from the ServiceRequest to the report involves a query for the matching Accession Number, or ServiceRequest reference, rather than navigating the reference from the ServiceRequest.

Query patterns will vary by practice and no specific query capabilities are required beyond that described in the Query Imaging Diagnostic Report [RAD-Y2] transaction . That said, the following are query scenarios and capabilities that would likely be useful to some sites.

The most common patterns (which cover primary clinical usage) include:

- Patient-based – find reports for a certain Patient
    - For a given Patient, find reports that reference it as .subject
        - Constrain to a given time range, and/or body part, and/or modality, and/or procedure

- Query by surgery department for images and reports for patients scheduled for surgery to do pre-surgical planning by each surgeon
- Query by admin staff for recent reports and images for a given patient to prepare for data export in support of a patient transfer or referral for care in a different institution.
- Order-based – find reports created for a certain Order.
    - For a given ServiceRequest, find reports that reference it as .basedOn
    - For a given Accession #, find the corresponding ServiceRequest, then find report
    - For a given Practitioner, find ServiceRequests that reference them as .requester, then find reports for those ServiceRequests
- Query by a referring for ordered report based on accession number, patient, study datetime, body part, and possibly modality or procedure
- Query by referring staff for reports from all procedures ordered recently their referring name/ID/practice to prepare for daily review and preparation
- Study-based – find reports on a certain Study
    - For a given ImagingStudy, find reports that reference it as .study
- Query by a reading radiologist for priors based on patient, datetime range, body part/region, modality, procedure type, and possibly impressions or finding values. Might need free text matching in the report body using NLP (could be client-side or server-side)
- Query by a tumor board for reports, key images, and cross-indexed lab and pathology results, for the list of scheduled patients/cases

Less common patterns (which also cover administrative and research use cases) may include:

- Author-based – find reports certain contributors contributed to.
    - For a given Practitioner, find reports that reference it as .resultsInterpreter
    - For a given Device, find reports that reference it as ???FHIRQ
- Query by reading radiologist for reports authored by them (or perhaps their attending for a resident) with a particular impression or finding to see "how did I describe that last time".
- Prior-based – find reports that cite a certain prior (perhaps there was a quality issue)
    - For a given ImagingStudy, find reports that reference it as .comparison
- Cohort-based – find reports with certain clinical or demographic factors
    - For a given Condition, find reports that reference it as .impression
    - For a given demographic, find Patients that match, then find reports for those .subjects

- For a given modality, find ImagingStudy with a matching .series.modality, then find reports for those

- Query by researcher for find studies with certain patient characteristics, indications, impression/conclusions to prepare research/paper
- Observation-based – find observations that were created as findings, without necessarily considering the entire report.
  - For a given Patient and DiagnosticReport, find Observations with particular observation codes and/or bodyPart or bodyStructures, etc.
  - Caveat: due to pre-post coordination variations, actually making Observation queries functional might be a challenge.
  - Caveat: some observations might not have been coded.
  - Caveat: if diagnoses are coded under .conclusionCodes rather than Condition resources under .impressions, they would not be available as separate Resources for query.
- Query by CDS agent for specific observations and observation values that are the basis for clinical guidelines to be applied to the patient/case.
  - Caveat: it is not yet clear whether it would be simpler to retrieve the current (and perhaps recent) reports and operate on that collection of observations rather than do queries on the entire FHIR store.

One could also imagine many of the above queries coming from another institution. Dealing with the associated code mapping, patient matching, access permissions and other privacy and security details are not addressed in this profile.

X.4.2.2.2 Report Storage & Distribution Process Flow

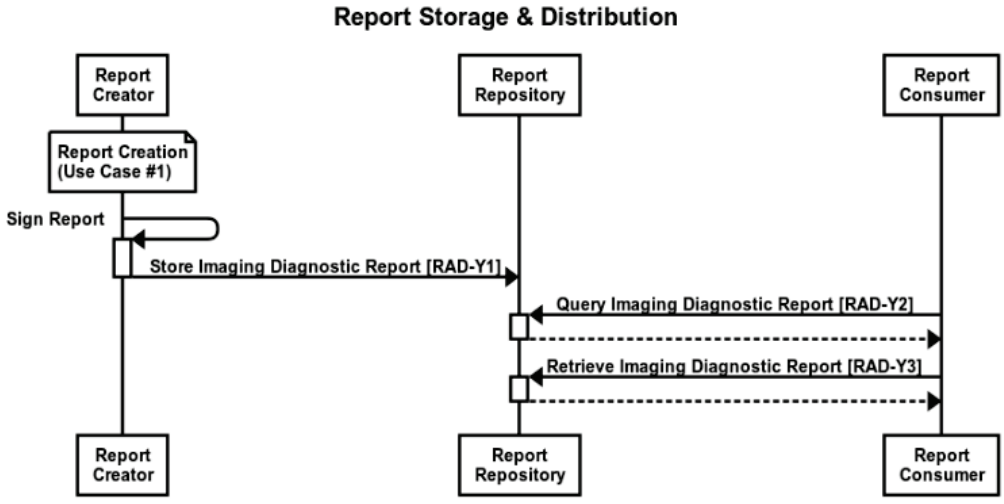

Figure X.4.2.2.2-1: Report Storage & Distribution Process Flow

The text in Figure X.4.2.2.2-2 was used to generate the diagram in Figure X.4.2.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title Report Storage & Distribution

participant Report\nCreator as RC
participant Report\nRepository as RR
participant Report\nConsumer as RCS

note over RC: Report Creation\n(Use Case #1)
end note
RC->+RC: Sign Report
RC->-RR: Store Imaging Diagnostic Report [RAD-Y1]
RCS->+RR: Query Imaging Diagnostic Report [RAD-Y2]
RR-->-RCS:
RCS->+RR: Retrieve Imaging Diagnostic Report [RAD-Y3]
RR-->-RCS:
```

Figure X.4.2.2.2-2: Diagram Pseudocode for Report Storage & Distribution Process Flow

X.4.2.3 Use Case #3: Report Presentation

A Report Reader presents the content of the diagnostic report to users performing clinical tasks.

X.4.2.3.1 Report Presentation Use Case Description

The most basic form of presentation will be the full display of the entire report, as provided in the .presentedForm of the DiagnosticReport resource. This might be a PDF, HTML, or formatted text. At this point in time, Report Readers will rely heavily on the presentedForm since only a subset of the semantic content of the report will be in coded form.

One could imagine the Report Reader serving the more specific needs of users with specific roles and tasks by providing more advanced viewing functions, such as highlighting key elements relevant to the users task/interest, collapsing and expanding sections based on user focus, or providing summarizations.

Large language models provide functions based on the narrative text. The use of coded content may be able to make such results more reliable due to the concrete nature of coded content, particularly when generating text in a different language than the original report.

Some user roles and goals to consider include:

- Referring Clinician
  - Finding the answer to their clinical question in the recent order for their patient
- Surgeon
  - Understanding the patient's condition and pathology to plan a surgical procedure
- Oncologist
  - Understanding the patient's condition and pathology as part of planning treatment
- Radiologist

- Understanding the main findings and impressions from a prior report in the context of a current read.

- Patient
  - Understanding the impressions, recommendations, and other report content, as part of providing informed consent for a subsequent treatment procedure
    - Consider the scenario of a report being provided directly to the patient, potentially before they have time to review the content with the referring physician. Some diagnoses provoke emotional reactions and patients benefit from corresponding education. Tools that "translate and contextualize the content" could provide significant value.
  - It can be especially useful to engage patients in tracking incidental findings and long-term follow-up recommendations.
- Registrar (of a registry; public health, cancer, etc.)
  - Reviewing a submitted case as part of the curation process

Support for hyperlinks in the report body to trigger presentation of associated images and measurements is addressed in the Interactive Multimedia Report (IMR) Profile.

X.4.2.3.2 Report Presentation Process Flow

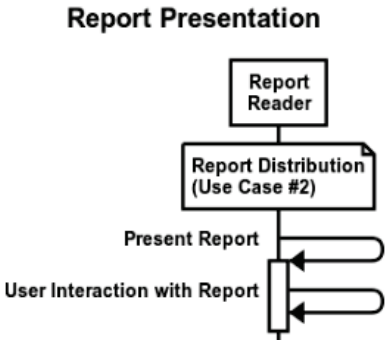

Figure X.4.2.3.2-1: Report Presentation Process Flow

The text in Figure X.4.2.3.2-2 was used to generate the diagram in Figure X.4.2.3.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title Report Presentation

participant Report\nReader as RC

note over RC: Report Distribution\n(Use Case #2)
end note
RC->+RC: Present Report
RC->RC: User Interaction with Report
```

Figure X.4.2.3.2-2: Diagram Pseudocode for Report Presentation Process Flow

X.4.2.4 Use Case #4: Report Processing

A Report Consumer extracts and processes relevant details from the diagnostic report.

X.4.2.4.1 Report Processing Use Case Description

This Use Case focuses on the extraction and processing of information from the Imaging Report and the other Resources with which it is encoded. The query and retrieves that make up the transactional part of this use case are described in Section X.4.2.2 Report Storage and Distribution.

It is worth highlighting that many of the potential Report Consumers may have very specific tasks to perform and correspondingly may be focused on certain details (e.g. the impressions and recommendations) rather than the report as a whole. Several examples are described here.

It is also important to note that some Report Consumers may do resource-level queries on some of the components of the report, e.g., the Conditions, Service Requests, and Observations that make up the Impressions, Recommendations, and Findings.

The following subsections describe some specific examples of report processing.

X.4.2.4.1.1 Ordering Support for Recommendations

Upon receiving an imaging diagnostic report, the referring physician may often want to place an order for follow-up studies recommended by the imaging clinician in the report.

The software used by the referring physician could start by extracting the ServiceRequest resources referenced in the DiagnosticReport recommendations. These already contain details such as the type of imaging procedure and suggested time frame which could be presented to the referring physician to select those they want to order now. The software might fill in additional details based on its configuration and local information, and ask the referring for the remaining details, if any. The software might also be able to interact with payer pre-approval systems.

The software might also be able to facilitate recommendations for non-imaging services such as biopsies, additional lab tests, referrals to other providers, etc.

X.4.2.4.1.2 Clinical Decision Support for the Referring Physician

Another task of the referring physician is to decide on subsequent patient care steps. Guidelines and Clinical Decision Support tools are increasingly available for various types of conditions. The software used by the referring physician could extract impressions from the report which could then be combined with guidelines and other details from the medical record to offer the referring physician potential diagnoses and/or recommended clinical care steps based on the reported information. In particular, the ACR *-RADS categories frequently have specific follow-up actions associated with them.

The referring physician (and their software) may have access to prior reports or clinical information that was not available to the imaging clinician.

X.4.2.4.1.3 Actionable Finding and Recommendation Follow-up

A specific goal of this profile is to allow imaging clinicians to tag impression items that constitute actionable findings and indicate the rough time horizon of urgency. (See the text on Condition.actionable in RAD TF-3: 6.Z.3.7).

Failure to notice and/or effectively follow-up on actionable findings (particularly non-critical actionable findings which are important but allow for a longer time horizon) is a known problem. The IHE Results Distribution (RD) Profile specifically included HL7 v2 mechanisms to try and improve this.

The software used by the referring physician could trigger off the actionability flag on all impressions in the DiagnosticReport and highlight or otherwise ensure that the referring physician is made aware of them. The patient portal software could similarly provide notifications and reminders to the patient.

The ACR has reported that "Up to 10% of all radiology reports contain follow-up recommendations, and approximately half of the recommended follow-up exams are never performed. Lung nodules represent about half of all imaging follow-up recommendations, and noncompliance with radiology lung nodule follow-up places patients at risk for delayed diagnosis of lung cancer."

Patient and referring physician software could review on all recommendation ServiceRequests and check the clinical records to see if an actual ServiceRequest manifested and was performed within the suggested time frame. Alternatively, this might be done as a two-step process. First an algorithm could extract and assess all recommendations in every report. Those determined to be significant (and/or likely to be overlooked) would be forwarded to an intelligent tracking and notification system.

Note: It is important to be careful of false positives to avoid alert fatigue. Recommendations might not have been performed because the condition was not met, or an alternative procedure was performed.

X.4.2.4.1.4 Clincial Registry Submissions

Automation to make it easier could greatly increase the rate of submissions to important registries such as the ACR Lung Cancer Screening Registry or the Pediatric Echo Registry. Since many submission processes are manual, the scale of submissions is quite restricted.

Submission software could start by extracting details from the report such as coded indications of certain diagnoses, and related information from the EMR. The software could vet reports to see if they meet the registry criteria, extract necessary details for submission, and perform any required anonymizations.

Because such registries might have specific code set transcoding requirements and other constraints, it is likely this use case would involve making reports available to a submission software rather than the referring physicians software doing it directly.

X.4.2.4.1.5 Smart Routing of Reports

Other functions that could benefit from improved machine readability of imaging report impressions and recommendations, are automated routing algorithms.

First, speed of awareness and access can be improved when there are critical urgent results in the impressions. The imaging clinician will also be trying to communicate with the primary responsible physician directly, but there are often other members of the care team that would benefit from being informed, and sometimes electronic routing can outpace telephone tag. Given the identity of the referring physician in the ServiceRequest, the routing system may have access to more up to date contact details than the imaging clinicians reporting workstation. Note also the special case where the patient has self-referred.

Second, particular things in the impressions and/or recommendations will be of interest to particular stakeholders such as the referring physician, ward nurse, emergency department, intensive care unit, surgeon, oncologist, other specialist, and the patient themselves.

X.4.2.4.1.6 Other Workflow Automation

The software used by the referring physician could also facilitate interacting with other EMR structures such as the Problem List and Allergies (contrast) based on information provided in and extracted from the DiagnosticReport. This will likely involve some selection by the referring physician and some intelligence and sophistication from the software to judiciously suggest updates to the master lists. It is also important to consider removal of entries from those lists when appropriate to help combat "note bloat".

Another useful workflow function that could be enabled is the often-discussed radiology-pathology correlation feedback. Many radiologists would appreciate a dashboard that collects certain impression entries, like nodules or masses that are suspicious for cancer, and tracks subsequent pathology reports to extract information on which were malignant and which benign.

X.4.2.4.2 Report Processing Process Flow

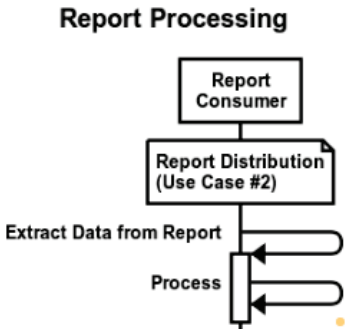

Figure X.4.2.4.2-1: Report Processing Process Flow

The text in Figure X.4.2.4.2-2 was used to generate the diagram in Figure X.4.2.4.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.


```
title Report Processing

participant Report\nConsumer as RC

note over RC: Report Distribution\n(Use Case #2)
end note
RC->+RC: Extract Data from Report
RC->RC: Process
```

Figure X.4.2.4.2-2: Diagram Pseudocode for Report Processing Process Flow

X.5 IDR Security Considerations

Imaging diagnostic reports contain personal health information (PHI) such as demographics, findings, and other clinical information. It is appropriate for products implementing the Imaging Diagnostic Report (IDR) Profile to include PHI security controls. Specifying such general mechanisms and features is outside the scope of this profile.

Similarly, products implementing the IDR Profile might implement general mechanisms and features for tamper-proofing, repudiation, and digital signatures, but specifying those is also outside the scope of this profile.

X.6 IDR Cross Profile Considerations

IMR – Interactive Multimedia Report

A Report Creator in IMR might be grouped with a Report Creator to incorporate multimedia hyperlinks in the created reports.

A Report Reader and/or a Rendered Report Reader in IMR might be grouped with a Report Reader to present, and allow the user to invoke, multimedia hyperlinks in the created reports.

IRA – Integrated Reporting Applications

A Report Creator in IRA might be grouped with a Report Creator to interact with other reporting applications during the interpretation and report composition process.

AIR – AI Results Profile

An Imaging Document Consumer in AIR might be grouped with a Report Creator to incorporate AI Result data in the interpretation and report composition process.

RRR-WF – Radiology Remote Reading Workflow

A Task Performer in RRR-WF might be grouped with a Report Creator to drive the reporting process from a reading worklist.

MRRT – Management of Radiology Reporting Templates

A Report Creator in MRRT might be grouped with a Report Creator to use report authoring templates to facilitate composition of findings and other report content by the imaging clinician.

AIW-I – AI Workflow for Imaging Profile

AIW-I manages AI processing. A reporting workflow manager might be directly involved in that workflow, but the Report Creator would not. It would interact with the resulting data objects in the imaging study.

RD – Results Distribution

A Report Creator in RD might be grouped with a Report Creator, Report Repository, or Report Consumer to initiate ORU-driven behaviors such as follow-up for critical findings.

SOLE – Standardized Operational Log of Events Profile

An Event Reporter in SOLE might be grouped with a Report Creator to log reporting events.

ATNA – Audit Trail and Node Authentication (with the Radiology Option)

A Secure Node in ATNA is recommended to be grouped with all IDR actors to secure the communication of, and record audit trails for, diagnostic reports.

Appendices to Volume 1

Not applicable.

Volume 2 – Transactions

NOTE TO REVIEWERS: The following transactions are placeholders. Both this profile (IDR) and IHE Interactive Multimedia Reports (IMR) have transactions to store and query/retrieve reports based on FHIR DiagnosticReport.

The current idea is to make IDR the base profile for reports. IMR would add the hyperlink details and behaviors either as a profile with IDR as a pre-requisite, or as named Options in IDR.

In TI, IDR will "adopt" the IMR transactions, generalize the names, add any general requirements (e.g. more query details), and factor out any multimedia content back into IMR.

Please review the IMR transactions linked below with a view to filling any IDR need gaps.

4.Y1 Store Imaging Diagnostic Report [RAD-Y1]

4.Y1.1 Scope

This transaction is used to transfer an imaging diagnostic report in the form of a bundle of FHIR resources. The structure of the bundle and other constraints are specified in the Content Definition LATER.

See the Store Multimedia Report [RAD-141] transaction:
https://profiles.ihe.net/RAD/IMR/RAD-141.html

4.Y1.6 Security Considerations

The patient and clinical details provided in the imaging diagnostic report constitute personal health information.

4.Y2 Query Imaging Diagnostic Report [RAD-Y2]

4.Y2.1 Scope

This transaction is used to query for imaging diagnostic report instances.

The structure of the bundle and other constraints are specified in the Content Definition LATER.

See the Find Multimedia Report [RAD-143] transaction:
https://profiles.ihe.net/RAD/IMR/RAD-143.html

[Kinson] Search parameters can be defined on extension attributes. See https://hl7.org/fhir/R5/searchparameter.html#srch for details.

For find reports with X (lung nodule) in the impression for patient Y over the last 2 years

GET [base]/DiagnosticReport?patient=Y&date=ge2022-01-01&impression:Condition.code=<lung nodule>

Where 2022-01-01 is two years ago from today.

Alternatively, if client knows the patient MRN but not the corresponding Patient resource id

GET [base]/DiagnosticReport?patient:identifier=http://example.hospital.org/mrn|12345&
date=ge2022-01-01&impression:Condition.code=<lung nodule>

For cohort build

GET [base]/DiagnosticReport?impression:Condition.code=<X>

For find reports for patient X over time range A and modality Y

GET [base]/DiagnosticReport?patient=X&date=ge2022-01-01&date=le2024-01-01&
study:ImagingStudy.modality=http://dicom.nema.org/medical/dicom|Y

Q. How do we query to get a list of references not a collection of the actual resources?

4.Y3 Retrieve Imaging Diagnostic Report [RAD-Y3]

4.Y3.1 Scope

This transaction is used to retrieve an imaging diagnostic report in the form of a bundle of FHIR resources. The structure of the bundle and other constraints are specified in the Content Definition LATER.

See the Retrieve Rendered Multimedia Report [RAD-143] transaction: https://profiles.ihe.net/RAD/IMR/RAD-144.html

FHIRQP It might not have the ability to return the "expanded bundle" with the root resource and inlined copies of the referenced resources unless we add an OperationDefinition (which is a really advanced/fringe feature) or some kind of extension.

Reasonable that the baseline support for GET Resource is just the resource. But there is obvious value to the expanded bundle and it's a bit odd to have to switch gears to FIND in order to activate that capability.

Volume 3 – Content Modules

Add new section as shown

4.3.2.W Codes for the IDR Profile

The following codes have been defined for the IDR Profile in the IHE coding system and should be used for Trial Implementation. IHE Radiology intends to migrate these codes to the LOINC Standard prior to advancing the IDR Profile to Final Text.

Table 4.3.2.W-1: IDR Codes

Code	codeScheme	Code Meaning	Definition	Reference
IHERADIDR1	99IHE	No active disease	*Proposing for consideration an Observation code to encode the absence of observed disease in a (post-coordinated) anatomical feature or region.*	RAD TF-3: 6.Z.3.7 Impression
LATER				

Add the following rows to RAD TF-3: Table 5.1-2

5.1 ITI-20 Record Audit Event

Table 5.1-2: IHE Radiology transactions and resulting ATNA trigger events

IHE Radiology Transaction	ATNA Trigger Event(s)	Actor(s) that shall be able to record audit event
Patient Registration [RAD-1]	Patient-record-event	…
…		
LATER New transactions	***Study-used***	***Image Display***
Query Analysis Results [RAD-137]	***Query Information***	***Image Display*** ***Image Document Consumer***

Add the following new sections to RAD TF-3 Section 6 IHE Radiology Content Specifications.

REVIEWERS may find it useful to use split-screen to see both the Section encodings here, and the corresponding "real-world requirements" for each report section in X.4.1.2

6.Z Imaging Diagnostic Report Content

6.Z.1 Scope

This IHE Radiology Content Specification defines standard encodings for diagnostic reports on imaging procedures. It is specifically intended to cover the output of reporting systems following the interpretation performed by an imaging clinician such as a radiologist.

Interventional procedures are not specifically addressed.

6.Z.2 Referenced Standards

- FHIR-R5: HL7 FHIR Release 5.0
- FHIR ImagingSelection: ImagingSelection
- LATER – Reference other FHIR Resources

6.Z.3 Imaging Diagnostic Report Encodings

Creators of imaging diagnostic reports shall be capable of encoding them as described in this section.

The encoding makes use of the following FHIR Resources:

- Patient
- ServiceRequest
- Encounter
- Procedure
- ImagingStudy
- DiagnosticReport
- Observation
- Condition
- Communication
- Provenance
- Practitioner

The Report Creator is expected to populate much of the contextual metadata (e.g., patient demographics, patient identifiers and issuers, study accession number, etc.) in the imaging diagnostic report resources based on values in the medical imaging data being processed, and/or the reporting worklist entry.

Note: This profile changes the cardinality from 0.. to 1.. for some FHIR resource attributes. This is done when absence of the attribute would break interoperability. It is not done to enforce the presence of information that is simply desirable or convenient.

This section describes requirements that are also represented in a companion IDR FHIR IG (Implementation Guide).

NOTE TO REVIEWERS: The following content will be kept here for Public Comment since it provides a useful conceptual map and discussion of profiling choices. For Trial Implementation, it is expected there will be a normative reference to the IDR FHIR Implementation Guide. Since there is the risk that reiterated/duplicated content could diverge, any remaining content here would likely be reframed as informative and moved to Concepts, to an Informative Annex, to an IG Resource page, or dropped if all the discussion can be conveniently captured in the IG.

In IMR, there is no Vol 3 Content Definition; the IMR Transactions reference directly to Profiled Resource pages in the IG. Finding a way to splice FHIR IGs into Content Definitions might be another option. Discuss with Lynn/ITI.

This profile adds extension attributes (marked as "<new>") to several existing resources.

The following text describes how the necessary structure and content of an imaging diagnostic report, as described in IHE RAD TF-1:X.4.1.2, would be encoded in FHIR.

6.Z.3.0 Diagnostic Report

Each imaging diagnostic report shall be encoded as a single DiagnosticReport resource. The following document sections here describe how various report sections and details are addressed and encoded within the DiagnosticReport and other referenced resources.

This content definition does not presume that all semantics in the report that are potentially codeable are actually coded in this resource. Profiles will likely identify some specific details which are required to be coded to conform to that profile; however, systems processing diagnostic reports should generally assume that there may be details in the narrative which are not also encoded. See also RAD TF-1: X.4.1.5 Narrative vs Encoded Content and Structure.

Status shall be encoded in DiagnosticReport.status. Specifically, imaging reports in this profile shall use the preliminary and final states when their conventional meaning applies. For addendums (see Section 6.Z.3.12 Addendum), a status of amended shall be used. Imaging report handling logic does not currently distinguish the other status values of modified, corrected, or appended.

Note: Other FHIR status values may be addressed in a reporting workflow profile.

ImagingStudy for the study being read shall be referenced from DiagnosticReport.study unless no such resource exists.

Note: It is expected that there will always be a relevant ImagingStudy resource, created by another system more integrated with image management, such as the PACS, VNA, or the EMR in response to messaging from the PACS or VNA. Report Creators are not the Source of Truth for imaging study management. In the absence of an ImagingStudy, the ServiceRequest and Accession Number will serve to maintain basic linkages between the images and the report.

DiagnosticReport.category shall record the diagnostic service that performed the study. This may be copied from the originating ServiceRequest.category. Potential codes may be drawn from DICOM PS3.16 CID 7030 "Institutional Department/Unit/Service" and the HL7 terminology

code set referenced in FHIR. It is recommended that this attribute focus on the service/department, not the specific modality which is reflected in DiagnosticReport.code.

DiagnosticReport.code shall record the name/title/type of the report. Imaging report titles are frequently site specific, but commonly communicate the modality, body part, and/or clinical focus of the performed imaging procedure. Some examples may be found at radreport.org. <*See associated Open Issue*>

The following uses of attributes are deprecated for imaging reports in this profile:

- DiagnosticReport.note: Statements about significant, unexpected or unreliable result values appear as needed in the Procedure, Findings, or Impressions sections, not in .note
- DiagnosticReport.composition: The required imaging report semantic content (sections) are addressed as described below without the use of .composition. Presentation is handled with .presentedForm. See RAD TF-1: X.4.1.3 for further discussion of Composition.
- DiagnosticReport.media: The interpreted study is referenced by DiagnosticReport.study, selected image parts are encoded as ImagingSelection, comparison studies are referenced from DiagnosticReport.comparison. Graphical elements such as charts and icons that appear in the presentedForm of the report may go in DiagnosticReport.media if they cannot be included inline in the format used (PDF, etc.).

6.Z.3.0.1 Section Codes

The codes in Table 6.Z.3.0.1-1 are adopted by this profile.

Table 6.Z.3.0.1-1: Section Codes

Code Value	Coding System	Code Meaning	Notes
55115-0	LN	Order	
11329-0	LN	History	
55111-9	LN	Procedure	
18834-2	LN	Comparison	
59776-5	LN	Findings	
19005-8	LN	Impression	
18783-1	LN	Recommendation	
73568-8	LN	Communication	This code is defined as communication of critical findings. A more general code may be needed since some communications do not involve critical findings.

6.Z.3.1 Patient

Patient information encoding shall reference a Patient resource in DiagnosticReport.subject. This profile places no constraints on the enterprise Patient resources that the DiagnosticReport is permitted to reference.

Note: Report Creators do not create patient resources. It is expected that there will always be a relevant Patient resource, even if only a John Doe, created by another system more integrated with patient management. Imaging systems are not the Source of Truth for patient demographics and management; directly creating/modifying patient resources would be disruptive. If a patient reference is a pre-requisite to publish an imaging DiagnosticReport resource, the local infrastructure will arrange for appropriate Patient resources for the Report Creator to use.

Narrative text in the patient section of the diagnostic report is a good candidate for auto-generation based on a subset of the coded content in the Patient resource, such as the sex and age of the patient. The name and medical record number are typically rendered into the top of the report as well.

- The Patient resource has a Patient.text attribute which can contain a one-line description of the Patient, although since the Patient resource is widely shared, the summary text may or may not match the needs of the imaging diagnostic report, so the Human-Readable Form in DiagnosticReport.text may be freshly generated.

6.Z.3.2 Order

Order information encoding shall reference ServiceRequest resources in DiagnosticReport.basedOn.

Notes: 1. The DiagnosticReport.basedOn attributes are always intended to reference the request being fulfilled by the current resource; i.e. basedOn references the authorization not the input data. So DiagnosticReport.basedOn references the imaging ServiceRequest, not the ImagingStudy.

2. Report Creators do not create order resources. It is expected that there will usually be a relevant ServiceRequest resource which may have been created by another system more integrated with order management. The hospital may be originating orders as ServiceRequest resources, or may be creating them based on HL7 v2 ORM or OMG messages. In either case, reporting systems are not the Source of Truth for order management; directly creating/modifying order resources would be disruptive.

3. In the large majority of cases, one report will correspond to one order (ServiceRequest) comprised of one study. Some reports do cover multiple orders, e.g., "group cases" where a single instance of a single report satisfies multiple ServiceRequests, so systems should be prepared to handle multiple ServiceRequests.

- For emergency cases, DiagnosticReport.basedOn may be empty if an order has not yet been backfilled.
- For "group cases" DiagnosticReport.basedOn may contain multiple references, however for billing and other workflow reasons some sites will prefer to create multiple DiagnosticReports, each referencing a single ServiceRequest, even if the narrative content of the reports are largely the same.

Note: Some workflows may involve the creation of local accession numbers in the imaging workflow which are later replaced by accession numbers assigned in enterprise systems. When such replacement takes place, it is important to consider the potential presence of the local accession number in the narrative text, or in rendered PDF documents, as well as in resource attributes.

- **Exam Type** shall be encoded in ServiceRequest.code using an "orderable" code. Some sites may use LOINC Playbook codes, or some other standard. Others will invent local code sets.
- **Indications** shall be encoded with references to Observation and Condition resources in ServiceRequest.reason. Indications are increasingly provided in the form of ICD-10

codes which may appear in the v2 Order messages or originating ServiceRequest resource.

- **Clinical Questions** from the referring physician to the imaging clinician are an important part of clinical practice but are not currently well handled. Most commonly they are included as free text in the comment field of the order message, or sometimes as the reason for exam. The presence of clinical questions are intended to trigger their presentation to the imaging clinician during protocoling and reporting, and result in text in the body of the diagnostic report that specifically addresses the question(s). Several approaches are under consideration:
    - ServiceRequest.note has no specific semantics. It allows 1..n blocks of markdown, each with a time and author.
    - ServiceRequest.supportingInfo is similarly weak on semantics. It allows 0..n references to any kind of Resource. There is precedent in lab to narrow the semantics to "ask at order entry questions" (aka AOEs), but those are questions asked by the performer (lab clinician) and answered by the requester (referring physician) at order time, rather than questions asked by the requester (referring) and answered by the performer (imaging clinician) at reporting time.
    - ServiceRequest.orderDetail might be a bit closer in semantics, but it's not clear how to encode questions. It seems to be more oriented to specifying certain parameters for how the order is to be performed.
    - ServiceRequest.reason doesn't have an appropriate resource type to reference currently, but arguably the fact that they had the question is one of the reasons the referring ordered the study. In the reporting workflow though, indications go into the report "verbatim" while we want the questions presented to the radiologist (for addressing) so handling is different.
    - Questionnaire and QuestionnaireResponse Resources might be relevant but they might not fit the answer-in-report pattern and we would need a reference hook to include it in the ServiceRequest and/or DiagnosticReport. [More about structured data collection]
    - Consider if a new attribute would be appropriate to communicate questions they requester would like answered in the course of the requested procedure.
- ServiceRequest.encounter, per FHIR, records the "health care event when the test ordered". The encounter where the imaging was performed is recorded in Procedure.encounter. In the case of encounter-based imaging, the two encounters might be the same if a corresponding ServiceRequest is created. Whether a ServiceRequest is created for encounter-based imaging and if it is, how it is populated, are left for future workflow profiling.

Narrative text in the Order section of the Diagnostic Report is a good candidate for auto-generation based on a subset of the coded content in the ServiceRequest resource. The ordered

exam in ServiceRequest.code is usually rendered as a single line, perhaps based on the display value of the CodeableConcept. The Accession # and the ordering physician may also be rendered into the top of the report.

- Each referenced ServiceRequest resource has a ServiceRequest.text attribute which can contain a one-line description of the order.

Notes: 1. The Indications and Clinical Questions, while captured at the time of the order and conveyed to the Report Creator in the referenced ServiceRequest, are rendered into the narrative in the History section of the report.

2. The details in the Procedure section are pulled from the imaging Procedure Resource (which is what was performed based on patient needs) rather than the imaging ServiceRequest (which is what was ordered and sometimes driven by billing requirements) since the two do not always exactly match. Sometimes there is an effort to update the Order to match the actual procedure; ideally that happens before image interpretation, but if not, there is a possibility that the ServiceRequest resource bundled with the DiagnosticReport may be out of date with respect to the master copy of the reference. Sometimes the original order is cancelled and replaced by a new one in which case the reference/link is broken.

6.Z.3.2.1 Examples for Order

The following bullets provide a sample of content typical to this section of the report.

- CT Sinus w/o Contrast
- MRI Brain with and without Contrast
- MRI Left Shoulder
- MG of the Screening (Bilateral) *<sic; likely "MODALITY of the BODY PART" template>*
- PET/CT of the Skull Base To Mid-Thigh
- US Guided Left Knee Injection
- MRI Right Hip Arthrogram Including Cartigram Study
- XR Chest 1 View

6.Z.3.3 History

History shall reference resource items in <new> DiagnosticReport.patientHistory.

Note: While the specification requires the ability to include coded history information, it does not specify which or how much history information is encoded. Reports include history details determined to be relevant to the study, usually by the imaging clinician, not the entire medical history available. Also, the details are coded as known to the imaging clinician at the time of interpretation; different information may be available when any given reader reads the report, but the report will reflect what was known at interpretation.

- Condition shall be used to encode past diagnoses.
- Observation shall be used to record relevant observations from the referring physician, nursing notes, past care, and past diagnostics such as pathology or lab values.
- Procedure shall be used to record past procedures performed on the patient such as knee surgery, an appendectomy, or spinal fusion.

- FamilyMemberHistory shall be used to record a person's relationship to the patient, along with the persons demographics, known conditions and procedures.

Narrative text in the History section of the Diagnostic Report is a good candidate for auto-generation based on the coded content in the referenced resources, however the process of selecting the relevant subset will likely require input from the imaging clinician or a sophisticated algorithm.

- This narrative is where indications for the exam (if any) and clinical questions from the referring are included. Information for those two items will be accessed via the imaging ServiceRequest referenced in the .basedOn attribute rather than this .history attribute.
- Each referenced Condition, Observation, Procedure, and FamilyMemberHistory has a .text attribute which can contain a brief description which may be assembled into the narrative text for the History section.
- See also the discussion of .text usage in Section 6.Z.3.11.1 Resources.text.

6.Z.3.3.1 Examples for History

The following bullets provide a sample of content typical to this section of the report.

- Memory loss, 2 weeks history of dysbalance and lethargy
- Right arm weakness; Difficulty expressing thoughts in writing beginning about 4-5 months ago.
- Work related injury on September 21, 2015, assess for traumatic tear left rotator cuff with superior shoulder pain and weakness.
- 24M with stent placement in the left main bronchus presents with right sided chest pain since 9am
- A 52-year-old with hemoptysis. Right middle and lower lung zone consolidation. Please evaluate.
- Spiculated right upper lobe lesion. The patient declined biopsy for follow-up. If increase in size would consent to biopsy.
- Shortness of breath, pulmonary opacity on CXR
- Left knee pain. Semimembranosus bursitis.
- Follow-up pleural effusion
- Sinusitis.
- Routine. *<for an MG Screening Study; perhaps not an example of good practice>*

6.Z.3.4 Procedure

Procedure and Materials information shall be encoded in Procedure resource(s) referenced in a <new> DiagnosticReport.procedure attribute.

Notes: 1. The DiagnosticReport.procedure attribute mirrors the .specimen attribute to describe how the data being reported was obtained and prepared.

2. In the large majority of cases, one report will correspond to one study comprised of one procedure. Some studies do involve multiple procedures, e.g. a cardiac stress-rest workup, so systems should be prepared to handle multiple procedures.

- Procedure.complication may reference Condition(s) caused by the procedure, including adverse events and reactions

  Note: Events during the imaging Procedure may also result in AllergyIntolerance and/or AdverseEvent resources being added to the patient record, however that is not driven by the diagnostic report and is outside the scope of this profile.

- Procedure.note may reference Annotations which the Technologist might create to record comments such as patient motion, or other details. This information is presented to the imaging clinician, but does not directly appear in the report unless dictated/selected by the imaging clinician.

Procedure resources describe a procedure that was performed with details about technique and execution using clinical imaging language and codes and is created using information from the modality. In contrast, the ServiceRequest resource describes the order using orderable language and codes, which are typically more general and billing-oriented, and is created using information from the order placer. Further, the ImagingStudy resource describes and provides links for the actual **Study** data produced by the procedure(s), and is referenced from DiagnosticReport.study.

Procedure likely needs more profiling for imaging workflow and record-keeping, however that is out of scope for this Diagnostic Report Profile, and would be better addressed in concert with profiling imaging ServiceRequest. Until it is fully profiled, the current practice of user-generated text in the Procedure section of the DiagnosticReport.presentedForm will need to serve.

Narrative text in the Procedure section of the Diagnostic Report is a good candidate for auto-generation, since it involves little to no interpretation. The text may be available in Procedure.text, which in turn would be based on a subset of the coded content in the referenced resource(s), usually the modality, date, procedure type, and details such as technique, pulse sequences, contrast usage, radiation dose, and generated images/views. The content of the Procedure resource likely originated from the image header, MPPS, RDSR, and performed procedure protocols.

- Recent FHIR IG work allows the Dose Reporter to provide the Report Creator with a formatted, locally-conformant block of text that assembles the correct subset of dose details for the specific procedure type for insertion into the report (typically to comply with local regulations).

During the imaging procedure, Observations might be created to capture things like nursing notes or technologist observations. Those would be associated with the Encounter for the

imaging Procedure. Conveying those to the radiologist as inputs for interpretation is not addressed here since this profile is about encoding the resulting report. Future work on reporting workflow and managing inputs to the radiologist could address this.

6.Z.3.4.1 Examples for Procedure

The following bullets provide a sample of content typical to this section of the report.

- Axial PD FS, coronal PD FS and PD, sagittal T1 and PD FS imaging is performed through the left shoulder without contrast.
- Sagittal and axial T1-weighted images, axial FLAIR images, axial diffusion weighted sequences, axial T2-weighted images and coronal gradient echo sequences of the brain were obtained. Following gadolinium administration axial and coronal T1-weighted images were obtained.
- Thin slice axial images through the paranasal sinuses were obtained and reconstructed in the coronal and sagittal planes.
- After intraarticular injection of diluted gadolinium in saline, axial T1 fat-sat, axial PD fat-sat, coronal T1 fat-sat, sagittal T1 fat-sat, axial oblique PD fat-sat, and coronal bilateral PD fat-sat images were obtained. This was followed by multiple acquisitions in the coronal and sagittal plane sequentially carried out with post processing and color mapping performed in order to obtain a T2 mapping cartigram study.
- Agents: F-18 fluorodeoxyglucose. Dose: 17.2 millicuries IV. Prior to the administration of the radiotracer, a fingerstick blood glucose level was drawn, measured as 121 mg/dL. CT images for attenuation correction and anatomic localization followed by PET images from the skull base to the thighs were obtained.
- A PET CT scan was performed from the level of the vertex of the skull to the proximal thighs following the administration of 18.6 mCi of FDG intravenously.
- CT scan of the abdomen and pelvis was obtained with intravenous and without enteric contrast material. Coronal and sagittal reformats were provided. Dose reduction technique: The CT scan was performed using appropriate/available dose optimization/reduction techniques.
- CT angiographic examinations of the head and neck were obtained utilizing 75 cc Isovue 370 intravenous contrast. Multiplanar MIP and 3D reformatted images were also created and reviewed. Stenosis measurements were performed based on NASCET criteria. CT scan performed using appropriate/available dose optimization/reduction techniques.
- Head CT without intravenous contrast. Axial images through the brain were acquired from skull base to the vertex with 5 mm slice thickness. Images were reviewed in brain, subdural and bone window settings.
- Single AP view of the chest

6.Z.3.5 Comparison

Comparison studies shall be encoded in ImagingStudy resources referenced from a <new> DiagnosticReport.comparison attribute.

This serves as the "library" of studies the imaging clinician took into consideration. Actual comparison observations, both new comparative statements and cited old statements from the prior study, are encoded below with the findings.

Narrative text in the Comparison section of the Diagnostic Report is a good candidate for auto-generation based on enumerating the coded content in the referenced resources, usually the modality, date, and procedure type.

- Each referenced ImagingStudy resource has an ImagingStudy.text attribute which can contain a one-line description of the study.

6.Z.3.5.1 Examples for Comparison

The following bullets provide a sample of content typical to this section of the report.

- CXR from mm/dd/yyyy, CT Chest from mm/dd/yyyy (two weeks prior)
- CT-PE of July 18, 2012 and limited CT chest from the declined biopsy of September 10, 2012.
- Left knee ultrasound DATE. Left knee radiographs DATE.
- Multiple, last dated August 8, 2023.
- No previous exams are available for comparison.
- None available.
- None.

6.Z.3.6 Findings

Implementations are permitted to create reports where none of the findings in the narrative are encoded. **Findings** that are encoded shall use Observation resources referenced from DiagnosticReport.result. Implementations shall be capable of creating at least one Finding encoded as an Observation and referencing it from DiagnosticReport.result.

The following metadata shall be populated in the Observation (despite being referenced, or implicit, in the DiagnosticReport). One reason for this is to facilitate usage of the Observation resources beyond the direct context of the parent DiagnosticReport. For example, to perform Observation-level queries.

- Observation.subject shall reference the imaged Patient.
- Observation.basedOn shall reference the imaging ServiceRequest
- Observation.encounter, if present, shall reference the imaging procedure Encounter.

- Observation.partOf shall reference the interpreted ImagingStudy
- Observation.category shall use the value "imaging"
- Observation.status shall use "final" for observations in the final report.

The scope and complexity of report findings can vary significantly.

NOTE TO REVIEWERS: Further profiling of the Findings section is deferred to future work.

As a strategic scoping decision of this profile, the use cases focus on subsequent viewing of reports by referring physicians and patients, and clinical pathway automation such as recommendation follow-up, critical finding tracking, and clinical decision support for referring physicians. Those use cases depend primarily on the Impression and Recommendation sections which are the primary interest for referring clinicians. The imaging clinician has summarized all the most important clinical information in the Impression section where all actionable findings should be represented.

Future work on Finding encoding will consider use cases centered on the interpretation process that leads to the report. This may bring together AI result review and transcoding, the IRA profile, selecting findings from prior reports for inclusion in the current report, and other automation functions for the imaging clinician. Such use cases will be helpful concrete drivers in resolving the many expected complexities. Should probably also consider how the use of LLM technologies will play into the composition and processing of such blocks of dense text.

Some preliminary thoughts and discussions on Findings are captured in a "Discussion Extract" document in the IHE Radiology Tech Cmte working folder.

6.Z.3.6.1 Examples for Findings

The following bullets provide a sample of content typical to this section of the report.

- Finding set (MRI Cervical Spine)
  - The cervical cord appears normal in its size and signal characteristics.
  - The C2-3 and C3-4 discs are degenerated.
  - There is some mild bulging of the C3-4 disc. Neither level demonstrates central or neural foraminal narrowing.
  - There has been prior fusion from C4 through C7 in good alignment and position. An anterior screw and plate device is present.
  - At C4-5 and C5-6 there is no recurrent central or neural foraminal narrowing.
  - At C6-7 there is mild bilateral bony neural foraminal narrowing without central canal compromise.
  - The C7-T1 level appears unremarkable.
- Finding Set (PET-CT)

- A right lower breast mass is seen measuring approximately 6.2 x 1.6 cm in transverse dimension with SUV max measuring up to 4.2. The patient has had prior bilateral axillary node dissections. There is no current adenopathy in the axilla bilaterally by size criteria or metabolic activity. There is no adenopathy in the mediastinum or hilum similarly.
- No pulmonary nodules or masses are identified. However, moderate right and small left perfusions are seen with low-level metabolism, SUV max measuring up to 3.0.
- Diffuse thoracic esophageal hypermetabolism is noted.

- No compressive mass within the carpal tunnel.
- Moderate extensor carpi ulnaris tendinosis. There is fluid reflective of tenosynovitis in the second and third extensor compartments as well along the region of the extensor digitorum tendons.
- Moderate amount of fluid in the radiocarpal and midcarpal wrist compartments.
- Mild dorsal angulation of the distal radius reflective of the fracture.
- Evidence of edema in the central and volar aspect of the ligament. Edema extends into the volar radiocarpal ligaments. The pattern is reflective of a volar injury and partial-thickness tear in this region. There is no complete tear. There is no DISI deformity.

6.Z.3.7 Impression

Impressions shall be encoded in Condition and/or Observation resources referenced from the <new> DiagnosticReport.impression attribute. Implementations shall be able to create at least one Condition and reference it in the DiagnosticReport.impression.

Notes: 1. In the presentedForm (PDF, HTML, etc.), the impression section frequently contains not just impressions, but also recommendations, and communications. This profile proposes specific encodings for recommendations and communications in the next two sections.

2. Condition is used here as a proxy for a diagnosis or problem that is not yet determined, per its FHIR documentation.

This section focuses on impression statements as structured coded data. The Report Creator is responsible for distinguishing and encoding dictated impressions, recommendations, and communications.

- Condition.category shall use the value **imaging-impression** *<new>* (vs problem-list-item | encounter-diagnosis)
- Condition.verificationStatus shall be populated. Typical values are **unconfirmed | provisional | differential | confirmed** | refuted
  - "confirmed" would not be used unless the radiology report is the definitive source of such a diagnosis.
  - Per https://www.hl7.org/fhir/R5/condition.html#9.2.4.5 "refuted" is used for subsequent disproof of a previously asserted condition so it would not be used

unless the condition was previously asserted, the radiology report is negative and is definitive for such an assertion. Other negative assertions are handled as observations.

- Condition.code shall record the condition or "disorder" described by the imaging clinician. Codes may be drawn from SNOMED or similar coding system.
- Condition.severity shall record the severity of the condition, if specified by the imaging clinician.

  Note: Severity does not map directly to patient risk. A mild stroke might present a greater risk than a severe ingrown toenail.
- Condition.stage and its subordinate attributes shall record the assessed stage of the condition, if specified by the imaging clinician for conditions that have formal (disease-specific) staging concepts.
- Condition.bodySite shall record the anatomic location of the condition. Codes may be drawn from SNOMED or similar coding system.
- Condition.laterality <new> shall record laterality if the bodySite is a paired structure. (See also Open Issue about bodyStructure)
- Condition.likelihood <new> shall record the likelihood of the condition, if expressed by the imaging clinician. (See Open Issue about adoption of a coding system)

  Note: "Consistent with" in the narrative form of an impression typically implies strong imaging support for an existing (tentative) diagnosis in place beforehand. Most other impressions represent conditions put forward by the imaging clinician. If the Condition resource for the existing diagnosis is known, consider referencing that instance and adding information to Condition.evidence.
- Condition.clinicalStatus is required to be present by the Condition resource. It will frequently be "unknown" in diagnostic reports, but the other defined values may be used when appropriate.
- Condition.participant shall be present and include the imaging clinician as "asserter".
- Condition.evidence may contain references to Observation resources in the Findings and/or Impression sections or other information elsewhere that contributed to the impression. Common practice today is to take it as read that the content of the report as a whole constitutes the evidence for the sum of the impressions which is what would be understood if this attribute is absent. Sometimes, however, the narrative for an impression is worded in a way that connects it to one or more specific observations.
- Condition.order <new> shall contain a positive integer indicating the relative order of the Conditions and Observations referenced in .impression. Since .impression may reference both Conditions and Observations, the integers for Conditions might not be contiguous if there are Observation resources intermingled with the Condition resources.

  Note: Using .order here is likely not the best way to model this . See Open Issue on the use of the FHIR List Resource as a potentially better way to manage an ordered list of references. There may also be value in being able to group several related Condition statements into a single "entry" in the impression list, as appears to be a convention in imaging diagnostic reports. Dictated impression narrative sometimes groups multiple conditions together in one

narrative impression statement, usually because they are related by anatomy, anatomical proximity, and/or the underlying process of the disorder.

- Condition.actionable <new> shall, if present, contain a code to indicate the degree to which the Impression finding is actionable. Codes may be drawn from the RadLex codes for the ACR Actionable Finding Categories described in IHE Results Distribution (RD):
    - (RID49480, RadLex, "Cat 1 Emergent Actionable Finding") defined as requiring immediate medical attention within minutes.
    - (RID49481, RadLex, "Cat 2 Urgent Actionable Finding") defined as requiring medical attention within hours.
    - (RID49482, RadLex, "Cat 3 Non-critical Actionable Finding") defined as requiring medical attention within days to months.
    - (RID50261, RadLex, "Non-actionable") defined as not requiring follow-up actions.

Note: The presence of a Recommendation for a given impression is an implicit indication that it is actionable. Having an explicit code can help with subsequent tracking and follow-up.

Note: Conversely, actionable findings do not always have a corresponding Recommendation. For example, an identified pneumothorax is a well-known entity to the referring clinician with standard actions to address it. The imaging clinician would be unlikely to re-iterate those actions in the report.

Note: Category 1 and Category 2 codes constitute "critical findings" which often result in direct Communications (see Section 6.Z.3.9) due to the clinical urgency.

- Condition.incidental <new> shall, if present, contain a Boolean value to indicate if the impression finding is determined by the imaging clinician to be incidental to the indications and reason for exam. Being unexpected, some institutions trigger special workflows to ensure that incidental findings receive appropriate attention and follow-up.

Some impressions do not correspond to well to the Condition model. For example, the codes in the *-RADS Systems correspond to the result of a composite assessment, and some are more representative of a point on a diagnostic pathway, which encompasses both a differential diagnosis and protocolized follow-up actions.

- Observation.code contains the assessment, such as (397137005, SCT, "Mammography Assessment") for BI-RADS
- Observation.value contains the coded result, such as (397143007, SCT, "Mammography assessment (Category 3) - Probably benign finding, short interval follow-up")

Note: Consider named options for each *-RADS system with requirements on the actors that create and use the values.

The narrative form of the Impression section is often directly dictated by the imaging clinician. Tools also exist that generate a draft of the Impression narrative based on the dictated Findings narrative. If the Impression narrative were built up from the coded Impression, the summary in Condition.text of each referenced Condition resource might be compiled into impression bullets sequenced according to the Condition.order.

In addition to rendering the Impression narrative as a section in the full report in the DiagnosticReport.text attribute, the Report Creator may also render the Impression narrative into DiagnosticReport.conclusion as a single markdown field. The Impression narrative may contain dictated text which goes beyond the semantics captured in the DiagnosticReport.impression references.

Note: DiagnosticReport.conclusionCode, which permits an unstructured list of individual conclusion code values, is not used in this profile. As seen in the example section below, individual impression statements frequently contain much more semantic content than can be adequately represented with a conclusion code.

If/when a Condition here is added to the patient Problem List, either by the referring physician or because the Condition.verificationStatus is confirmed, that would likely create a new Condition resource that might point to the Impression Condition instance as Condition.evidence (or maybe the biopsy result instead). While the Problem List Condition instance would be updated over time, for example when the condition is abated, the Impression Condition persists as a medicolegal snapshot that is an integral component of the Report. If the Report is exported, that bundle would contain the Impression Condition at the time of the report, not any "current" version.

6.Z.3.7.1 Examples for Impression

The following bullets provide a sample of content typical to this section of the report.

In some cases, a set of impressions for a particular type of exam are provided as a group to get a sense of the ordering and grouping patterns. Some impression sentences encompass multiple Conditions. Some impressions are shown broken down into more codable components.

When the imaging clinician has interposed a recommendation amongst the impressions, it has been highlighted here {underlined between braces}.

As an exercise to explore the suitability of the specification, a sample encoding [shown in square brackets] is provided for some impressions. Also, the encodings do not always capture 100% of the intended semantics and nuances of the radiologist.

- Findings suggesting left peripheral lung base pulmonary infarct.
    - [Condition.code = (64662007, SCT, "Pulmonary infarct"), .bodySite = (10024003, SCT, "Structure of Lung Base"), .laterality = right, *.modifier = peripheral?,* .likelihood = may represent]
- Impression Set (Abdomen US)
    - Fatty infiltration of the liver.
    - Small left pleural effusion.
    - Distended inferior vena cava and hepatic veins, findings consistent with congestive heart failure.
        - [*code distended veins as observations, code CHF as Condition with the observations referenced from .evidence, and .likelihood is high]*

- Impression Set (XR Foot, Ankle, Tibia/Fibula, Knee)
  - Acute nondisplaced fractures of the proximal tibia and fibula.
  - Acute fracture of the distal fibular diaphysis.
  - Intact intramedullary nail fixation hardware.
    - *[Create an observation code of "intact" for application to any given anatomy, device, (or intervention/modification?) Or should this be coded as a set of negations: no loosening, breakage, protrusion or other visible complication of the nail fixation hardware?]*
- Impression Set (MRI Hip)
  - Moderate right hip osteoarthritis, with labral tearing and para labral cyst formation.
    - [Condition.code= (396275006, SCT, "Osteoarthritis"), .bodySite= (24136001, SCT, "Hip joint"), .laterality=right, .severity=moderate]
    - [Condition.code=(202336002, SCT, "Acetabular labrum tear"), .bodySite= (182439007, SCT, "Acetabular labrum"), .laterality=right]
    - [*Need code for para labral cyst*, .bodySite= (182439007, SCT, "Acetabular labrum"), .laterality=right]
  - Chronic partial-thickness tears of the gluteus minimus and medius with small overlying greater trochanteric bursal fluid.
- Impression Set (CT Neck, Chest, Abdomen/Pelvis)
  - No acute abnormality in the neck, chest, abdomen, or pelvis. No pathologically enlarged lymph nodes.
  - Multiple peribronchial bilateral pulmonary nodules, measuring up to 5 mm in the left lower lobe, likely infectious/inflammatory.
    - *[… (786838002, SCT, "pulmonary nodule (disorder not finding) … how to code size generalization, likely etiology (infections/inflammatory) …]*
  - No active GI bleed.
  - Mesenteric vessels are patent without evidence of end-organ ischemia.
- Impression Set (MRI Brain, MRI Cervical Spine)
  - No evidence of acute infarction, hemorrhage, or a mass lesion. Chronic changes as described above.
  - A 1.1 cm focus of enhancement within the left parietal bone that does not demonstrate any cortical destruction or any other destructive features. There is a lucency at this site on the previously performed head CT. It is favored to represent a **venous lake**.

- Congenitally small central canal from C3/C4 down to C5/C6 level.
- Moderate to severe degenerative changes of the cervical spine as described above and summarized below.
- At C3/C4, moderate central canal stenosis with flattening of the ventral surface of the cord. Moderate left neural foraminal stenosis.
- At C4/C5, moderate central canal stenosis with flattening of the ventral surface of the cord. Moderate to severe left neural foraminal stenosis.
- At C5/C6, moderate bilateral neural foraminal stenosis.
  - See below
- At C6/C7, moderate right neural foraminal stenosis.
  - [Condition.code =(371000119109, SCT, "Stenosis of intervertebral foramina"), .bodySite= (281875002, SCT, "C6/C7 intervertebral foramen"), .severity=Moderate, .laterality=right]

- Impression Set
  - Prominent bilobed paramedial extra-axial **mass** along the convexity centered at the level of the posterior frontal and anterior parietal lobes with prominent posterior dural tail and occlusion of the adjacent superior sagittal sinus. Prominent surrounding reactive edema, left greater than right. Mild lateral shift but no herniation. Smaller extra-axial mass overlying the right mid temporal lobe.
  - [Prominent bilobed (SHAPE) paramedial extra-axial (LOC) **mass**
    - along the convexity (LOC)
    - centered at the level of the posterior frontal and anterior parietal lobes (LOC)
    - with prominent posterior dural tail (SHAPE)
    - and occlusion of the adjacent superior sagittal sinus (LOC?).
    - Prominent surrounding reactive edema (RELATED CONDITION & LOC), left greater than right (SEVERITY?).
    - Mild lateral shift but
    - no herniation.
    - Smaller extra-axial mass (RELATED CONDITION & SHAPE)
    - overlying the right mid temporal lobe (LOC).]
  - Atypical meningioma including hemangiopericytoma or variant or malignant subsidence of meningioma. Other less likely considerations include extra-axial dural based metastasis, lymphoma and less likely solitary fibrous tumor.

- Impression Set
    - There is mild supraspinatus **tendinosis** with minimal articular sided **fraying** of the distal tendon and a 3 mm low grade **interstitial tear** at the distal attachment site.
    - There is marrow edema within the distal clavicle. There is a small AC joint effusion with mild pericapsular edema. This may represent mild stress related change of the AC joint versus a grade 1 sprain of the AC joint. There is no elevation or fracture of the distal clavicle.
    - There is no occult fracture or bone contusion. No malalignment of the osseous structures.
    - The age of injury is indeterminate.
- There is a metastasis located within the right temporal lobe surrounded by a moderate size area of vasogenic edema. {Further evaluation with an enhanced MRI examination of the brain is recommended.} There are large confluent right hilar/parahilar and mediastinal metastases located within the chest. There is a complete atelectasis/consolidation of the right upper lobe (drowned lung). There are numerous metastases located within the peripheral portions of both lungs. There are multiple hepatic metastases. Please see report.
- Impression Set
    - Complete full-thickness disruption of the anterior cruciate ligament.
    - Associated osseous contusion of the lateral condylar patellar sulcus: Pivot shift injury.
    - Grade 1 MCL complex injury.
    - No other associated injury identified <*How should we code negation when there is no concrete condition being negated?*>
- Impression Set
    - Hydrocephalus without evidence of obstructing mass lesion. Acute hydrocephalus cannot be excluded since there are no prior studies available for comparison. Extensive chronic white matter changes may mask transependymal CSF edema. {Correlate with short-term followup to exclude acute hydrocephalus. Correlate with clinical symptoms to exclude normal pressure hydrocephalus.}
    - Chronic white matter changes.
    - Cerebral atherosclerosis.
- Impression Set

- Markedly abnormal multifocal hypermetabolic predominantly osteosclerotic lesions scattered throughout the axial and proximal appendicular skeleton consistent with wide spread osseous metastases
- Right lower breast mass that appears hypermetabolic. {Please correlate with mammography and consider biopsy if indicated.} Recurrent disease is a consideration.
- Indeterminate bilateral pleural effusions and ascites with low-level metabolism. Consider thoracentesis and evaluation of fluid for malignancy if clinically indicated.
- Diffuse thoracic esophageal uptake. This pattern can be seen in patients with esophagitis. Please correlate clinically.

- Spiculated mass within the posterior segment of the right upper lobe has increased minimally in size from September 2012, now with maximal dimension of 2cm versus 1.6cm previously. Radiographic staging of this presumed malignancy is T1a N0. No new pulmonary nodules and no findings of metastatic disease.
- Impression Set (CTA Chest)
  - Moderate pericardial effusion with apparent mass effect on the right ventricle, leftward bowing of the intraventricular septum, a contrast level within the IVC, and severe reflux of contrast into the hepatic veins and right lobe parenchyma are highly suggestive of tamponade physiology. Pericardial enhancement suggests pericarditis as etiology.
  - No aortic dissection or intramural hematoma.
- Impression Set (Lung Cancer screening Chest CT)
  - Lung-RADS CATEGORY: 2/S. Multiple pulmonary nodules. The dominant solid nodule is located in the right middle lobe and has a mean size of 5 mm (series 3, image 285). The category-determining solid nodule has a very low likelihood of becoming a clinically active cancer, due to size and/or lack of growth.
  - There are potentially significant incidental finding(s): thyroid lesion, incompletely characterized by CT
    - *[how to code "incompletely characterized by CT"? Or is that narrative limitations of study and coding is less important?]*
  - {RECOMMENDATIONS: Continue annual Lung Cancer Screening Chest CT examination if patient meets eligibility criteria.}
  - {RECOMMENDATION FOR POTENTIALLY SIGNIFICANT INCIDENTAL FINDING: Thyroid ultrasound, unless recently obtained}
  - Explanation of the Lung-RADS CATEGORIES CAN BE FOUND AT: HTTP://healthcare.partners.org/lung/rads.pdf

    - A clinically significant result was communicated on 2/--/202x 10:08 PM, Message ID ------.
- Unremarkable CT evaluation of the paranasal sinuses. No obstructive pathology is seen.
- (Chest X-ray) No acute cardiopulmonary process.
- (MRI Brain) No acute or subacute infarct, mass effect, or acute intracranial hemorrhage.
- Impression Set (CT Head)
    - No acute intracranial findings.
    - Mild left parietal scalp swelling and contusion. No acute calvarial fracture.
- Impression Set (Screening Mammogram)
    - No mammographic evidence of malignancy in either breast.
    - {Annual screening mammography is recommended.}
    - BI-RADS 1 NEGATIVE [(397140005, SCT, "Mammography assessment (Category 1) – Negative")]
        - *[This is an example of the rare case where .conclusionCode fits well. Should we also allow .conclusionCode and make consumers look in more places all the time? Or model it as an Observation?]*
    - The patient will be notified of the results and recommendations.
        - *[Look into coding intended, not attempted/completed, communications]*
- Impression Set (OB US)
    - 24 y.o. G3P2 at 21 weeks by 18 week ultrasound with reassuring fetal anatomic survey. Ms. X has a significant psychiatric history and is maintained on Lithium with good effect; she reports her mood is stable and she is in close contact with her psychiatrist. We reviewed the plan for a fetal echocardiogram and a referral was placed.
        - *[much of the above likely should be in other sections]*
    - Worksheet finished by ---- -----, sonographer on 1/--/202- 1:2-:5- PM.
        - *[Such workflow/provenance probably belongs in Procedure?]*
- No evidence of acetabular labral tear or detachment. There is no high-grade chondral loss or delamination.
- Very dense breasts without comparison studies limiting sensitivity. Comparison to previous mammograms would be helpful to assure stability of dense parenchymal pattern.
- No active disease in the chest.

6.Z.3.8 Recommendations

Recommendations shall be encoded as ServiceRequest resources referenced from the <new> DiagnosticReport.recommendation attribute.

These draft ServiceRequests, when created, may omit various details that the imaging clinician would not know or would not be responsible for choosing. They are intended to serve as a skeleton that facilitates the referring provider adding any needed details and activating it as an order.

- serviceRequest.status shall use the value draft ("The request has been created but is not yet complete or ready for action.")
    - This reflects the fact that the request will be sparsely encoded and things like procedure codes might not be locally correct so completion of details and code re-mapping might be needed before the request can be activated
- serviceRequest.intent shall use the value proposal (to leave it up to the referring physician) or plan (if the imaging clinician feels it would be inappropriate if the recommended action does not take place)
- serviceRequest.reason may reference a Condition resource in the Impression when the recommendation was motivated by that specific impression. This serves both to justify the recommendation, and to associate the recommendation with the impression which can influence their presentation.

  Note: If it is useful to capture specific clinical/practice guidelines that were applied in making the recommendation (e.g., the Fleischner Criteria for lung nodule follow-up), those could also be referenced from ServiceRequest.reason. In HL7 v2, the IHE Results Distribution (RD) Profile encoded this in OBX-15. Since there is not currently a PracticeGuideline resource, it would be necessary to create a DocumentReference resource for the relevant policy or guideline document.
- ServiceRequest.occurrence supports encoding a Period, i.e., a time range. Per FHIR, the context of use will make it clear that one value from the period applies. To encode a recommendation that a follow-up scan take place 6-9 months from now, the Report Creator calculates a start date 6 months from the current date, and an end date 9 months from the current date.
- ServiceRequest.performerType can be used to encode a referral to a particular type of specialist.

There is idiosyncratic variation between specialties, regions, and facilities as to whether recommendations are presented in the impressions section or presented separately. Since the underlying encoding of a recommendation differs from an impression, this profile separates the two. Implementations may still choose to group the two together in the presented form based on configuration and customer preferences.

A recommendation is often directly associated with a specific impression. This may be expressed in the dictated text by following the impression with a recommendation before moving on to the next impression. The Report Creator is responsible for maintaining the order and relationships between impressions and recommendations.

The narrative form of the Recommendations may be directly dictated by the imaging clinician. Tools also exist that generate a draft of the Recommendation narrative based on the Impressions and associated guidelines. If the Recommendation narrative is built up from the coded Recommendation, the summary in ServiceRequest.text of each referenced ServiceRequest resource might be compiled into recommendation bullets.

The narrative Recommendation text may include conditional logic, e.g., if A is true then procedure X is recommended; if B is true then procedure Y is recommended; else procedure Z is recommended. This profile does not yet model this logic in the coded recommendations; as a placeholder, the condition text could be included in ServiceRequest.note, but this does not support automated tooling. In the example, all three procedures would be included as referenced draft ServiceRequest resources and the referring physician would apply the logic in the narrative to decide which to activate, If any.

6.Z.3.8.1 Examples for Recommendation

The following bullets provide a sample of content typical to this section of the report.

- Referral to the DAP service is recommended. The lesion is amenable to CT guided biopsy.
- Further evaluation with an enhanced MRI examination of the brain is recommended.
- Recommend further evaluation with dedicated breast imaging at XXX Breast Imaging Center by calling xxx-xxx-xxxx to schedule an appointment.
- Please correlate with mammography and consider biopsy if indicated.
- Annual screening mammography is recommended.
- Correlate with short-term followup to exclude acute hydrocephalus. Correlate with clinical symptoms to exclude normal pressure hydrocephalus.
- Continue annual Lung Cancer Screening Chest CT examination if patient meets eligibility criteria
- Recommendation for potentially significant incidental finding: Thyroid ultrasound, unless recently obtained
- Recommend discussion of X with the patient.

6.Z.3.9 Communications

Communications shall be encoded as Communication resources referenced from the <new> DiagnosticReport.communication attribute.

- Communication.partOf shall reference the DiagnosticReport resource.
- Communication.subject shall reference the Patient that is the subject of the report and thus the subject of the communication.

- Communication.topic may contain the code for "summary-report". Sites may wish to use a code for critical findings.
- Communication.reason may reference one or more of the specific impression Conditions or recommendation ServiceRequests that prompted the communication.
- Communication.about may reference any or all of the specific impression Conditions or recommendation ServiceRequests discussed if such information is made available to the encoding system.
- Communication.encounter shall reference the encounter for the imaging procedure, or be absent.
- Communication.status should be COMPLETED in most cases.
- Communication.medium will typically be PHONE, or in the case of leaving a voicemail message, DICTATE.
- Communication.sender should be the imaging clinician in most cases but may be their staff.
- Communication.recipient should be the patient or the referring clinician in most cases, but may be their staff.
- Communication.sent shall be present. Due to the nature of phone communications, .received will typically be the same time or may be absent.
- Communication.text shall contain a summary sentence describing the communication, as currently appears in report narratives.
- Communication.basedOn is likely absent unless there was a specific request for a communication.

This information is included in the body of the report, in part for medicolegal purposes. If future HIT infrastructure handles tracking such communications directly in the EMR, the practice of using the diagnostic report to implement such accountability and tracking might change, but for now it is expected to persist.

This information may also support performance metrics such as the speed with which the Referring Physician is notified of key clinical results.

The corresponding section narrative text may be created by concatenating the .text contents for each of the referenced Communication resources. This narrative often appears at the bottom of the report under the Impressions and Recommendations.

Communication resources where the .status is not COMPLETED may trigger subsequent follow-up workflows, but the management of such follow-up is not reflected in the diagnostic report.

6.Z.3.9.1 Examples for Communications

The following bullets provide a sample of content typical to this section of the report.

- Findings discussed with Dr. REFERRING at 1630 hrs
- Telephone message was left at Dr. DAVID LIVESEY office at the time of dictation.
- A clinically significant result was communicated on 2/--/202x 10:08 PM

6.Z.3.10 Signature

Signature of the report shall be encoded as a Provenance resource referenced by a <new> DiagnosticReport.signature attribute.

- Provenance.signature.type shall have a value of ProofOfApproval.
- The entity to which the Provenance applies defaults to the resource of which it is a part.
- DiagnosticReport.resultsInterpreter shall reference a Practitioner resource for the primary result interpreter, aka Reported By. This shall match the person identified in Provenance.signature.who (or Provenance.signature.onBehalfOf).
    - Practitioner resources for additional report authors may also be referenced from DiagnosticReport.resultsInterpreter using PractitionerRole resources to record residents, collaborating clinicians, and similar use cases and the role they played.
    - DiagnosticReport.performer references the organization or diagnostic service responsible for the report.

Narrative text for the signature typically appears at the bottom of the report with a statement in a form similar to "This report was digitally signed by Dr. X at <time> on <date>"

In the unprofiled DiagnosticReport resource, the signature appears to be implicit. It is left to receivers to presume that if the report status is final and there is an interpreter listed, that means that practitioner approved the content of the report at some point in time.

6.Z.3.11 Human-Readable Form

The fully rendered human-readable form of the diagnostic report shall be encoded in the DiagnosticReport.text attribute.

The DiagnosticReport.text attribute shall at least include sections for Order and Impression. It shall include sections for History, Procedure, Comparison, Findings, Recommendations, and Communications if there is content for those sections.

Notes: 1. As a Narrative attribute, the content of .text is encoded in XHTML with additional FHIR constraints.

2. The IHE Interactive Multimedia Report (IMR) Profile also constrains the content of the diagnostic report.

- Sections shall be defined using tags.
- Each tag shall have an ‘id’ attribute with a unique value assigned to the section.
- Each tag shall have a ‘class’ attribute with a code drawn from Table 6.Z.3.0.1-1, and formatted as <coding system>|<code value>. This class code will facilitate extraction of section text by report consumers.

- Each section shall contain a human readable title reflecting the code meaning for the section. The title may be localized and/or translated. The title may be enclosed in a header tag.
- Each section may contain HTML 4.0 Text, List or Table elements to organize content within the section
- Each section may contain the 'narrativeLink' or 'originalText' extension to link between data and narrative text. See https://hl7.org/fhir/R5/narrative.html#linking for details and an example.

See Figure 6.Z.3.11-1 for an example of the use of tags that shows two sections, one for Finding and one for Impression. The Finding section uses simple paragraph tags <p> to separate multiple contents. The Impression section uses an unordered list. This is not an example of a full report.

```
"text" : {
   "status" : "generated",
   "div" : "<div xmlns=\"http://www.w3.org/1999/xhtml\">
<div id=\"111\" class=\"http://loinc.org|59776-5\">
   <h2>Findings:</h2>
            The imaged portion of a thyroid gland is unremarkable. Prominent or mildly enlarged mediastinal and bilateral hilar
            lymph nodes measure up to 1.2 x 0.8 cm in the right paratracheal station (2:12) , 2.3 x 1.4 cm in the subcarinal station
            (2:18), and 1.4 x 0.9 cm in the right hilar stations (2:16). No significant axillary lymphadenopathy is detected. The
            esophagus is unremarkable. The thoracic aorta is normal in caliber with a typical 3 vessel takeoff from the arch. The
            pulmonary arterial trunk is normal in caliber. The heart is normal in size without pericardial effusion.
   <p/>
            Within the pulmonary parenchyma, there is diffuse peribronchovascular nodular and ground-glass opacities becoming
            confluent in the right middle (601:52) and left upper (601:65) and lower lobes (601:72) consistent with multifocal
            pneumonia. There is a small left and trace right pleural effusion. No pneumothorax is present. There are no suspicious
            masses or pleural abnormalities.
   <p/>
   …
</div>
<div id=\"222\" class=\"http://loinc.org|19005-8\">
   <h2>Impression:</h2>
   <ul>
      <li>Multifocal pneumonia involving the right middle, left upper and left lower lobes with small left and trace right pleural
effusions.</li>
      <li>Central mediastinal lymphadenopathy is likely reactive.</li>
   </ul>
</div>
</div>"
  },
```

Figure 6.Z.3.11-1: Section Example

All coded content of the diagnostic report should be present in the .text rendering. The .text may also contain additional information which is not yet modelled in the coded form of the report. Some practices include links or references at the bottom of the report to educational material that may be helpful to the patient and/or referring physician to understand the impressions and/or recommendations.

Additional renderings of the report in other formats such as PDF, HTML, or RTF, may be included as Attachments under .presentedForm. The .presentedForm.contentType shall contain a MIME code indicating the format of the content.

Since additional renderings are optional, DiagnosticReport consumers may wish to refer to the .text rendering first. If present, renderings in .presentedForm are typically targeted at the human readers (physicians, patients).

The additional renderings may contain graphical embellishments and/or improved formatting for better readability, but should not introduce clinical semantic content that is not present in the .text rendering.

6.Z.3.11.1 Resources.text

Every FHIR Resource, as children of the DomainResource, includes an optional .text attribute which, if present, contains a text summary of that resource instance for human interpretation. In the context of the imaging diagnostic report, these can be useful components for the construction of the human-readable form of the entire report.

Each ImagingStudy resource referenced in DiagnosticReport.comparison could have a one-line description of the study in ImagingStudy.text. Each Observation resource referenced in DiagnosticReport.results could have a brief text rendering of the observation in Observation.text.

As noted above, many of these pieces of narrative text are good candidates to be generated automatically from the coded content of the resource itself. Some report consumer applications will sometimes find the .text attributes a useful source of text for certain purposes, such as presenting a specific component of the report, or populating part of an HL7 V2 message segment.

The .text.status is required to be present and contains codes that describe the extent to which the semantic content of .text covers or exceeds the coded content of the resource. See https://www.hl7.org/fhir/R5/valueset-narrative-status.html

For resources, such as Patient, that are used widely beyond the scope of the diagnostic report, it the content of .text may or may not be well suited to direct copying or concatenation without some processing.

6.Z.3.12 Addendum

See Addendum Open Issue.

6.Z.3.13 Bundle Resource Usage

See Bundle Resource Open Issue.

Appendices to Volume 3

(Eventually) Add the following new Appendix to RAD TF-3

Appendix A – Example Imaging Diagnostic Report Encodings

These examples are provided in support of the Imaging Diagnostic Report (IDR) Profile. See Section 6.Z.3 Imaging Diagnostic Report Content for the encoding specifications.

This appendix contains a limited set of illustrative examples. Additional examples may be available in IHE Connectathons or as part of the implementation materials associated with this profile which may be found via Appendix G of the IHE Technical Frameworks General Introduction and Shared Appendices.

<To be completed as part of TI preparation>

