



FHIR Use Case Proposal

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1 Use Case Background

As health data interoperability becomes an increasingly pressing concern for providers, developers and vendors are paying a great deal more attention to the data standards that will enable seamless, on-demand information exchange. The Fast Healthcare Interoperability Resource, commonly known as FHIR, is well on its way to becoming one of the most popular protocols for joining disparate systems together. It holds great promise for the development of an application-based approach to interoperability and health information exchange.

1.1 Use Case Name: FHIR-Based API Data Access

1.2 Contributors

Individual	Organization
Bill Mehegan	Carequality
Dave Cassel	Carequality

1.3 Vision

FHIR is a draft data standard developed and nurtured by HL7 International. It was created with the complexity of healthcare data in mind, and takes a modern, internet-based approach to connecting different discrete elements.

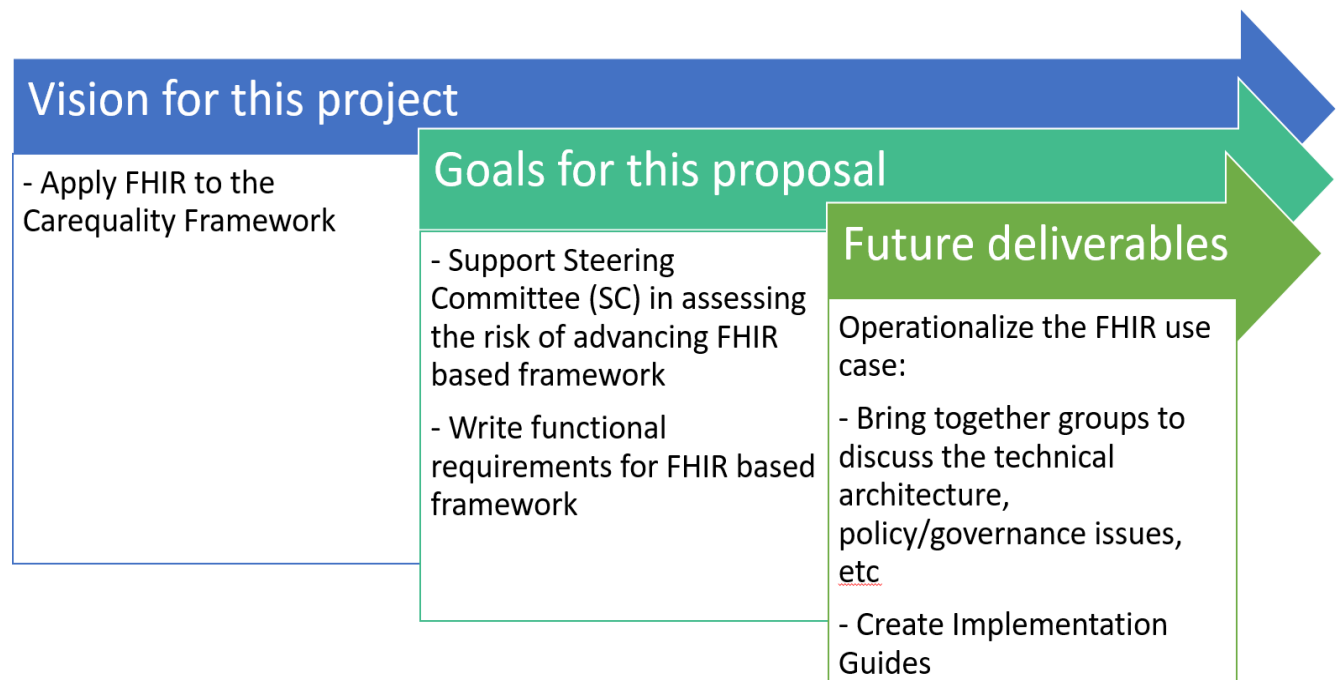
1.3.1 What is the problem being solved?

FHIR offers a number of new capabilities, relative to health information exchange that relies on SOAP web services to retrieve CDA documents. Data elements, or 'resources' each have a tag that acts as a unique identifier, just like the URL of a web page. These resources can be used to build chart elements, one data set at a time. For example, basic elements of healthcare like diagnostic reports and medications can each be retrieved and manipulated via their own resource URLs. This allows an end-user the flexibility of targeting specific chart data instead of having to sift through the whole chart to find what they are looking for. Where CDA documents remain valuable for particular workflows or information needs, the documents themselves can also be retrieved as FHIR resources. In general, FHIR aspires to provide a next-generation, evolutionary improvement over information retrieval via SOAP-based web services.

That said, from a health information exchange governance perspective, the use of FHIR does not represent a fundamental change. FHIR resources provide a newer, simpler, and arguably more flexible way to access data at a technical level, but still require a custodian of patient records to release PII in response to a request that arrives from the Internet. Such a release can only occur if the record holder has trust not only that it can accurately identify the requester, but that the request itself, and the requester's policies and practices around the information once it is released, are appropriate.

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Such trust is straightforward to establish for an individual connection between two partner organizations, by relying on new or existing contractual relationships bolstered by negotiation of security and other technical details. Such an approach is not scalable, however, as the healthcare industry discovered in the context of document exchange via SOAP-based web services. Carequality's governance framework can provide a "single on ramp" that allows an organization to sign one contract, implement one technical platform, and connect universally to a broad ecosystem of other participants.



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1.3.2 Glossary of Terms

Term	Definition
Data Source	In the interoperability world, data goes from point A to point B. The source is where the data is coming from. Relative to this document, a data source can be a Query Responder or a Push Initiator.
Data Receiver	In the interoperability world, data goes from point A to point B. The receiver is where the data is going to. Relative to this document, a data receiver can be a Query Initiator or a Push Recipient.
Record Locator Service	The Record Locator Service (RLS) provides the ability to identify where records are located based upon criteria such as a Person ID and/or record data type, as well as providing functionality for the ongoing maintenance of this location information.
Provider	A clinician or organization that is directly engaged in treatment services.
Patient	A person who is the subject of health records, or an authorized representative acting on such a person's behalf.
Transaction	Per the HL7 website ; an interaction that submits a set of actions to perform on a server as a single atomic action. Multiple actions on multiple resources of the same or different types may be submitted, and they may be a mix of other operations (e.g. read, search, create, update, delete, etc.)
Research	Work done to improve healthcare costs, outcomes, quality, safety, and innovation via systematic investigation and structured data analysis.

1.3.3 Roles

The following table outlines the specific value that Carequality would like to provide for organizations in specific FHIR data exchange roles. The overarching goal of any healthcare interoperability project is to improve outcomes, lower costs, and/or broadly improve overall population health. We believe that adoption of FHIR in the Carequality framework can advance all of these goals by dramatically expanding the scope of exchange, improving the availability of useable clinical information, and significantly lowering the costs of participating in interoperable exchange. On the table below, do not focus on reasons for various entities to be a part of health information exchange via FHIR, but rather, on the particular value that can be added by applying Carequality's governance framework in a FHIR setting for each entity.

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Role	Candidate Implementer?	Value of Carequality to this Role
Data Source	Yes	<ul style="list-style-type: none"> Data Sources could serve or be any stakeholder group (see table in section 1.3.4 below), but some of the Carequality value proposition is common to any Data Source, regardless of the stakeholder, workflow, or data access need being addressed. Data Sources generally have a value proposition to be gained by allowing other parties to access the data it holds or can provide. Data Sources generally have a fundamental responsibility to maintain its privacy and security. The one exception to this rule is the patient, who nonetheless will typically have a strong desire to maintain the privacy of his/her data. As a result, holders of data have a need to determine if a particular request or destination for the data should be trusted, with data ultimately released/sent. The Carequality Framework allows these entities to sign one contract that binds a large ecosystem of data Receivers to a known trust mechanism. There is no need for individual contracting and negotiation with each party. Data Sources should have a need on the Receiver side to support the Source's API, and accompanying security approaches and infrastructure. In the absence of a governing Framework, they are on their own to identify the best implementation of standards (typically, resource definitions) and incentivize Receivers to adopt their variant of any resources needed. The Carequality Framework, by identifying the resource definitions to be used, takes away this unknown/risk and allows the Data Source to minimize costs involved in accommodating multiple versions/variants.
Data Receiver	Yes	<ul style="list-style-type: none"> Data Receivers could serve or be any stakeholder group (see table in section 1.3.4 below), but some of the Carequality value proposition is common to any Data Receiver, regardless of the stakeholder, workflow, or data access need being addressed. Data Receivers generally have a value proposition to be gained by accessing information held by other parties. Data Receivers should have a need to establish trust with those who are holders of data, as noted above in the Source section. There is a strong on the Receiver side in having the Carequality Framework provide a single mechanism (both contractual and technical) for doing so with many different sources of data in one step. Data Receivers should also see strong value in having a single set of technical specs (including resource definitions, but also any supporting infrastructure) that they can be confident will allow access into a large number of Data Sources without custom development for each Source. The Carequality Framework, by identifying the resource definitions to be used, allows these entities on the Receiver side to greatly minimize costs involved in accommodating multiple versions/variants that would otherwise likely be needed to connect to a broad array of different source systems.
Record Locator Service	Yes	<ul style="list-style-type: none"> Record Locator Services could serve multiple stakeholder groups (see table in section 1.3.4 below), but some of the Carequality value proposition is common to any Record Locator Service, regardless of the stakeholder, workflow, or data access need being addressed. Record Locator Services generally should have some value proposition to be gained by providing record location information to those who need to access a patient's complete health story. Typically, this value proposition is of a commercial nature; the

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Role	Candidate Implementer?	Value of Carequality to this Role
		<p>Record Locator Service has invested in compiling information that others need, and should be willing to pay to access. Other underlying rationales could exist, however.</p> <ul style="list-style-type: none">Record Locator Services should want to make its service as easily accessible as possible, to as large an audience as possible. Providing a service within the context of a widely-adopted exchange ecosystem like Carequality's can help on both these fronts.Record Locator Services are also a holder of data, and should have similar considerations to entities in the Data Source role with respect to the need to determine if a particular request or destination for the data should be trusted, with data ultimately released/sent. The Carequality Framework allows these entities to sign one contract that binds a large ecosystem of data Receivers to a known trust mechanism. There is no need for individual contracting and negotiation with each party, individually.

1.3.4 Stakeholders

The following table outlines the specific value that Carequality would like to provide for particular stakeholder groups. There may be significant value that is not specific to a particular stakeholder group, and would be realized by anyone in a particular data exchange role as outlined above in Section 1.3.3. In some cases, however, a stakeholder group may see particular value from Carequality's governance framework in a FHIR setting, and the table attempts to identify these cases. As in the above Role table in Section 1.3.3, we are narrowly addressing the value that the stakeholder group would ideally receive from Carequality playing a governance role. We are not addressing the value of health information exchange in general, or specifically using FHIR, to that stakeholder group.

Stakeholder	Role stakeholder plays in the use case	Candidate Implementer?	Value Proposition to the stakeholder
Healthcare IT Vendors	Data Source / Data Receiver / Record Locator Service	Yes	<ul style="list-style-type: none">Healthcare IT vendors generally see the value propositions as described above for Data Sources/Receivers, but will likely see these value propositions magnified, relative to other stakeholders.Healthcare IT vendors typically support many different clients (of various stakeholder groups, depending on the vendor's market) nationwide. These clients will have a wide variety of different data exchange needs, with a potentially vast number of other parties. Each client individually, especially if it is a small organization, may see real but modest benefits from the Carequality Framework. Cumulatively across a vendor's whole client base, however, the benefits afforded by the Carequality Framework can provide significant reductions in the costs not only to develop and maintain different connections, but also to discuss and analyze such connections.

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Stakeholder	Role stakeholder plays in the use case	Candidate Implementer?	Value Proposition to the stakeholder
Patients	Data Source / Data Receiver	No	<ul style="list-style-type: none"> Patients should see the value propositions described above for Data Source/Receiver, in particular on the Data Receiver side. Patients should still have limited market power in healthcare relative to many other industries. As a result, it is critical for patients, and the apps that support their data exchange needs, to have the ability to participate in data exchange without requiring much special effort from other stakeholders. Taking advantage of the standardization afforded by the Carequality Framework, and specifically allowing patients to benefit from investments already made by other stakeholders based on other value propositions to those stakeholders, should significantly increase patient access into health data exchange. Patients in niche groups, e.g. those with a specific condition, could be strongly affected. Data Sources/Receivers serving such niche groups should be more likely to find a successful business model if they can lower their development costs, as the Carequality Framework could support. There is a cost lowering value for the entity that is supplying the patient with the with ability (typically via an app) to play the Data Receiver role. Over time, greater access to information should result in more apps being developed to provide patients with more independent action capabilities, presenting opportunities to lower costs for all stakeholders across healthcare.
Provider	Data Source / Data Receiver	No	<ul style="list-style-type: none"> Providers should largely see the benefits as described in the Data Source/Receiver sections above. Providers, like all stakeholders, are likely to benefit due to the fact that greater access to data enables innovation and cost savings. Providers should be able to move the needle on improving patient outcomes and the overall health of the population by giving them improved access to relevant data.
Payers	Data Source / Data Receiver	Yes	<ul style="list-style-type: none"> Payers should see the benefits as described in the Data Source/Receiver sections above. Payers should also have a strong secondary value from broad participation by lots of different stakeholders, as generally improved data liquidity should open opportunities for innovation and lowered costs, as noted above for Patients. The more that the Carequality Framework enables participation by all relevant stakeholders who might play a role in reducing

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Stakeholder	Role stakeholder plays in the use case	Candidate Implementer?	Value Proposition to the stakeholder
			costs, improving patient outcomes, and the overall health of the population, the more value payers are likely to see.
Public Health	Data Source / Data Receiver	Yes	<ul style="list-style-type: none"> Public Health services should see the benefits as described in the Data Source/Receiver sections above. In addition to the general benefits as described for any Data Source/Receiver, these types of services can have a particularly strong benefit to the overall health of communities across the country. The more that the Carequality Framework fosters participation in a common health data exchange community by a broad and deep set of players, the more sources of information are available to Public Health services. The more data these services can access, the more value they can provide to the public communities.
Benefit Providers (e.g. Social Security Administration Benefit Eligibility Information)	Data Source / Data Receiver	Yes	<ul style="list-style-type: none"> Benefit Providers services should see the benefits as described in the Data Source/Receiver sections above. In addition to the general benefits as described for any Data Source/Receiver, these types of services have a particularly strong benefit from widespread access to data. The more that the Carequality Framework fosters participation in a common health data exchange community by a broad and deep set of players, the more sources of information are available to Benefit Providers services. The more data these services can access through a single framework like Carequality's, in an automated fashion, the less they need to pursue in more manual, paper-based methods that add time and expense into the Benefit Provider's processes.
Population Health Services / Analytics	Data Source / Data Receiver	Yes	<ul style="list-style-type: none"> Pop Health and Analytics services should see the benefits as described in the Data Source/Receivers sections above. In addition to the general benefits as described for any Data Source/Receiver, these types of services have a particularly strong benefit from widespread access to data. The more that the Carequality Framework fosters participation in a common health data exchange community by a broad and deep set of players, the more sources of information are available to Pop Health and Analytics services. The more data these services can access, the more value they can provide to their customers.
Research	Data Source / Data Receiver	Yes	<ul style="list-style-type: none"> Research services should see the benefits as described in the Data Source/Receivers sections above. In addition to the general benefits, these types of services have a particularly strong benefit from widespread access to data. The more that the Carequality Framework fosters

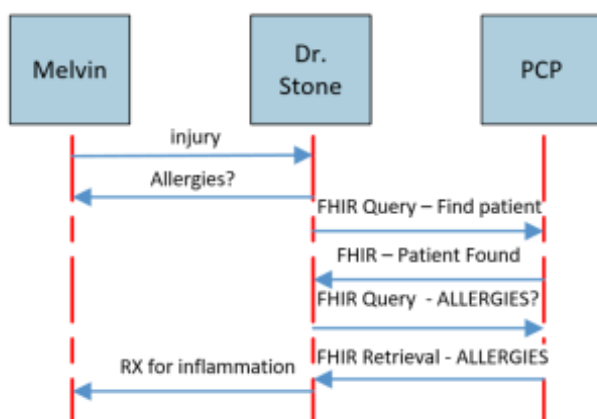
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Stakeholder	Role stakeholder plays in the use case	Candidate Implementer?	Value Proposition to the stakeholder
			participation in a common health data exchange community by a broad and deep set of players, the more sources of information are available to Research services. The more data these services can access, the greater the chance for innovation leading to improved patient outcomes and the overall health of the population.

1.3.5 Vignettes – Helping to Tell the FHIR Story

Vignette 1: Improve Outcome

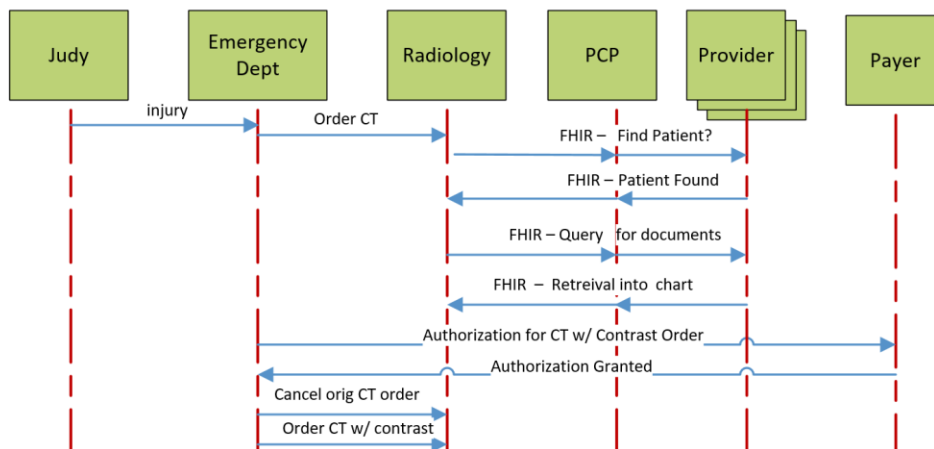
Melvin is a 56-year-old male with who lives with his family in the Bronx, New York. Every summer, they visit Melvin’s parents in Grady, South Carolina for a week-long vacation. Grady is a very rural town with a small hospital. While Melvin is visiting, he injures his shoulder and goes to the Grady Hospital & Clinic for treatment. While he is there, he meets with Dr. Ben Stone, who properly diagnoses the minor injury and initially wants to prescribe Melvin some Naproxen to help with his inflamed shoulder. Dr Stone asks Melvin if he is allergic to any medications as part of his diagnosis. Melvin states that he believes he’s allergic to something, but cannot recall the name of the drug. Melvin gives Dr. Stone the name and location of his Primary Care Physician, who would have this data in his chart. Both Grady Hospital and the PCP are with vendors who are Carequality implementers and FHIR capable. Dr. Stone does a quick query on his EHR tablet and is able to pull the allergy information (including the fact that Melvin is allergic to Naproxen) into the local Grady chart. Dr Stone, now armed with this new information, prescribes an alternative medicine that Melvin is not allergic to. A possible adverse outcome is avoided and Melvin is able to enjoy the rest of his family vacation.



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Vignette 2: Lower Cost

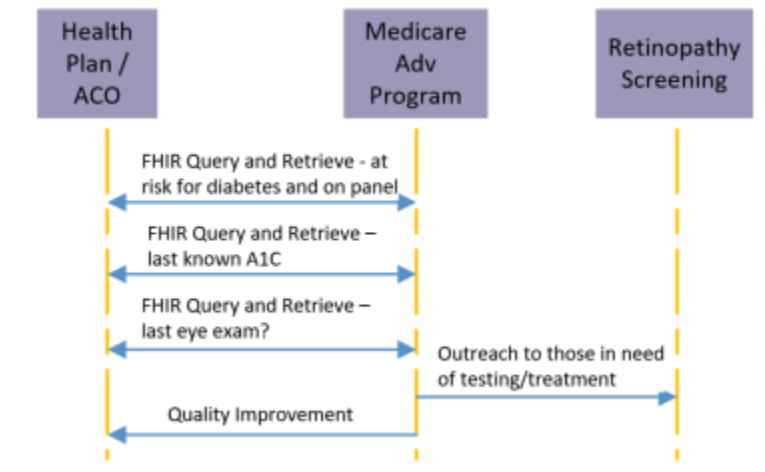
Judy is a 57 year old woman that comes into the Chicago Medical Emergency Department because she slipped and fell on the ice. She is alert and answering questions. She has a serious mid-back contusion and a thoracic spine CT scan without contrast is initially ordered to evaluate the trauma. Down in the radiology department, the radiologist inquires about past surgeries and metal implants. Judy reveals to the radiologist that she had a previous back surgery and gives the radiologist the name and location of her Primary Care Physician. Judy also gives the names of other providers who have treated her over the years. The radiologist then utilizes the FHIR Directory to see what providers are part of the Carequality framework. The radiologist gets a couple of hits on these searches and proceeds to see what documents and other clinical data are available for the patient. The radiologist retrieves all of the relevant data for the patient and confirms the details of the previous back surgery. Due to that surgery, the study would need to be performed with contrast in order to be interpreted correctly. The hospital gets authorization from the payer for the study, while the physician is subsequently able to cancel the original order, and put the proper order into the system. A potentially wasteful test is avoided, quality of care is improved, resulting in time and money saved for the patient, provider, and payer.



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Vignette 3: Quality Improvement

A health plan / ACO, i.e., an at-risk healthcare entity, contracted with an analytics company that is using a FHIR-based analytics app to analyze data for members of its Medicare Advantage Plan for a value-based care initiative. As a covered entity, the analytics company is subject to the privacy and security requirements of a "Business Associate" defined under HIPAA and authorized to retrieve PHI for Healthcare Operations permitted purposes. The FHIR app deployed targeted queries to collect both the last known A1C levels and the date of the last eye exam for the panel of patients identified per the quality measure specification. The health plan / ACO was able to stratify the data obtained using the FHIR queries, identify the highest risk patients based on diabetes control levels, and reach out to those who should be screened for early signs of diabetic retinopathy. The FHIR-based app allowed the health plan / ACO to manage their at-risk patients using a strategically limited set of data. This enabled the health plan / ACO to identify and intervene on behalf of patients at-risk, resulting in improved care for the patient, and quality performance for the health plan / ACO.



1.3.6 Where would this solution be positioned relative to complementary industry initiatives?

1.3.6.1 Enabling Initiatives

The Argonaut Project is a private sector initiative to advance industry adoption of modern, open interoperability standards. The purpose of the Argonaut Project is to rapidly develop a first-generation FHIR-based API and Core Data Services specification to enable expanded information sharing for electronic health records and other health information technology based on Internet standards and architectural patterns and styles. This effort follows on recommendations from the Joint HIT Standards and Policy Committee's [JASON Task Force Report](#), the HIT Standards Committee's [NwHIN Power Team](#), the MITRE JASON Reports of [2013](#) and [2014](#), and the [2010 PCAST Report](#).

SMART Health IT is an open, standards based technology platform that enables innovators to create apps that seamlessly and securely run across the healthcare system. Using an electronic health record (EHR) system or data warehouse that supports the SMART standard, patients, doctors, and healthcare practitioners can draw on this library of apps to improve clinical care, research, and public health. SMART on FHIR addresses the needs of

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end users and data Sources/Receivers while providing an open-standards-based platform that aligns with the needs of clinical system vendors.

DirectTrust is a collaborative non-profit alliance of 123 healthcare organizations whose common goal is to accelerate the adoption of interoperable health information exchange with a focus on Direct. DirectTrust serves as the membership, policy and governance body for a vibrant community of Direct exchange participants, who have voluntarily established a Security and Trust Framework that serves as the “rules of the road” for Direct exchange. The Framework prescribes the technical, legal, security, and identity policies and practices that all members of the community agree to follow. Carequality will be tracking DirectTrust Framework progress as it relates to security around FHIR based transactions (more specifically, PKI certs) and possibly incorporate any advances in this realm into our offering.

Carequality is involved in many healthcare initiatives throughout the healthcare industry, while at the same time, participating in them. Carequality participates in the CARIN Alliance, which is a bi-partisan, multi-sector group formed to help advance the adoption of receiver-directed exchange across the healthcare industry. Additionally, Carequality is a member of HL7 and we’ll be tracking the Da Vinci Project’s progress, especially as it relates to FHIR and how payers can utilize this standard to help enhance their offering.

Healthcare delivery is dynamic and rapidly evolving. There are ranges of standards, technology platforms, and capabilities within the current healthcare IT ecosystem that support healthcare organizations in communicating emergent situations and sending and requesting electronic health information. Previous HL7 standards were not a perfect solution, but they did meet the basic needs of the healthcare industry. The industry has sought to develop a newer standard that incorporates the best of HL7 while solving concerns that have cropped up throughout its lifecycle. FHIR is still in its infancy and there is still work to be done before the industry will recognize it as the latest standard. But the healthcare industry is definitely progressing towards adding FHIR based exchange to their HL7 repertoire. We should therefore be prepared to deploy the necessary framework that will allow our implementers to reap the benefits that will come with utilizing FHIR.

Technology

What started as HL7’s Project Argonaut [and its set of implementation guides](#), has evolved into US Core. The US Core Implementation Guide is based on [FHIR Version 3.0.1](#) and defines the minimum conformance requirements for accessing patient data as defined by the Argonaut pilot implementations and the ONC 2015 Edition Common Clinical Data Set (CCDS). These profiles are intended to be the foundation for future US Realm FHIR implementation guides. In addition to Argonaut, they are used by DAF-Research, QI-Core, and CIMI. Under the guidance of HL7 and the HL7 US Realm Steering Committee, the content will expand in future versions to meet the needs specific to the US Realm.

The future of FHIR is expected to be an evolving one because of the nature of it being open source. FHIR must remain adaptable as trends and standards evolve. As the standard grows, we expect more features that aren’t really standardized in any kind of way, [such as compartments](#) (ways to find all associated resources given one resource) will become normalized.

Programs and Policies

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[Health Level Seven \(HL7\)](#) has been developing healthcare information exchange and related standards since 1987. In that time, the organization has produced a number of standards families - many used throughout the world to automate healthcare data sharing and improve patient care. FHIR has been written to be implementable without any knowledge of these other specifications. However, FHIR does leverage this prior experience, both in terms of applying best practices learned from experience and attempting to avoid some of the pitfalls of earlier work.

1.3.6.2 Competing Initiatives

FHIR can satisfy the needs covered by all of the previous primary HL7 interoperability standards ([HL7 v2](#), [HL7 v3](#) and CDA). In many cases, it also provides additional benefits in terms of ease of interoperability. Therefore, the possibility exists that FHIR could gradually replace some or all of these standards. It's also very likely that most of these standards will exist in parallel for quite some time. HL7 has committed to ongoing maintenance of existing standards for as long as the HL7 membership requires.

2 Use Case Context

2.1 Issues

None.

2.1.1 Open Issues

None.

2.1.2 Closed Issues

None.

2.2 Functional and Nonfunctional Requirements

The solution provided by Carequality must:

- 1) Support, at a minimum, the Permitted Purposes for Trusted Exchange as outlined in [the TEFCFA](#). There are currently 6 Permitted Purposes and they are noted in items (a) through (f) below. Please note, the list will be amended should the TEFCFA Permitted Purposes change in the future.
 - a. Treatment
 - b. Payment
 - c. Health Care Operations
 - d. Individual Access
 - e. Public Health
 - f. Benefits Determination
- 2) Provide a standard mechanism for implementers to discover which other implementers support FHIR-based transactions, and for determining which resources each implementer supports.

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- a. The Carequality Directory is a logical mechanism to be considered, and other solutions should be adopted only with compelling evidence that the Carequality Directory is not, and can't reasonably be enhanced to be, sufficient.
 - b. [The FHIR Capability Statement](#) is a logical mechanism to be considered for determining what resources are supported, and an approach for facilitating its use through the Carequality Directory, if necessary, should be considered.
- 3) Establish a consistent, industry-standard technical security approach that is able to accommodate various types of exchanges between various types of stakeholders, such that a single technical security approach is accessible to providers, consumer apps, payers, and other appropriate stakeholders.
 - a. The security mechanism should provide not only a means of establishing "basic" technical trust, as at the TLS level, but also a means of confirming that a transaction originates specifically from a valid Carequality participant who is covered under the Carequality governance framework.
- 4) Determine the degree to which access controls around the specific originating user, as opposed to an originating system, can or should be implemented. Provide for such user-level access controls if identified as necessary. Definition of such controls should include:
 - a. An authentication mechanism that identifies and authenticates the user.
 - b. Policies defining appropriate and inappropriate application of access controls, especially in the context of Carequality's non-discrimination principle.
 - c. Requirements for transaction audit logs.
- 5) Specify a role for a Query Responder including:
 - a. Any general technical capabilities that must be supported, independent of the resources that the Initiator supports, beyond the basic discovery, security, and user-level access control mechanisms described in the above requirements.
 - b. Policy requirements, including non-discrimination, relevant to the role, including in particular any obligations to respond based on attributes of the requester or their purpose.
- 6) Specify a role for a Query Initiator including:
 - a. Any general technical capabilities that must be supported, independent of the resources that the Responder supports, beyond the basic discovery, security, and user-level access control mechanisms described in the above requirements.
 - b. Policy requirements, including non-discrimination, relevant to the role.
- 7) Specify a role for a Push Initiator including:
 - a. Any general technical capabilities that must be supported, independent of the resources that the Recipient supports, beyond the basic discovery, security, and user-level access control mechanisms described in the above requirements.
 - b. Policy requirements, including non-discrimination, relevant to the role.
- 8) Specify a role for a Push Recipient including:
 - a. Any general technical capabilities that must be supported, independent of the resources that the Initiator supports, beyond the basic discovery, security, and user-level access control mechanisms described in the above requirements.
 - b. Policy requirements, including non-discrimination, relevant to the role.
- 9) Specify a role for a Record Locator Service (RLS) including:
 - a. Technical transactions used by entities in the Receiver role, to interact with the RLS, including identifying or defining FHIR resources that will provide the record location data.
 - b. Policy requirements unique to the RLS role, including considerations for secondary transactions, including queries, that the RLS provider might (or might not) be permitted to perform under the

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Carequality Framework. Moreover, these policy requirements should be consistent with those established for the Query Based Document Exchange model.

- 10) Define the Permitted Purposes for which a transaction may be initiated, including:
 - a. A common technical mechanism that shall be used to denote the permitted purpose for that transaction.
 - b. Policy requirements that must be met in order to legitimately claim each defined purpose, including, for example, such considerations as circumstances for consuming the data, type of user consuming the data, type of organization consuming the data (Note: that these considerations should be regarded only as examples, and that developing policy around permitted user or organization types is not meant to be inherently required for any permitted purpose definition.)
 - c. Non-discrimination policies specific to each defined purpose.
 - d. Any other relevant policy requirements that may be identified.
- 11) Support “plug and play” connectivity such that pre-coordination is not required for Data Sources and Data Receivers who support the same FHIR resource to exchange information
- 12) Provide a mechanism for defining/specifying/identifying which resources/profiles may be accessed under the Carequality Framework. This mechanism might be very broad, such as indicating that any resources conforming to FHIR versions x, y, etc. can be used, or might be very specific such as a list of resources defined by Carequality. An intermediate approach that points as much as possible to the work of others who are specifying resources/profiles, is preferred, as long as it is feasible.
- 13) Specify policy requirements around auditing of transactions.
- 14) Specify any additional policies needed to ensure that FHIR-based exchange is built upon and in harmony with [The Carequality Principles of Trust](#)

It should be noted that Carequality expects one or more Working Groups will be needed to develop all of the Requirements denoted in section 2.2 above.

2.3 Legal and Regulatory Considerations

21st Century Cures Act

One aim of the 21st Century Cures Act recently passed by Congress is to make digital health data more accessible, emphasizing the use of APIs in healthcare to increase EHR interoperability and improve patient records matching. Aligning closely with the SMART Health IT focus on creating a app ecosystem for healthcare, the Act states that a year from now, open APIs will be necessary for EHR system certification. The following passages are taken directly from the Act itself:

<https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf>

“[...] that the entity has in place data sharing programs or capabilities based on common data elements through such mechanisms as application programming interfaces without the requirement for vendor-specific interfaces;

[...] publish application programming interfaces and associated documentation, with respect to health information within such records, for search and indexing, semantic harmonization and vocabulary translation, and user interface applications;

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[...] demonstrate to the satisfaction of the Secretary that health information from such records are able to be exchanged, accessed, and used through the use of application programming interfaces without special effort, as authorized under applicable law.”

The healthcare industry appears to be leaning towards using FHIR as the technological backbone to the API functionality specifically called out in the Act. We therefore believe it would make sense to offer FHIR as another Use Case, in addition Query Based Document Exchange, to the Carequality framework.