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	Submitter	Category Type: 75	Summary Comment	Actual Comment	FINAL Response: Yellow highlighted items require follow up with Image Sharing Use Case Implementers.
1					<p>The choice to make XDS-I.b/XCA-I the foundation of the Implementation Guide was based on an assessment of the maturity of those IHE profiles that are in Final Text. These profiles have a history of successful testing and deployment.</p> <p>Carequality recognizes that there are emerging approaches, using DICOMweb and HL7 FHIR that may supplement the web service standards already included. Our position, echoed in some of the comments received on this subject, is that the best approach is to implement the current specification as rapidly as possible, while simultaneously working on refining an approach based on RESTful interfaces (FHIR, DICOMweb) that addresses the key image sharing use cases.</p> <p>This work will involve engagement with the relevant standards bodies (HL7, DICOM, IHE) towards specification development that leads to testing and deployment activities to drive the underlying standards toward maturity. The FHIR Imaging related IG components would likely be folded into the Carequality Implementation Guide for FHIR-based exchange, which is under development at the present time.</p> <p>For more information on Carequality's support for FHIR-based exchange, visit https://carequality.org/get-involved/technical-workgroup/</p> <p>If you wish to participate, please send an email to admin@carequality.org.</p>
2	Epic	REST vs SOAP	XCA-I first, FHIR soon after with a well defined transition plan	<p>Adopt a phased implementation approach</p> <p>Ongoing discussions with industry stakeholders suggest there is interest in the adoption of both FHIR, and XCA-I based approaches for data element/image access and exchange. However, we are concerned that the development and support of two distinct technologies during initial implementation will be less effective in promoting adoption of image exchange capabilities. Instead, we recommend a phased approach focused on implementing an XCA-I based solution first. This has a couple of key benefits.</p> <p>First, an XCA-I based solution would be a natural progression of the successful query-based document exchange Carequality implementers support today. By adopting an XCA-I based solution, organizations would be able to leverage the existing, well-understood framework for query exchange and promote faster adoption. In contrast, a FHIR-based approach to exchange of DICOM images has not yet been demonstrated effective at scale, and would likely require greater investment, and longer timelines to operationalize.</p> <p>Second, adopting a single approach will promote more rapid usage amongst users by focusing the attention and resources of implementers and connectors. By phasing implementation to focus on adoption of an initial, single standard, connectors will have an unambiguous understanding of how to exchange images with their partners.</p>	
3	Canon	REST vs SOAP	Points out that REST is documented and supported by PACS and VNAs	<p>Retrieve Imaging Data: It is worth noting that in recent years there has been increasing interest in RESTbased solutions (in imaging and for document oriented records). Specifically, IHE Radiology examined how to better support image exchange and some of the associated challenges. The IHE Web-based Image Access Profile has mapped out a query/retrieve interface based on QIDO-RS and WADO-RS which is supported by a number of PACS and VNAs.</p>	<p>The Image Exchange Use Case implementers on Carequality have expressed interest in adopting REST based solutions as mentioned in this comment. It is expected that once these implementers go into production on Carequality, focus can then be directed to other standards that they wish to document as appropriate in the other guides such as the FHIR Implementation Guides.</p> <p>Carequality has been working to specify how FHIR-based exchange, general, can occur via the Carequality Framework. Draft documentation can be found here: https://carequality.org/get-involved/technical-workgroup/</p> <p>The workgroups building this documentation are open to the public. If you wish to participate, please send an email to admin@carequality.org.</p>
4	Canon	REST vs SOAP	WIA incorporates some proxy/gateway concepts	<p>Retrieve Imaging Data: WIA incorporates some proxy/gateway concepts in that the Imaging Document Responder and Imaging Document Source use QIDO-RS and WADO-RS as the interface and the Imaging Document Source can be a proxy/gateway for a backend that uses QIDO-RS/WADO-RS, or XDS-I.b or MHD. The latter two are named options of the WIA profile.</p>	<p>Thank you for this information. This can be considered by implementers for a future Carequality Implementation Guide.</p> <p>SOAP / XCA-I was selected over RESTful (WIA) approaches for the following reasons:</p> <ul style="list-style-type: none"> * IHE XCA-I is at Final Text and is mature * IHE XCA-I defines the behavior of gateway actors that need to support multiple systems inside a community with respect to multiple responding systems * WIA talks about proxy / gateway behavior but is not explicit
5	Canon	REST vs SOAP	QIDO-RS and WADO-RS do not include a homeCommunityID. Perhaps this should be revisited.	<p>Retrieve Imaging Data: At one point it was proposed to propagate a homeCommunityID in the QIDO-RS and WADO-RS request/responses (or create a new pair of transactions as XDS/XCA did) so that WIA could be used in parallel to XCA or could use XCA as a back-end. There was no champion indicating active interest in such an architecture at the time, but the Carequality document seems to indicate that adding an ID or URL/endpoint to identify a community is worth exploring, perhaps as part of maintenance work this cycle</p>	<p>This can be revisited for future Imaging Guide updates.</p>
6	Canon	REST vs SOAP	Why is RSNA specifying SOAP when vendors are moving to REST?	<p>SOAP vs REST: A significant variety of vendors have implemented REST-based image query/retrieval functions, but rather than encouraging that behavior, it seems odd for RSNA to be rejecting that in favor of insisting on SOAP.</p>	<p>The Image Exchange Use Case implementers on Carequality have expressed interest in adopting REST based solutions as mentioned in this comment. It is expected that once these implementers go into production on Carequality, focus can then be directed to other standards that they wish to document as appropriate in the other guides such as the FHIR Implementation Guides.</p> <p>Carequality has been working to specify how FHIR-based exchange, general, can occur via the Carequality Framework. Draft documentation can be found here: https://carequality.org/get-involved/technical-workgroup/</p> <p>The workgroups building this documentation are open to the public. If you wish to participate, please send an email to admin@carequality.org.</p>
7	Canon	REST vs SOAP	Charles stated that Carequality believes that REST is not workable in a gateway architecture.	<p>SOAP vs REST: My understanding from Charles is that Carequality is taking the position that REST is fundamentally incompatible with a gateway architecture. It would be helpful to see an explanation of the technical gaps, and how they apply to this use case, to better understand this assertion.</p>	<p>This is NOT a true statement. Carequality is actively working on FHIR support, as noted in multiple comments above.</p>
8	Canon	REST vs SOAP	What is the path to using REST in the future?	<p>What's your plan for supporting RESTful endpoints in general? Many new PACS have QIDO-RS and WADO-RS endpoints and as HTTP protocols would be naturally aligned with proxying through gateways.</p>	<p>The path to support RESTful endpoints in the future is part of the scope of the Carequality FHIR Policy and Technical Workgroups. See multiple comments above for more information on this work.</p>
9	LifeImage	REST vs SOAP	Does this approach support WADO?	<p>The XCA-I Integration Profile only supports the RAD-75 transaction between the gateway systems. RAD-75 is a heavyweight SOAP protocol. DICOMweb is far superior; WADO, STOW, QIDO represent the current state of the art with DICOM. Imaging-003: Does this scheme support DICOM WADO retrieves?</p>	<p>The implementation guide does not support WADO retrieve in its initial version. We welcome feedback from Carequality's early adopter Implementers on adding such support to an XCA-I gateway-based architecture.</p>
10	MITA	REST vs SOAP	Include RESTful approaches to support future direction.	<p>We also recommend that that Carequality incorporate RESTful approaches, such as IHE Web-based Image Access (WIA) which would better align with FHIR-based solutions in the future. This would reduce the risk of fragmentation and standardize the uniformity of the platform technology.</p>	<p>Please see above comments on support for FHIR-based exchange.</p>

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11	Philips	REST vs SOAP	RESTful is not mature enough. Network speeds are fast enough to support query on demand	We concur it is time to "Make this Real Today". While it is appropriate to look to FHIR and RESTful interfaces for clinical data exchange (including images eventually), the fact of the matter is these newer methods for the exchange are not mature enough for widespread adoption particularly in imaging. We believe, as you do, that it is time to embrace the existing standards and use them at scale. Internet speeds are fast enough today to support a direct query model for exchange between institutions and healthcare communities. Implementation of the XCA-i profiles is a great solution for image exchange today and we believe it will likely have many years of practical usage if we simply do it.	We believe that our proposed approach to future support for FHIR-based exchange aligns well with this comment. See multiple comments above for more information on this future support.
12	Canon	Find imaging data	Wants to know if XDS-I.b is actually in the field to justify the XCA request for a KOS object.	Find Relevant Imaging Data: Based on Open Issue Imaging-005, the Responding Gateway is responsible for providing KOS manifests for all available imaging in the community and handling queries against those manifests. If the responding community is using XDS-I.b, this is relatively straightforward since the Responding Gateway just proxies the requests to the local infrastructure, but if it is not using XDS-I.b, the Responding Gateway must implement the KOS manifests and the rest or else it cannot support the imaging case. Do you know how many sites have active XDS-I.b deployments that can be leveraged?	The original IG was written with separate Responding Gateway and Responding Imaging Gateway actors. As you point out, this requires the responding community to have an XDS-I.b infrastructure. The architecture changed slightly to combine the Initiating Gateway and Initiating Imaging Gateway actors into a single actor and to combine the Responding Gateway and Responding Imaging Gateway actors into a single actor. The responding gateway on the responding side is most likely from an imaging gateway vendor (already in the business) that would know how to manage the XDS-I.b infrastructure even without the full implementation. That is, it could manage KOS objects and act as the Repository for those objects in the absence of a full XDS-I.b implementation.
13	Epic	Use case	Please document workflows	Define stubbed-out workflows We recommend that stubbed-out workflow(s) be defined to outline how the community anticipates the information being exchanged and used. A shared workflow understanding is necessary so that stakeholders have the same understanding of how the standards will be applied and evolve. Including an illustrative, non binding workflow example will help build this understanding. We believe the stubbed-out workflow could help organizations address the following:	The implementers can suggest additional edits and content to be added to the updated implementation guide published 12/2/2019. It is assumed the exchange will be between PACS systems for Radiologist to access and/or the use case where a physician (non radiologist) using an EHR and deciding to retrieve images for review. That physician is not sitting at a PACS workstation and is not importing data into the local PACS / VNA.
14	Epic	Use case	Document push (referral) vs pull (chronic care) workflows. Align with regular EHR/PACS workflows.	Exchange trigger and metadata We recommend the IG provide guidance on when push and pull workflows are most appropriate. For example, in referral scenarios, a push workflow may be most appropriate, while a pull workflow may be more appropriate in chronic or longitudinal care management scenarios. Additionally, access to imaging study metadata will not always be sufficient to determine which images to retrieve. Having the ability to exchange imaging studies between healthcare organizations will have limited success if it is difficult for end users to decide which studies to push/pull, or if it is difficult for end users at the receiving organization to find these studies using their regular EHR or PACS based workflows. Addressing these challenges through an illustrative, non binding workflow would mitigate that risk.	<u>The current Imaging IG uses a pull workflow for documents because it is a supplement to the existing Query Based Document Exchange IG.</u> The primary use case it addresses is acquisition of prior studies for comparison or treatment, providing a network-based solution to replace the practice of a patient walking in with a CD and asking the Radiology Department to import the CD into their record. A pull model seems most appropriate to address this use case. Future Carequality support for push-based paradigms, in general, can also address imaging.
15	Canon	Use case	Please specify use cases	It would be REALLY helpful to have a set of image sharing use cases written up in a whitepaper. If one hasn't been written yet, it would be great for RSNA/ACR/SIIM to write one since they could enumerate the answers and variations to the questions in the next bullet.	<u>Carequality and RSNA will discuss the idea of creating a whitepaper describing an expanded set of image sharing use cases.</u> <u>The clinical use case described in section 10 of the Imaging IG is retrieval of prior images, replacing the current practice of using CDs (mailed or carried by the patient) for transmission of images. The Imaging IG implements a query-based workflow in keeping with the widely implemented Query Based Document Exchange IG to which it is a supplement.</u>
16	Canon	Use case	Format/content of a use case	Use cases: Each case would describe when, where, why, how, and by whom image sharing is initiated and what are the desirable criteria	The Imaging IG describes a high-level technical use case and a single simple clinical use case. Other use cases are permitted as long as they are compatible with the requirements of the Imaging IG and the Query-Based Document Exchange IG to which it is a supplement. Carequality provides a flexible Framework that can address many use cases, and generally does not explicitly specify all possible use cases supported under the Framework. That said, additional clinical use cases could be laid out as examples in future versions of the Imaging IG or successor documents.
17	Canon	Use case	Coverage: push/pull, volume, performance, privacy/consent	Use Cases: There would be pull use cases, push use cases, cases that differ in the volume of data and/or timing, have potential privacy/consent issues, etc. etc.	Use cases are permitted as long as they are compatible with the requirements of the Imaging IG and the Query-Based Document Exchange IG to which it is a supplement. Carequality provides a flexible Framework that can address many use cases, and generally does not explicitly specify all possible use cases supported under the Framework. That said, additional clinical use cases could be laid out as examples in future versions of the Imaging IG or successor documents. As noted in above comment responses, the current support focuses on query-based use cases because it is a supplement to the Query-Based Document Exchange IG and relies on the broader policy requirements in that IG.
18	Canon	Use case	Thinks Sequoia already has a set of use cases documented.	Use Cases: (My understanding from Charles comments is that Sequoia has documented and analyzed a set of image sharing use cases, they just weren't included in the review document. If Sequoia could share those, that would help both this project and a variety of other standards work.)	Carequality has not conducted an analysis of use cases as described for image sharing. If any such analysis is completed in the future, Carequality will post this publicly.
19	Canon	Use case	If a site (B) pulls data from site (A) and makes clinical decisions, site B is required to archive a copy of the imaging data.	Use Cases: From what I gather, Carequality is mostly targeting one type of pull use case where a patient presents at Site B and informs a care provider that they have imaging records at Site A and give consent for care providers at Site B to view and use any Site A records relevant to their current treatment. In one sub-case, Site B uses the imaging to inform care without doing additional imaging. In another sub-case, Site B performs additional imaging and uses the images from Site A as priors. For medico-legal reasons, Site B needs to locally archive copies of any data used in clinical decision making.	The use case addressed in the current Image Sharing IG enables image exchange to support the use case you describe, though it does not specify the details of ingestion by the receiving site. The variety of local policies and practices makes defining a single solution challenging. Carequality may consider addressing that functionality in future versions of the Image Sharing IG.
20	Canon	Use case	Elaborate all use cases	Use Cases: Are other use cases on the table?	Use cases are permitted as long as they are compatible with the requirements of the Imaging IG and the Query-Based Document Exchange IG to which it is a supplement. Carequality provides a flexible Framework that can address many use cases, and generally does not explicitly specify all possible use cases supported under the Framework. That said, additional clinical use cases could be laid out as examples in future versions of the Imaging IG or successor documents.

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21	Canon	Use case	Is this pull only? That is, no push use cases?	Use Cases: (Charles seemed to indicate that one result of the Carequality analysis was that all push use cases (patient submits data from a PHR or media, patient at Hospital A asks Hospital A to send their data to Hospital B where patient is going next for care, Hospital A sends a referral to Hospital B and pushes data supporting the referral, etc) were explicitly off the table and that most hospitals would prefer not to support those)	As noted in above comment responses, the current support focuses on query-based use cases because it is a supplement to the Query-Based Document Exchange IG and relies on the broader policy requirements in that IG. By no means does this keep all push use cases off the table for future work, if Carequality provides general support for push-based architectures.
22	Canon	Use case	Is the only pull use case the one where a patient presents at site B and that triggers a pull? Or, are there other ones, such as a physician triggering a pull for some other reason?	Use Cases: (It also sounded like the 2 particular pull type sub-cases described above were considered to be the prototypical pull use case and other pull use cases that were initiated by physicians, or that followed a different timeline, or pulled data for multiple patients, etc were not of interest)	Use cases are permitted as long as they are compatible with the requirements of the Imaging IG and the Query-Based Document Exchange IG to which it is a supplement. Carequality provides a flexible Framework that can address many use cases, and generally does not explicitly specify all possible use cases supported under the Framework. That said, additional clinical use cases could be laid out as examples in future versions of the Imaging IG or successor documents.
23	Canon	Use case	Is the use case one where the viewer determines content to retrieve based on metadata, or do we pull everything? Charles thinks it is the former, but who gave him that impression? It is not written anywhere.	Find Relevant Imaging Data: Charles confirmed the intention is to filter for relevancy in this query based on procedure, body part, and modality rather than retrieve the patient's entire imaging record each time they present at a new location	The Query Based Document Exchange IG in production is silent, in its current version, with respect to filtering based on meta-data. The Imaging IG Supplement could be updated to address this if the implementers wish to do so.
24	LifImage	Use case	Two workflows to consider: * Pull model / on request * Push model Both require work at the receiver to normalize data that is stored locally.	In our opinion, there are generally 2 basic workflows in the image exchange universe: 1) I request exams from an institution, in which case the requester has no way of knowing the internal Patient ID of that institution, and the request must be handled by demographic query and human judgement on the receiving end – demographics are not part of the KOS search and even if they were, there is no way to automate this search without risking PHI exposure. 2) I send exams to an institution, in which case the receiving institution has to have a process to assign the incoming exam a Patient ID that it understands before that exam goes into its internal storage system. This is the first use case solved by Life Image, by allowing an operator to ingest a CD and "normalize" a DICOM study by manually entering the new Patient ID before pushing it to a PACS. Unless they have a "dirty PACS" workflow, most hospitals cannot accept an insufficiently normalized study into their storage.	The Image Sharing IG is based on a query-retrieve (pull) model. Within the pull model, the Carequality workflow expects an IHE XCPD transaction to allow matching of the patient. When you pull images from a responding gateway, the first step is to find the patient identifier for the responding community. That is a demographic query. The responding gateway is then going to be responsible for mapping that identifier to whatever internal identifiers are used in the responding community. As you suggest, the system that ingests the images will have to normalize the patient identifiers to match the local scheme. Push-based use cases could be supported in the future, if Carequality provides general support for push-based architectures.
25	MITA	Use case	Specify how data is used within receiving hospital (IHE IDEP)	MITA recommends Carequality consider specifications on how the received imaging data will be localized for seamless use inside receiving hospitals. IHE has recommended approaches in the Import and Display of External Priors Profile (IDEP).	The Image Sharing IG considered image ingestion out of scope because of the difficulty of standardizing the variety of existing policies and practices. The intent of the IG is to define how community A can retrieve data from community B. Once community A has the data, it is free to implement a scheme to ingest and manage that data.
26	Philips	Use case	They list possible use cases	We believe when implemented, the proposed imaging extension to the current Query-Based Document Exchange will have an immediate impact on standard departmental workflows that require the exchange of full DICOM including but not limited to: - Specialty referral/consult - Second opinion - Review of priors - Patient receives treatment while traveling	Carequality believes the Image Sharing IG provides core functionality that will support these workflows. In general, use cases are permitted as long as they are compatible with the requirements of the Imaging IG and the Query-Based Document Exchange IG to which it is a supplement. Carequality provides a flexible Framework that can address many use cases, and generally does not explicitly specify all possible use cases supported under the Framework.
27	Epic	Patient ID	Patient matching between EHR and Imaging vendors is not typically well defined. This comment has recommendations.	Patient matching Carequality participants and connectors have demonstrated the scalability of deploying XCPD for patient matching at the EHR level. The image exchange implementation guide should provide guidance that will replicate those successes for image exchange purposes. In particular, it will be important to clearly define the role of the EHR in facilitating that success. Historically, the systems of many imaging vendors have not aligned capture and storage of patient demographic data with EHR systems, leading to challenges with patient matching. Entities will need to consider how they will handle patient matching and demographic reconciliation between systems as they implement image exchange. We recommend that imaging studies received from other organizations update the associated demographics data stored in the DICOM to match the local EHR before being stored in the local VNA.	The Image Exchange Use Case Supplement relies heavily on Carequality's Query-Based Document Exchange Use Case Implementation Guide (QBDE IG), and patient matching is a specific instance of this overall pattern. The proposal is for Image Exchange to use the IHE XCPD profile as further constrained by the QBDE IG. We expect that Record Locator Services - an optional component - also can function for Image Exchange under the same policy and technical requirements outlined in the QBDE IG. We do note a challenge, to the extent that imaging systems do not capture or store robust patient demographics. To the extent that this is the case, it may be a barrier to participation by such systems, at least in the short term, but it's not clear that any different standard or approach would fundamentally address this challenge.
28	Canon	Patient ID	Need to perform patient matching across sites	Match Patient: Need to confirm the existence and ID of a Site A account for the patient that matches their Site B account	The Image Exchange Use Case Supplement relies heavily on Carequality's Query-Based Document Exchange Use Case Implementation Guide (QBDE IG), and patient matching is a specific instance of this overall pattern. The proposal is for Image Exchange to use the IHE XCPD profile as further constrained by the QBDE IG. We expect that Record Locator Services - an optional component - also can function for Image Exchange under the same policy and technical requirements outlined in the QBDE IG. We do note a challenge, to the extent that imaging systems do not capture or store robust patient demographics. To the extent that this is the case, it may be a barrier to participation by such systems, at least in the short term, but it's not clear that any different standard or approach would fundamentally address this challenge.
29	Canon	Patient ID	Not sure how to summarize	Match Patient: Doesn't inherently commit you to any particular mechanism to find and access imaging data	The Image Exchange Use Case Supplement relies heavily on Carequality's Query-Based Document Exchange Use Case Implementation Guide (QBDE IG), and patient matching is a specific instance of this overall pattern. The proposal is for Image Exchange to use the IHE XCPD profile as further constrained by the QBDE IG. We expect that Record Locator Services - an optional component - also can function for Image Exchange under the same policy and technical requirements outlined in the QBDE IG. We do note a challenge, to the extent that imaging systems do not capture or store robust patient demographics. To the extent that this is the case, it may be a barrier to participation by such systems, at least in the short term, but it's not clear that any different standard or approach would fundamentally address this challenge.

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30	LifelImage	Patient ID	Solution does not adequately support searching by patient ID	Imaging-001: The proposed implementation guideline doesn't specify a framework for a solution to the issue of Patient ID. How does the XCA-I Initiating Imaging Gateway find the Patient Identifier to search for the DICOM KOS document? The XCA-I Initiating Gateway is either grouped with an XCA Initiating Gateway that can find the Patient Identifier or is driven by another system that utilizes both the XCA Initiating Gateway and XCA-I Initiating Imaging Gateway. The XCA-I Initiating Imaging Gateway itself does not know the Patient Identifier. It operates at the level of the DICOM Imaging Study.	The Image Exchange Use Case Supplement relies heavily on Carequality's Query-Based Document Exchange Use Case Implementation Guide (QBDE IG), and patient matching is a specific instance of this overall pattern. The proposal is for Image Exchange to use the IHE XCPD profile as further constrained by the QBDE IG. We expect that Record Locator Services - an optional component - also can function for Image Exchange under the same policy and technical requirements outlined in the QBDE IG. We do note a challenge, to the extent that imaging systems do not capture or store robust patient demographics. To the extent that this is the case, it may be a barrier to participation by such systems, at least in the short term, but it's not clear that any different standard or approach would fundamentally address this challenge.
31	Epic	Capacity	Document storage retention policies so receiving VNAs can plan appropriately.	Storage management Organizations may have concerns about the capacity for their local VNAs to handle high volumes of received imaging studies, and the ongoing storage costs incurred. The IG should acknowledge the need for imported study retention policies so organizations can proactively plan their storage needs.	Retention policies do need to be discussed and addressed. We expect that the image exchange implementers may provide feedback related to study retention policies. Such policies could be addressed in a future version of the IG Supplement.
32	Canon	Receiver Requirements	Receiver needs to modify retrieved data to work within local environment (accession number, procedure code, ...)	"Localize" Imaging Data: Modify the retrieved records to work correctly and not trigger errors in the Site B environment (fix accession #s, procedure codes, etc.)	The current Image Sharing IG Supplement leaves outside image ingestion and management out of scope. As you suggest, the system that ingests the images will have to normalize/localize the study information to match the local scheme.
33	Canon	Receiver Requirements	No explicit proposal from proposal	"Localize" Imaging Data: Carequality proposal – (Not sure what is proposed)	The current Image Sharing IG Supplement leaves outside image ingestion and management out of scope. As you suggest, the system that ingests the images will have to normalize/localize the study information to match the local scheme.
34	Canon	Receiver Requirements	Explore IHE IRWF.b for requirements for importing data	"Localize" Imaging Data: Alternatives: IHE IRWF.b (which is referenced by IDEP) defines localization business logic and behaviors for imaging data.	The current Image Sharing IG Supplement leaves outside image ingestion and management out of scope. As you suggest, the system that ingests the images will have to normalize/localize the study information to match the local scheme.
35	Canon	Receiver Requirements	Please review IDEP for issues surrounding importing data	"Localize" Imaging Data: IHE Radiology has found coercing data during import so that it can be used smoothly in the receiving institution to be a non-trivial issue. IHE Rad has documented the challenges and proposed solutions in the IHE Import and Display of External Priors (IDEP) Profile. In one form or another, it might be helpful to consider that profile content in the Carequality context since it specifically describes a cross-enterprise form of the Carequality imaging use case. Even if Carequality decides to rule out the use of REST technologies for the next three or four years, there is material in the profile that could be applied to a SOAP environment.	The current Image Sharing IG Supplement leaves outside image ingestion and management out of scope. As you suggest, the system that ingests the images will have to normalize/localize the study information to match the local scheme.
36	Charles Parisot	Data Consistency	Harmonize procedure codes	Type Code is defined by XCA-I to convey a procedure code. The use of an agreed, nationwide value-set for the most common imaging procedures should be considered seriously. If only such a subset on the basis of Snomed or Radlex was used the service would gain in robustness. This effort in some other countries have resulted in a rather robust list of less than 4000 imaging procedures across 9 modalities.	The Image Sharing IG provides minimal detail on the value sets to be used in transaction metadata. For imaging procedure codes we will encourage implementers to consider adopting the LOINC-RSNA Radiology Playbook.
37	Canon	Data Consistency	Need to harmonize procedure codes so that the users find relevant data.	Find Relevant Imaging Data: Charles pointed out that the use of disparate procedure codes in different sites and communities means mapping is a particular challenge. It should be pointed out that there are some similar challenges with body part since even if they converge on, say, SNOMED codes for anatomy, different sites still use different levels of granularity. Addressing that would require either converging on a standard list, or requiring intermediate systems to use a model of anatomy to map between different levels of granularity. The risk is not finding or using relevant imaging because the queries didn't match. A related issue is coercing data during import so that it can be used smoothly in the receiving institution. (See below)	The Image Sharing IG provides minimal detail on the value sets to be used in transaction metadata. For imaging procedure codes we will encourage implementers to consider adopting the LOINC-RSNA Radiology Playbook.
38	Charles Parisot	Reporting	Comments on retrieving radiology reports	Page 11 and 12, sections 4.7.2 XCA Gateway Requirements and 4.7.3 XCA-I Gateway Requirements The reports can be in any of three formats: * CDA Imaging Report with Structured Headings * CDA Wrapped Text Report * PDF Report In addition several deployments around the world are also using for reports: a CDA header with a PDF body per the XDS-SD Profile. These projects have found the "naked PDF" (option 3 above) not functional and have replaced it with XDS-SD (that is taking imaging reports out of XDS-I). It is suggested that the implementation guide be more precise and takes the following approach to enhance interoperability: The reports shall be shared by IIG in both of the following formats: ** CDA Imaging Report with Structured Headings ** XDS-SD (PDF Option: CDA header with a PDF/A body) The reports shall be accessed by IRG in either one or both of the following formats: ** CDA Imaging Report with Structured Headings ** XDS-SD (PDF Option: CDA header with a PDF/A body) In both cases, the approach to reference images from within the report in either form shall follow the requirements stated in Section IHE RAD TF Vol 3: 4.684.68.4.1.2.2 Sharing of Report. The rationale for the above approach is: * To keep the complexity acceptable for most sources of imaging reports * Offer the flexibility for consumer systems of reports with both a "ready to print" report and a minimally structured report that can be reduced to text for	Radiology reports can be handled by the document-based queries and can be exchanged under the Query-Based Document Exchange IG that the Image Exchange IG supplements. However, these comments provide good suggestions for discussion with the implementers to determine how/if they should be described more explicitly in the final published implementation guide.
39	Philips	Reports	Radiology would benefit from access to raw DICOM data and reports	Ironically, image interpretation regularly requires access to historical data and would greatly benefit from better digital exchange capabilities. Additionally, while the data sets can indeed be very large, the interoperability need is relatively simple. While clinical data often needs to be transformed, normalized and deduplicated to be useful, the imaging departments are looking for original, RAW data (DICOM format) and text based reports to enable most of their departmental workflows. Through XCA and the imaging extension XCA-I, both of these types of data can be exchanged across system boundaries. While there is rarely a need to print film in radiology and cardiology anymore, there is still a lot of CD/DVDs burned with many patients subsequently required to secure them and transport them. Using these proven web technologies to securely exchange this data has the potential to replace this process both fostering better provider and patient satisfaction and facilitating more advanced departmental workflows.	This comment is supportive of the program and does not suggest any edits/additions.

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1	Submitter	Category Type: 75	Summary Comment	Actual Comment	FINAL Response: Yellow highlighted items require follow up with Image Sharing Use Case Implementers.
40	Canon	Retrieve data	States that the client will connect to provided endpoint. This is getting away from the gateway model. Kevin wants a point to point solution.	Retrieve Imaging Data: For the desired records in the query return, connect to the provided endpoint and retrieve	It appears you are suggesting that a responding system which actually has the data (not the Responding Imaging Gateway) would publish an endpoint and that client systems would connect directly to that endpoint. The Image Exchange Implementation Guide is silent about what happens behind the gateway to retrieve the images to exchange via the gateway. Implementers can choose their own methodology for the last mile transfer. The existing Carequality framework leverages an initiating and responding gateway model. End systems communicate with gateways, although an implementer has architectural discretion for the number of gateways it supports and how many end systems a gateway serves. If the implementers wish to put constraints on this discretion, other details can be added as needed.
41	Epic	Testing	Systems sending images should validate images before sending them. This requires some thought and follow up questions. A site that originates CDA files might have a limited number of applications that create documents, making CDA validation easier. A large site may have many modalities, and task of validating content from each modality could be daunting.	Require DICOM validation We recommend the IG include an expectation that systems responding to a query complete DICOM validation prior to sending imaging studies. A similar conformance expectation exists in document exchange workflows. Requiring validation prior to exchange will result in higher quality data exchange, thereby reducing the storage and bandwidth footprint of image exchange while simultaneously improving clinician experience. Carequality should also consider a governance/arbitration process for actors consistently exchanging poor quality data.	This is not part of the Image Sharing IG Supplement but could be considered as part of implementation / onboarding process. Carequality is in process of defining a similar process for requiring validation of the C-CDA document content. This will be discussed with the implementers to determine if language shall be added. DICOM validation differs from CDA validation in one regard. An imaging center at a larger institution might have 10-20 sources of DICOM data. That same institution might have a much smaller number of systems that produce CDA documents. We recognize that there can be different types of CDA documents, so that is similar to multiple imaging modalities. There are likely more potential sources of poorly formatted files/content on the imaging side.
42	Epic	Architecture	Consider the use of async operations because limiting to only synchronous operations may be a huge performance issue.	Distinguish between asynchronous and synchronous directory endpoints Section 8.7.5 prohibits Initiating Imaging Gateways from using the Asynchronous Web Services Exchange option of the XCA-I integration profile. This restriction makes sense within the context of the current Carequality network because the Carequality directory does not distinguish between synchronous and asynchronous endpoints, which would pose an interoperability problem if the prohibition were not in place. However, we have observed significant performance and scalability challenges with the use of synchronous communication, particularly when retrieving CDA documents, and are concerned that these challenges will worsen with the additional traffic introduced by image exchange. We have found that asynchronous communication greatly improves scalability, and meets the needs of the largest healthcare organizations. Therefore, we recommend that Carequality enhance its directory infrastructure to allow differentiation between synchronous and asynchronous endpoints. Initiating Imaging Gateways should then be permitted to choose to initiate asynchronous communication to a system with an endpoint that is known to support it.	Implementers will start with the synchronous use case first, and async options can be considered for a future version. This comment will be discussed with the image exchange use case implementers to determine an appropriate timeline.
43	Canon	Consent	Consent at site A means consent given at site B	Communicate Consent: Need to make Site A aware of the consent given by the patient at Site B so Site A allows access to Site B	The updated image exchange implementation guide merged gateway actors. This should help with the consent issues. The Carequality Query Based, Document Exchange Implementation Guide discusses consent in section 8.2.5 Asserting Policies and Policy Instance.
44	Canon	Consent	Proposes IHE XUA or is stating IHE XUA is what is used. Not sure	Communicate Consent: Carequality proposal – IHE XUA with Authz-Consent Option	This will be reviewed by the implementers to determine if amendments to the current use of IHE XUA should be socialized with the current Carequality practice.
45	Canon	KOS Objects	Big lift for XCA Responding Gateway if that infrastructure is not already in place.	I think this is part of the point that Kinson was making. The assumption is that the Responding Gateway will return the XDS-I.b KOS objects. If it is not an XDS-I.b enabled community, then it becomes a pretty big lift for the gateway to instantiate a mirror repository of KOS instances.	The architecture design in the updated implementation guide published December 2019 was changed slightly to combine the Initiating Gateway and Initiating Imaging Gateway actors into a single actor and to combine the Responding Gateway and Responding Imaging Gateway actors into a single actor. Making a single Responding Gateway that combines returning KOS objects and referenced images should simplify this.
46	GE	Reference	Review requirement for 2010 versions of profiles	Query-Based Document Exchange Implementation Guide specifies 2010 versions of IHE profiles, will these be updated to a more current version?	A migration to newer IHE profile versions has not been prioritized by Carequality's Query-Based Document Exchange Implementers, although some elements from future versions have been added as Carequality constraints/clarifications. A migration to newer versions can be completed if prioritized.
47	MITA	Reference	Review requirement for 2010 versions of profiles	In section 8, there are references that specify 2010 versions of IHE profiles. Will these be updated to a more current version? What is the planned frequency of IG updates to reflect applicable change proposals?	A migration to newer IHE profile versions has not been prioritized by Carequality's Query-Based Document Exchange Implementers, although some elements from future versions have been added as Carequality constraints/clarifications. A migration to newer versions can be completed if prioritized.
48	Epic	Requirements	Clarify requirements on Responding Imaging Gateway. Do they need to support all of XCA-I or just the RAD-75 transaction that comes from the Initiating Imaging Gateway?	Clarify community and actor obligations (Regarding open issue Imaging-004) The XCA-I integration profile, unlike XCA, assumes that the XCA-I gateway actors will be deployed in XDS-I.b communities and are thus required to support the transactions appropriate for that deployment mode. We believe that this is an unnecessary assumption for the purposes of the proposed IG. If Carequality does not intend to carry on that assumption then it should explicitly note that the Imaging Query Initiator and Imaging Query Responder actors are only required to support the RAD-75 transaction from the XCA-I integration profile.	This comment will be discussed with the implementers to determine if improvements should be made to the Draft IG published December 2019. We will work with the early adopter implementers to clarify requirements on Responding Imaging Gateway, including whether image exchange use case implementers need to support all of XCA-I or just the RAD-75 transaction that comes from the Initiating Imaging Gateway.
49	Epic	Use case	Physicians are afraid that they have to take the time to identify key images in order to participate. This is false. All you need is to have an index of images. This index might not actually be the key images; it might include key as well as other images.	Clarify applicability of key object selection requirement A common misconception we have encountered in our support of image exchange is the need for participants to indicate key images in their imaging workflows. In particular, some organizations may operate under the incorrect assumption that they need to use key images to participate in exchange. We anticipate that Carequality may encounter misconception as connected sites examine its implementation guide. To address this misconception, we recommend that Carequality clarify the need for key images in its implementation guide. Specifically, it should clarify that clinicians do not need to indicate key images in their workflow to participate in exchange. Rather, it should state that participants only need to make an index of available images accessible using the key objects selection document format. The implementation guide should explicitly state that such a key object selection document may include items that are not key images, while still being acceptable for use in image exchange workflows.	Carequality understands the need for this clarification. We will discuss with the implementers to determine how best to provide it.
50	GE	Testing	Include IHE Connectathon testing	We would like to see thorough testing at an IHE connectathon included as an option for "non-production test" in Section 6.	Carequality will take this suggestion into consideration and will bring this topic up for future implementers to discuss.

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	Submitter	Category Type: 75	Summary Comment	Actual Comment	FINAL Response: Yellow highlighted items require follow up with Image Sharing Use Case Implementers.
51	MITA	Testing	Clarify requirements for non-production testing. Include testing at an IHE connectathon	"Non-production test" is defined in section 7 of the Imaging Data Exchange Implementation Guide, but details about the process are not clarified. Do the production test and ongoing validation also apply as specified in the Query-Based Document Exchange Implementation Guide? We would like to suggest that testing at an IHE connectathon be included as an option.	Carequality will take this suggestion into consideration and will bring this topic up for future implementers to discuss.
52	MITA	Marketing	Create a collective body to promote and drive demand	MITA urges Carequality to organize a forum (or other collective body) of health systems that "pull" information (e.g. cancer treatment centers, high acuity cardiac centers, etc.) and potential sources of patient referrals to drive demand for the image share offering. This would help to ensure a more successful adoption of the program.	Carequality will work with RSNA and the implementers to brainstorm on specific outreach to increase the adoption of the image exchange use case to improve patient care.
53	Charles Parisot	Editorial		Page 11 Section 8.7.2.XCA Gateway Requirements Correct as follows: CONF-10xx: An Initiating Gateway MUST support the metadata requirements for the DICOM KOS document defined in IHE RAD TF Vol 3: 4.68. CONF-10xx:A Responding Gateway MUST support the metadata requirements for the DICOM KOS document defined in IHE RAD TF Vol 3: 4.68	These updates were made to the draft IG published 12/2019. Carequality will verify with implementers that no further references should be made and that these are agreed upon by consensus.
54	Canon	Editorial		Editorial for Query Based Doc Exchange: Retitle 5.2 - the content is consistent about scope/scale of connectivity but doesn't seem to measure seamless-ness. Retitle 5.3 - covers the operational performance metrics but doesn't really have any "interoperability metrics" like consistency of codesets, etc. Would be good to add as a separate section. :-)	Carequality is currently evaluating its measures and expects to publish updates later in 2020.
55	Canon	Editorial		5.3 asks for the number of queries, not the number of documents so this paragraph is not relevant. If you do want to count documents, that matches closer to instances than studies.	Carequality is currently evaluating its measures and expects to publish updates later in 2020.
56	Canon	Editorial / Musing	Carequality uses IHE XCPD	Match Patient: Carequality proposal – IHE XCPD	Carequality leverages IHE XCPD to allow network gateways to perform patient matching. Record Locator Services can also assist with this workflow.
57	Canon	Editorial / Musing	Overview statement	Find Relevant Imaging Data: Need to identify relevant imaging data for the Patient	This seems to be narrative and not a specific question.
58	Canon	Editorial / Musing	Statement: XCA to get XDS-I imaging document manifest.	Find Relevant Imaging Data: Carequality proposal – SOAP-based XCA query to get XDS-I imaging manifests for Patient	This seems to be narrative and not a specific question.
59	Canon	Editorial / Musing	Statement: XCA-I retrieve	Retrieve Imaging Data: Carequality proposal – SOAP-based XCA-I retrieve (RAD-75)	This seems to be narrative and not a specific question.
60	Charles Parisot	General	Supportive of approach	Page 11 and 12, Sections 8.7.2 XCA Gateway Requirements and 8.7.3 XCA-I Gateway Requirements The answers to the section 9.0 Questions and Issues are sound.	Thank you for this feedback and support, it is helpful.
61	Epic	General	Supportive of approach	Thank you for the opportunity to provide feedback on Carequality and RSNA's proposed Imaging Data Exchange Implementation Guide. As you know, Epic is an EHR vendor based in Verona, Wisconsin and a strong proponent of both interoperability and Carequality's efforts to advance it in the health IT industry. As part of our commitment to driving progress towards increased interoperability in healthcare, we have invested significant time and development effort in technology to facilitate the exchange of clinical imaging for our users that builds on the successes we've seen in the document exchange realm. It is this experience developing and supporting image exchange capabilities for our community that informs our feedback on Carequality's proposed implementation guide. We are happy to participate in ongoing discussions as Carequality continues the implementation guide development process. If you have any questions regarding our feedback, please contact info@epic.com.	Thank you for this feedback and support, it is helpful.
62	GE	General	Supportive of approach	We are supportive of the IHE profiles identified in the guide.	Thank you for this feedback and support, it is helpful.
63	Canon	General	Governance framework helpful	Governance Framework: Definitely helpful to have pre-arranged business agreements, PHI agreements, dispute resolution processes, etc. between sites that share imaging.	Thank you for this feedback and support, it is helpful.
64	Canon	General	Governance framework helpful	Governance Framework: Carequality proposal - https://carequality.org/governance/	This seems to be narrative and not specific input.
65	Canon	General	Governance framework helpful	Governance Framework: This seems pretty full-fledged and must have been a ton of work to get set up and get people to buy into. Can't imagine redoing this if you don't have to.	Thank you for this feedback and support, it is helpful.
66	Canon	General	Governance framework helpful	Governance Framework: Doesn't inherently commit you to a given technology platform.	Thank you or your feedback and support. This is a true statement. Carequality's trust framework was built to be technology agnostic.
67	Canon	General	Supportive of approach	Retrieve Imaging Data: XCA basically lets a local document consumer use its preferred local XDS Q/R transactions (ITI-18 & ITI-43) and introduces a pair of gateways that act as proxies for the remote document source using versions of ITI-18 & 43 with a homeCommunityId added (ITI-38 & ITI-39). A gateway strategy is sensible.	Thank you for this feedback and support, it is helpful.
68	Canon	General	Supportive of approach	Historically, since 1995, imaging data has been exchanged between healthcare sites digitally using CD media. In 2000, DICOM secure communication profiles specified how to use the DICOM protocol over the internet using internet security mechanisms. WADO, a DICOM protocol for web-based image transfers was introduced in 2004 and made fully RESTful in 2012, however adoption interest has been low until recently, ostensibly due to concerns about bandwidth. Fortunately, this seems to be changing.	Agree that innovation is changing the landscape. Thank you for your supportive comment.
69	LifImage	General	Supportive of approach	Life Image supports the RSNA / Carequality implementation guide and has been supporting the RSNA Image Share Project since inception. While the XCA-Gateway has been around for some time, without a larger framework, the proposed architecture is in our opinion insufficient to implement large-scale image sharing. A couple of relevant questions to that end:	Carequality thanks Life Image for being an early adopter of the Imaging Data Exchange IG.
70	LifImage	General	General	We are meeting internally to discuss the plan forward for the Sequoia Project Interoperability testing platform and will have a response to you by the end of the week.	Carequality thanks Life Image for being an early adopter of the Imaging Data Exchange IG.
71	MITA	General	Supportive of approach	We support the initial focus of the effort on the IHE profiles identified in the Imaging Data Exchange Implementation Guide. We recognize XCA-I is built upon XCA, which is deployed across thousands of institutions, small and large, in all US states, as well as in federal health delivery environments. The framework utilizes existing XCPD patient identification IGs, security, privacy, trust and on-boarding policies, and XCA-I is already adopted outside the US. This would initially support interoperability on a global scale.	Global interoperability is a long-term goal for Carequality. This is the reason Carequality chose to leverage the IHE International standards as a basis for interoperability to allow for this to be a reality in the future.
72	Philips	General	Supportive of approach	Philips would like to thank Carequality for taking a public step forward toward image interoperability in the United States and for giving us the opportunity to comment on draft version .1 of the Imaging Data Exchange Implementation Guide. In short, we enthusiastically support the effort and believe Carequality is taking the right, pragmatic approach given Carequality's existing technical framework by choosing XCA-I to enable the exchange of images across providers and communities.	Carequality thanks Philips for being an early adopter of the Imaging Data Exchange IG.

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73	Philips	General	XCA-I and XDS-I are widely adopted in Europe but not so well in the US	IHE and the XDS framework are a mature set of standards with a significant quantity of contributors and participants both in the United States and internationally. Even though IHE was started in the United States, some of the standards have not had great levels of adoption here in the while still proving to be highly effective around the world. The “-i” or “image” extensions to the exchange model under XDS are a great example of an under adopted set of standards here. Outside the US, many countries have successful, active XDS-i networks and/or XCA-i networks which enable cross community and national exchange using standard web technology.	Carequality is happy to support the IHE International standards to enable interoperability that will allow for ubiquitous access to data when and where it is needed to improve the patient care process.
74	Philips	General	Supportive of web based approach with DICOM images and not using a CD. This is not a comment in favor or against the choice of XCA-I	Philips is proud to support these standards and equally proud to be the underlying technology for some of the largest image exchanges systems in the world. For example, in the Canadian province of Ontario, almost all past images and reports produced throughout the entire province can be retrieved electronically – in their original, RAW format – over the web without ever having to produce or transport a CD/DVD. This implementation of open standards, as well as many installations worldwide, prove the technology works at scale and can be of great benefit to many workflows.	Carequality looks forward to achieving this same success in the US with the implementers of the image data exchange IG.
75	Philips	General	Supportive of web based approach with DICOM images and not using a CD. This is not a comment in favor or against the choice of XCA-I	Now that EHR adoption is high and we all seek greater adoption of data exchange in the support of the quadruple aim, there is potentially no better place to kick interoperability into the next gear than in healthcare imaging. Imaging started to convert from analog to digital in the 90s and was nearly 100% adopted by the end of the 2000s – well before many other clinical areas. Unfortunately, partly due to this early success, imaging was not a focus of Meaningful Use and such, it was also mostly left out of the interoperability discussion.	Carequality and RSNA agree. This was a goal of the collaboration between RSNA and Carequality to support the deployment of interoperable image exchange as a use case in the US.
76	Philips	General	XCA-I today with an eye toward evolving standards	We agree with you that this is not hard to achieve with the standards under the XCA-i profiles as they exist today. We look forward to working with Carequality and the overall healthcare community to leverage open standards and create a secure, low friction network method for image exchange nationwide. We also expect that as new, targeted use cases emerge and are implemented by participants in the network, the technology standards will evolve and we welcome proceeding on this journey with the rest of the connected healthcare community.	Carequality thanks Philips for being an early adopter of the Imaging Data Exchange IG.