Knowledge Artifact (KNART) Recommendations

Executive Summary of Recommendations

It is the recommendation of the study group that two projects be formed; one to continue to evolve the existing KNART specification, develop a common logical model that spans both the older KNART work and existing efforts in the FHIR Clinical Reasoning module, and the other to handle technical maintenance of the HeD representation. The first of these should also consider the relationship of HL7 defined clinical knowledge artifacts to efforts for defining types of knowledge artifacts, and standardizing their expression outside of the HL7 community. Ideally such work should include decoupling the definition of the expression language used inside the definition of a KNART from the KNART specification, following similar principles to the ones that already allow to use a variety of information models and terminology systems. There is a clear need to construct clinical knowledge artifacts that can both be composed of other knowledge artifacts and to package such artifacts in a common representational structure. The study group has also concluded that there is a need for knowledge artifacts in the health community to be able to interact with other artifacts created in other non-KNART representations (e.g. BPMN, CMMN, DMN, OWL, UML, etc). Many key technical objectives have been identified that should be addressed by a number of standardization efforts, some of which are clearly of medical importance while others clearly belong in the more general realm of knowledge management and are best handled by more general standards organizations such as OMG. The development of a consistent logical model to express the basic dynamics of knowledge artifacts, the various user viewpoints, and common action and event models that crosscut the various efforts in HL7 is seen as a significant potential benefit. The study group also recognizes that such a model would provide a useful bridge between evolving representational standards. Potential specific projects relating to this study include but are not limited to the following:

- updating said standard to include variable expression languages,
- the development of a generalized conceptual model that bridges various efforts relating to knowledge artifacts,
- the creation and/or adoption of a normalized logical model for actions and events, and profiling known logical models for classes of clinical activities and events.
- the development of common mechanisms and metaphors for composition and reference between artifacts, and
- development of mechanisms for supporting the co-evolution of different knowledge representation formats and their integration. [TODO: Added better lifecycle support for knowledge artifacts - e.g. authoring, governance, etc.]]

For immediate next steps, we recommend preparation of project scope statements to cover:

1. Conceptual Model
    - Composite / compound support
    - Map to FHIR
        - Consistent use of FHIR as a (semantic) information model in a KNART

        - Re-align with the FHIR community effort to standardize knowledge representation
    - Lifecycle support (Authoring, Governance, etc)

2. KNART Spec Update (HeD)
    - Support alternate expression representations
    - Composite / Compound Support
    - Change requests against existing spec (potentially an STU update rather than full ballot)
    - Bring up to date with the last version of CQL & ELM
    - Support for post-coordinated concept expressions

Introduction

This document comprises the deliverable for the project 1336, Composite KNART Investigation. During the period from May - September 2017, a project team was convened to review the current state of the KNART specification, explore additional use cases that have been identified (eg support for composition of knowledge artifacts), and recommend next steps for the specification.

This effort was sponsored by:

- Clinical Decision Support (primary)
- Clinical Quality Information
- Clinical Information Modeling Initiative

Project work items and links to call recordings and document repositories can be found on the CDS wiki at:

http://wiki.hl7.org/index.php?title=Composite_KNART_Investigation

Discussion and meeting notifications are distributed on the listserv:

knart@lists.hl7.org

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Background

Current Standard

The Clinical Decision Support Knowledge Artifact Specification, Release 1 (KNART) was initially published as a “Draft Standard for Trial Use DSTU”, (now referred to as STU), in July 2015. The specification was developed in support of the Standards & Interoperability (S & I) Framework Health eDecisions (HeD) Artifact Sharing Use Case. This use case focused on the support for the structure and encoding of knowledge artifacts for the purpose of exchanging knowledge in the form of event-driven clinical decision support rules, order sets and documentation templates. The specification has since undergone 3 STU Update releases and is currently at STU Release 1.3. The STU comment period for the specification expired in August 2017.

The specification can be obtained from the HL7 Standards Grid at

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=337

Related Initiatives

The FHIR Clinical Reasoning module (http://hl7.org/fhir/clinicalreasoning-module.html) includes knowledge artifacts as part of a larger scope, including the use of FHIR-compatible approaches to the representation of the artifacts, as well as the information processed by them. Due to ongoing maintenance of the specification, there is now a functional gap between the HeD KNART representation and the FHIR one. Some known differences are summarized in Appendix A.

Two major initiatives underway at the Object Management Group (OMG) are of direct interest to this effort. The API4KB (API for Knowledge Bases) effort is defining the process and semantics relating to knowledge artifact use in a domain and representation agnostic way, supporting a wide class of artifact types and representation languages. In addition there is an extensive effort OMG to identify the opportunities, gaps and best practices for applying BPMN (Business Process Modelling Notation), CMMN (Case Management Model and Notation), and DMN (Decision Model and Notation) in the healthcare domain.

The Clinical Information Modeling Initiative (CIMI) is developing a logical reference model for clinical content and an associated set of Detailed Clinical Models (DCMs) intended to fully specify clinical concepts and terminology.

Approach

The project team focused on reviewing use cases and goals from three perspectives: Clinical; Management, Administration and Governance; and Technical. Input from the current KNART authoring project at Veteran’s Affairs informed the discussion. That project is authoring knowledge artifacts that captures in a structured manner the knowledge captured in narrative form in clinical white papers. An example for chest pain was used to support the discussion and can be found in Appendix B.

Additionally, STU comments from initial authoring efforts were considered.

Use cases and goals

Clinical

Although the existing standard's support of order sets, documentation templates and rules can address many clinical needs, it has become apparent that being able to support composite collections of these atomic types will dramatically increase the functionality of the standard. Some of the use cases uncovered by this initial investigation are listed below, along with clinical examples:

- **Composing** a KNART from other KNARTs to support reuse. For example, a cardiology consult request that requires a documentation template to capture information regarding the patient's chest pain for the consult and an order set for orders (diagnostic and therapeutic) to be performed while the consult is pending. Another example would be a general clinical note documentation template composed of other, targeted documentation templates such as family history, tobacco cessation, etc.
- **Orchestrating** behavior between KNARTs to enable workflow sequencing reflective of clinical intent. For example, an endocrinology ECA rule for patients at hypoglycemic risk that coordinates documentation templates for endocrinology and orders to mitigate hypoglycemic risk. Extending on this example, another would be a composite KNART for electrophysiology that uses a documentation template to activate respective order sets and can be expanded to include other electrophysiology use cases by modifying the documentation template and adding order sets to the composite.
- **Chaining** artifact behavior through data, ensuring consistency. For example, a documentation template filled by a patient at home collects several pieces of information about a patient's behavior, including their smoking habits. Together with occupational health information already present in the record, the smoking habit data triggers an ECA rule that infers a substantial increase to the patient's risk for developing lung cancer. This rule then fires an event, which triggers another rule - a recommendation/reminder for the physician to discuss smoking cessation options at the patient's next visit.
- **Exposing** clinical intent to support appropriate use of KNARTs. Examples of this would be the prerequisite of hemodynamic stability to use a chest pain documentation template, or indicating the components of an osteoporosis screening guideline for women that may apply to men.
- **Expressing** a KNART at clinical, logical and implementation levels, including the ability to maintain information from a number of different perspectives (e.g. clinical, technical, operational, review, etc.). For example, capturing the behavior associated with the display of an orderable item in conjunction with the clinical rationale for that behavior.
- **Relating** various elements between KNARTs to support encapsulation by common elements. An example of this would be the clinical context for a composite KNART as the common context for all KNARTs contained within. For subcomponent KNARTs, the composite context is referenced and expanded upon for the specific subcomponent. Another example would be communicating information captured within a documentation template for use in an ECA rule or order set.

- **Identifying (and Resolving)** conflict between KNARTs, such as in a situation where a KNART recommends a teratogenic drug to a female patient, but another KNART recognizes that she has expressed a desire to become pregnant in the near future. Another example would be simultaneous membership by a patient in multiple patient cohorts with divergent objectives.

Known issues

There is a limited ability to express an artifact at various logical levels in the same physical package, and to express the logic at a given logical level in alternative - but conceptually equivalent - ways for consumption by different audiences. In other words, there is no unique evident way to create different levels of detail in an artifact, to separate the clinical intent from its technicab3dl implementation (e.g. determine whether a patient is diabetic, vs querying the patient's problem list for 'diabetes'), and the expression of certain parts of the artifact in human narrative, as opposed to structured XML, is difficult to add to the KNART. The decomposition between KNART vs an expression language (e.g. CQL) that can be 'stratified' goes in the right direction, but the emphasis is more on the 'how' logic is computed, rather than 'what' the intent is, and there is no easy way to focus on the latter other than using comments and naming conventions.

Management, Administration and Governance

The team evaluated knowledge artifacts in the broader context of the management, administration, and governance of their lifecycle. The scope of the lifecycle includes all steps from initial conceptual authoring of knowledge artifacts through to its eventual retirement or recall. While the existing specification provides basic metadata that is of general use is believed that a more detailed examination of the model is necessary to ensure that each stage in the artifact lifecycle has sufficient data and context. In addition, it is clear that adding the notion of a compound or composite knowledge artifact requires thorough review and likely enhancement.

The team identified a number specific management and governance issues around knowledge artifacts that it believes could be strengthened in future work. One such example is the development of a robust lifecycle model accompanied by clear understanding of context. Another major issue that should be explored is the nature of the associative couplings between artifacts and their effect on the governance and management process. It is desirable to support both loosely coupled and very tight bindings between artifacts and likely most of the continuum between. This provides both a useful mechanism and a unique challenge for management and governance. Mechanisms must exist that support the transparent adoption of knowledge artifacts into environments that require local substitutions to properly map to the context of use for that artifact. For example, the specific order sets used a particular hospital location (i.e. instance of a non-artifact) should be includable by abstract reference in a common shared artifact. Other use cases considered by the team include providence, integrity, search and retrieval, community sharing, community evaluation, digital rights management, update lifecycle, dynamic composition, versioning and version referencing, and conditional use.

1. Dynamic selection, composition and runtime deployment of KNARTs for a particular clinical context. Example: a rule may require the execution of a treatment order set for the management of a condition, but the actual set of orderables may vary by institution. There has to be a way to create loose dependencies between composable artifacts, and define if and how an artifact is safely customizable within the boundaries of the author's intent.
2. Ad hoc search and retrieval of artifacts of clinical interest, potentially for intra-organizational sharing and portability. Sharable artifacts are such that their content can be exposed by an institution, and acquired and understood by another institution.
   Furthermore, portable artifacts are such that the recipient institution can deploy and use them effectively in their setting.
3. Meet organizational demands which include: Timely updates of KNARTS for clinical review; identification of KNARTS requiring updates based on new evidence; and definition of runtime constraints to adhere to policy and regulatory requirements.
4. Management of KNARTs to ensure context of deployment is always appropriate to the original intent.
5. Versioning metadata to facilitate management, similar to terminology management. This is incredibly important in composition. If artifact A-v1 uses artifact B-v1, there is no guarantee that it will also be able to use B-v2 with no changes. This will sound familiar to software engineers, replacing 'artifact' with 'library'.

Known issues

The general intent of the metadata section in KNART is to make the most common use cases extremely simple. The trade-off is that other use cases may become complex. The metadata, including applicability, context of use, governance and provenance currently has a limited ability to structure the required contextual information.

'Knowledge Representation' serves two purposes: capturing faithfully, and formalizing, pieces of knowledge about a domain. The focus here is accuracy and expressiveness. Then 'Knowledge Reasoning' focuses on enabling a computer to make use of formally represented knowledge for computation.

When there is a gap between what needs to be represented, and what can be actionable on current technology implementations, a conflict necessarily arises. Often, it is either the case that (clinical) logic is downplayed for the sake of implementation, or very rich specifications are created that are not implementable.

The 'sweet spot' has yet to be found - and maybe there is not a sweet spot other than on a case by case basis.

For example: Decision Modeling Notation, has "solved" the problem by defining two 'profiles' - a 'naturalistic' one where the language focuses on capturing a decision process for human

reference, and an 'executable' one where the specification is constrained, and the technical details are added, to enable computers to implement decisions.

For composite knowledge artifacts, there is a need to define how the metadata context applies to the components of the composite, particularly in the case of dynamic composition.

An enhanced method of handling citations and references is required. The authoring team has suggested that the citation approach used by Docbook should be considered.

Technical

The analysis of the general clinical and governance use cases resulted in a number of clear technical requirements relating to the potential nature, capabilities, and structure of knowledge artifacts. At general technical level is clear that, from HL7 perspective, there is clear value in creating a common conceptual model of knowledge artifacts in the healthcare domain and how they can interact with knowledge artifacts and standards from outside the healthcare sphere. In addition, it becomes clear that the existing KNART standard is best classed as an implementation of the HeD model. At a technical level is desired that both the conceptual and physical specification of knowledge artifacts exhibit certain capabilities and constructs. Examples of these capabilities include the ability to compose knowledge artifacts from other knowledge artifacts. Such composition might or might not include explicit packaging of the related components into the same physical package. The packaging mechanism itself could either be considered a knowledge artifact in its own right or a convenience mechanism. In general it is recommended that any form of packaging include the essential knowledge artifact metadata to enable management of such assets.

- **Referencing:** Given that there is a requirement for the composite knowledge artifact to be able to be composed of separate discrete physical packages there is a technical requirement for a mechanism to provide intra-package references. Likewise there is a need for knowledge artifacts that reference or use in some manner other knowledge artifacts. The nature of such usage includes capabilities such as direct inclusion, templating, execution etc. In order to accomplish this, a general reference mechanism will be necessary, that supports ‘named’ or ‘typed’ references to express the nature of the relationship between artifacts. By implication there is also a need for a clear identification mechanism for knowledge artifacts that can locate them when they are either standalone or embedded within packaging mechanisms. Such identification information should include both the notion of concept identity, physical location, and the relationship with the human or semantic meaning.

  Broadly speaking there are a number of clear interrelationships between knowledge artifacts that should be captured in the overall metadata of any particular packaging of said artifacts. For technical purposes it may be useful to make a distinction between a composite and a compound; where a composite KNART is one where the referencing is not necessarily within the same physical package mechanism whereas a compound KNART is a composite KNART where all of the components are in the same physical package.

- **Context:** One of the clear desires when working with any form of composite KNART is the ability to establish the context(s) in which this knowledge artifact is intended to be used. This includes clinical context information as well as technical context

information such as the triggering events, dependencies, and expected inputs and outputs. The scope and nature of such contexts should be included in the conceptual model of knowledge artifacts.

- **Orchestration**: In looking at the general operational models for knowledge artifacts one clear use case is the ability to orchestrate the lifecycle of various knowledge artifacts. In the simplest case is nothing more than simple branching logic used when knowledge artifacts are executed. Execution is in this case only one of many possible states that should be identified in the general conceptual model relating to the lifecycle of a knowledge artifact. Not all knowledge artifacts are actually executed nor or all orchestration cases about the execution of a knowledge artifact. In the discussion and analysis relating to artifact behavior it has become clear that one requirement is the ability to dynamically compose the artifacts used in a particular context of execution. Arguably, orchestration logic could be considered a form of knowledge - especially when the orchestration is driven by clinical (workflow) considerations - for which there is no current proper artifact type (action groups are the closest concept, but they are inadequate to express complex orchestrations).

- **Granularity and User Context:** In the general analysis it also became clear that a particular knowledge artifact should be capable of encoding multiple logical levels of user presentation of the content of that artifact. In other words, an artifact should be able to express knowledge appropriate to a particular use perspective; for example a clinician, a knowledge engineer, an execution engine. In looking at governance of such artifacts this would include facilities for managing the long-term lifecycle of individual components within a particular artifact. The relationships between the levels, and the way(s) each level is expressed, possibly by automated translation, will have to be investigated.

- **Digital Rights Management and Integrity:** Another identified issue of the technical level was the ability to control the presentation and use of component parts of an artifact based upon the rights granted to the using context. In other words, in a commercial knowledge economy there needs to be sufficient support for digital rights management such that content vendors can be assured that their artifacts are being appropriately used. The security label and privacy services from HL7 could provide a starting point for such a mechanism. Likewise there is a clear technical requirement that a particular packaging of a knowledge artifact capable of being endorsed or signed any tamper proof manner to ensure trust and confidence.

Examples of composition use cases include:

1. KNART_A selects either KNART_B or KNART_C for execution. (Process and Flow)
2. KNART_D executes KNART_E and KNART_F in sequence feeding information between them. (Sequence,Order, Information sharing)
3. KNART_G is always executed after KNART_H and KNART_J are run and can reconcile the work produced produced by each. (Dependency, Information control, maybe Dynamic detection)
4. Composite KNART that forms reference to other KNARTS
5. Composite that was originally references is fully bundled together into a single artifact.
6. Pre and Post coordinated bundling and composites.

Questions

1. Multiple representations and Presentation, Common conceptual roles, multiple projections and realizations?
2. Support for Parentage Relationships?
3. Concept Identity vs Physical Identity, Identity with Human/Semantic Meaning. Projection of Identity. Nested Identification
4. Replaces and Represents.
5. Abstraction of Context(s)

Known issues

In the current KNART specification, the expression language is fixed to ELM. The specification is a mixture of physical and logical models, and has only one physical representation in the form of the HeD XML schema. With the advent of FHIR representations and the need to interact with other knowledge representations, a conceptual model is required to ensure consistency and interoperability.

The specification references three specific artifact types (Documentation Templates, Order Sets and Event Condition Action rules), but actually defines Libraries, Value Sets and Vocabularies. The HeD representation does not support composition, intra-artifact referencing or packaging other than as a singleton artifact.

Knowledge artifact lifecycle is managed as a whole; there is no facility to manage the lifecycle of component artifact types. Actions and events within an artifact are not explicitly scoped so there is no mechanism to deconflict user definitions from standard definitions.

More explicit support for additional phases of the knowledge artifact lifecycle, including authoring, testing and validation is needed.

FHIR Clinical Reasoning Model (CRM) Comparison

The scope of CRM is larger than the scope covered by the KNART specification, and includes quality reporting and clinical decision support execution and delivery in addition to the representation and sharing of knowledge artifacts. Also, the scope of represented clinical knowledge is broader (e.g. Quality Measures have been introduced, which are not in the KNART specification). In the KNART specification, everything is a knowledge document. In CR, different resources are used for different types of information structures (eg - Library, Order Set, Activity Definition, etc). The Library resource supports compositional structures and allows bundling of multiple knowledge artifacts.

Significant effort was put in to harmonizing metadata from the HeD model and clinical reasoning resources - most attributes ended up in the FHIR metadata resource.

In summary, CRM is the natural evolution of the KNART specification (and the HL7 DSS standard for artifact execution ‘as a Service’), but has done so in a FHIR-specific way, that prevents the immediate use of clinical knowledge artifacts in a non-FHIR compliant environment.

Conclusions

In order to enable sharing of and interoperability between knowledge representations in an heterogeneous environment, a conceptual model is required, along with separation of the platform independent and platform specific representations. Within HL7, conceptual documentation to confirm business requirements is still produced in support of v2, v3, SOA and CDA efforts, aligned with the Interoperability Specification Matrix (ISM) of the Service Aware Interoperability Framework (SAIF). The Standards Governance Board (SGB) is encouraging these efforts to enhance the ability to map between HL7 implementation paradigms. The current HeD XML representation is not directly mappable to existing HL7 artifacts.

CIMI increasingly relies on stable logical models to drive transformation maps, For knowledge to be sharable and cost effective, these mappings should be easily maintained. A single conceptual model for knowledge artifacts would facilitate map maintenance between XML and FHIR representations of the same knowledge. An underlying framework should elevate and encourage adoption of all specifications.

Benefits of conceptual documentation include:

- Future durability independent of the platform de jour
- Conceptual representations are best suited to interacting with clinical authors and reviewers
- A pure technical perspective can reverse value drivers and focus on technical convenience vs business value
- Specific physical representations will survive based on their uptake and implementation convenience.

This approach is consistent with SOA/OMG pattern, with HSSP/HSPC pattern, relates internally to SAIF/SGB pattern and should be non-restrictive to the FHIR community,

Stable logical models enable automated transformations between HL7 technical platforms For knowledge to be sharable and cost effective those mappings should be easily ...should elevate and encourage adoption of all specifications

There is the potential to facilitate cross domain validation/input/evolution of knowledge management approaches to leverage commercial "engines" being developed for other industries.

Why not focus on one representation - FHIR?

Research in composition and knowledge representation generalizes beyond FHIR and beyond HL7. Creation and maintenance of a conceptual model provides continuity and an ability to describe the relationship of HL7 knowledge artifacts to artifacts and specifications outside of HL7. The valuable conceptual work represented by FHIR Clinical Reasoning is applicable outside of FHIR implementations.

Alternative representations provide better support for the heterogeneity of the technical landscape, relative to the current focus of FHIR. The HL7 community includes members with implementation environments all along the continuum from legacy to emerging technology. Architectural considerations include:

- Specific focus on REST (Representational State Transfer) based architectures. Other models are supported but have been less well developed / tested.
- Focus on CRUD (Create Read Update Delete) versus more complex operations.
- Need to distinguish between transport models, persistence models, and analytic models
- Base resources are designed to support many use cases - implementation guides and profiles still need to be developed to support a predictable exchange architecture in specific use cases.
- FHIR focuses on the 80% of current systems. 80% of what? Newer care delivery models are evolving faster than implementation designs.

Design principle to cover 80% of common use cases is neither right nor wrong, but it does entrench existing current practice to the potential detriment of more efficient and effective separation of concerns and service/resource boundaries.

Recommendations

The project team recommends the creation of a conceptual KNART specification to supplement implementational level knowledge artifact representations. This will include:

1. Mapping and translation.
2. Provide a common bridge to FHIR.
3. Elements to support source referencing and possible reverse translation.
4. Evolving to take advantage of FHIR innovations.
5. Get a good name for the XML representation of a KNART (HeD KNART, Conceptual)
6. Develop a compounding and referencing mechanism.
7. Develop a composite packaging method.
8. Enhance the Meta data.

In parallel, we should request an additional STU period for the HeD KNART specification, and create a project to maintain that specification. This would include”

1. Resolving and responding to the existing STU comments
2. Updating the physical specification to include enhancements from innovations in the FHIR Clinical Reasoning.
3. Include the ability to dynamically bind to an expression language.
4. Bring the specification up to date with the current versions of related specifications.
5. Develop physical representations of the composite support and features defined by the conceptual model.

Appendix A - Differences between HeD KNART and FHIR CRM

Reference minutes CDS Work Group Conference Call, August 16, 2017

- Everything in KNART is a knowledge document, whereas FHIR Clinical Reasoning Module defines different resources used for different purposes
- Added Measure and MeasureReport

- GuidanceResponse and ServiceDefinition have been voted to be deprecated. This is more part of DSS scope. KNART uses pieces of vMR to work with GuidanceResponse
- DataRequirement has been more formally defined in Clinical Reasoning.
- The structure of a knowledge document in KNART is almost the same as in PlanDefinition, the main difference being the use of ActivityDefinition to enable both reuse of activities, and structural representation of the most common aspects, whereas the equivalent functionality in KNART is provided by the “actionSentence”, which is always an expression of ELM
- Clinical Reasoning Module allows use of any expression language, whereas KNART is tightly bound to ELM.
- Metadata elements of the FHIR Knowledge Resources were based on KNART Metadata, but subsequently harmonized with the core FHIR Conformance resources, so a one-to-one metadata review might be useful.
- The structure of KNART matches Plan definition - it may be reasonable to define a transform between them.
- Biggest difference is the actions - in HeD it is an expression, and the entire expression evaluates to the object to be performed. Within CR actions are defined more structurally and needed reuse in ways other than re-use of expressions. This led to Activity Definition, which can capture any kind of intent resource, lab orders, documentation templates, etc
- The Library artifact allows you to bundle composites in any way you want to bundle them. Library has been expanded to cover asset collection.
- KNART has specific points where you can put expressions; within Plan Definition there are specific points where you can put an expression as well, but in general there is a more flexible means to apply expressions since you use an extension to apply the expression - eg applying questionnaire resource via the expression extension

Appendix B - Example Clinical Whitepaper

Clinical Decision Support (CDS) Content and Health Level 7 (HL7)-compliant Knowledge Artifacts (KNARTS)

Cardiology: Chest Pain (CP) / Coronary Artery Disease (CAD) Clinical Content White Paper

DRAFT

Clinical Decision Support (CDS) Content and Health Level 7 (HL7)-compliant Knowledge Artifacts (KNARTS): Cardiology: Chest Pain (CP) / Coronary Artery Disease (CAD) Clinical Content White Paper

Order Set (B5, CLIN0004AA), Documentation Template (B35, CLIN0005AC), Consult Request/Composite (B56, CLIN0006AB)

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Aiden Abidov, MD, PhD	Professor of Medicine, Wayne State University; Section Chief, Cardiology, John Dingell VAMC	SME

Introduction

The VA is committed to improving the ability of clinicians to provide care for patients while increasing quality, safety, and efficiency. Recognizing the importance of standardizing clinical knowledge in support of this goal, VA is implementing the HL7 Knowledge Artifact Specification for a wide range of VA clinical use cases. Knowledge Artifacts, referred to as KNARTs, enable the structuring and encoding of clinical knowledge so the knowledge can be integrated with electronic health records to enable clinical decision support.

The purpose of this Clinical Content White Paper is to capture the clinical context and intent of KNART use cases in sufficient detail to provide the KNART authoring team with the clinical source material to construct the corresponding knowledge artifacts using the HL7 Knowledge Artifact Specification. This paper has been developed using material from a variety of sources: VA artifacts, clinical practice guidelines, evidence in the body of medical literature, and clinical expertise. After reviewing these sources, the material has been synthesized and harmonized under the guidance of VA subject matter experts to reflect VA's clinical intent for this use case.

Unless otherwise noted, items within this white paper (e.g., documentation template fields, orderable items, etc.) are chosen to reflect the clinical intent at the time of creation. To provide an exhaustive list of all possible items and their variations is beyond the scope of this work, so these exemplars have been chosen by the subject matter expert team as representative of the clinical intent.

Chapter 1. Chest Pain (CP)/Coronary Artery Disease (CAD)

1. Clinical Context

Patients often present in the primary care setting with chest pain that is thought, possibly, to be cardiac in origin. This poses the problem of separating those with non-cardiac chest pain from those with cardiac chest pain and separating unstable from stable patients. Unstable patients with cardiac chest pain (e.g., those suspected with acute coronary syndrome (ACS), ST-segment elevation or non–ST-segment elevation myocardial infarction) require triage to appropriate emergent care, such as to the emergency department. Stable patients with cardiac chest pain require risk stratification, office-based workup, initiation of disease-specific medications, and subspecialty referral to a cardiologist. The care of patients with clearly non-cardiac chest pain (e.g., chest pain secondary to GI, musculoskeletal or pulmonary causes) is a separate clinical problem not addressed herein. Patients should be risk-stratified to estimate their 10-year cardiovascular disease risk (D'Agostino 2008) and guideline-based options for the ordering of diagnostic tests and therapeutic interventions to facilitate efficient resource utilization and subspecialty referral (Finh 2014).

The Cardiology chest pain (CP) and coronary artery disease (CAD) group of KNARTs are intended to assist primary care providers in the management of adult patients with stable chest pain (with or without known CAD); aid in determining when a cardiology consultation is appropriate; provide guidance for initial noninvasive diagnostic orders (stress testing) and provide a structured documentation template for the process. Stable patients with cardiac chest pain require risk stratification, office-based workup, initiation of disease-specific medications, and subspecialty referral to a cardiologist.

This context excludes emergent patients (new/ongoing/unstable pattern CP). Included are those patients with stable CP with or without known CAD, to be considered for evaluation by cardiology. These context domains are summarized below:

Table 1.1. Clinical Context Domains

Target User	Provider in a Primary Care Clinic
Patient	Adult with stable chest pain being considered for cardiology consultation (excluding unstable symptoms and acute coronary syndromes)
Priority	Routine
Specialty	Primary Care
Location	Outpatient

2. Knowledge Artifacts

This section describes the knowledge artifacts that are intended for users caring for adult patients who might present to a Primary Care Clinic with stable chest pain/CAD. The intent of these artifacts is to ensure a minimum workup is initiated prior to a Cardiology Consultation. Specific constraints for these artifacts are that:

- They apply to outpatients with stable chest pain with or without prior documented CAD needing cardiology Consultation
- They exclude emergent patients (new/ongoing/unstable pattern CP suggestive of acute coronary syndrom (ACS))

There are three knowledge artifacts that define this clinical use case, and are described in detail in the following sections. They are:

- Consult Request

- High-level, encompassing artifact meant to communicate the request for cardiology consultation
- Relies upon the documentation template and order set artifacts

- Documentation Template
  - Documents the information provided by the referring provider
  - Includes logic for appropriate display of documentation sections
- Order Set
  - Orderable items associated with the consult request
  - Includes logic for appropriate display of the order set

Conventions used within the knowledge artifact descriptions include:

- <obtain>: Indicates a prompt to obtain the information listed
- [...]: Square brackets enclose explanatory text that indicates some action on the part of the user, or general guidance to the clinical or technical teams. Examples include, but are not limited to:
  - [Begin …], [End …]: The start and end of specific areas to clearly delineate them for technical purposes.
  - [Activate …]: Initiate another knowledge artifact or knowledge artifact section.
  - [Section Prompt: ...]: If this section is applicable, then the following prompt should be displayed to the user.
  - [Section Selection Behavior: ....]: Indicates technical constraints or considerations for the selection of items within the section.
  - [Attach: ...]: The specified item should be attached to the documentation template if available.
  - [Link: ...]: Rather than attaching, a link to the item should be included in the documentation template.
  - [Clinical Note: ...]: Clinical rationale or notes.
  - [Technical Note: ...]: Technical considerations or notes.
  - [If …]: The beginning of a conditional section.
  - [Else, …]: The beginning of the alternative branch of a conditional section.
- Check boxes: Indicates items that should be selected based upon the section selection behavior.

Chapter 2. Composite

1. Knowledge Narrative

[See Clinical Context.]

2. Consult Request

[Technical Note: The following list provides the basic components of the consult request. This is the high-level, encompassing artifact, and must be combined with the documentation template and order set to form a fully functional knowledge artifact.]

[Section Prompt: To request a cardiology consult to evaluate chest pain in a stable patient with or without known history of CAD, please provide the following information.]

- Reason for Consult: Chest pain evaluation (with or without known history of CAD)
- Consult Specialty: Cardiology

[Technical Note: Routine priority, as defined by the implementing institution, is the default for this consult. Other priority levels may need to be defined (e.g., stat, today, urgent, emergent, etc.).]

- Priority: Routine
- <obtain> Referring Physician
- <obtain> Referring Physician Contact Information

[Activate associated documentation template]

3. Evidence

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Chapter 3. Documentation Template

1. Knowledge Narrative

[See Clinical Context.]

2. Clinical Stability

[Section Prompt: This documentation template is not applicable for use with patients who are unstable based on clinician judgement. Examples of unstable patients include, but are not limited to, patients with chest pain pattern suggestive of ACS (e.g., those with new onset resting CP, CP with minimal exertion, new unstable angina pattern, ST-segment elevation, non–ST-segment elevation myocardial infarction on ECG, or suspected aortic dissection), and patients with any of the following symptoms or findings:

1. Ongoing resting chest pain for > 20 minutes with ST elevation or depression on ECG

2. Onset of new resting chest pain episodes within the past week

3. New onset, recurrent chest pain with minimal exertion over the past 2 months

4. Previously stable exertional angina now occurring with minimal activity over the past 2 months.

[Consider transferring unstable patients to the nearest emergency department immediately.]

3. Coronary Artery Disease Risk

[Clinical Note: For this documentation template, please assess the patient's 10-year cardiovascular disease risk using either clinical judgement or a risk calculator such as that provided by the AHA.

[Technical Note: Provide a link to the calculator at: http://static.heart.org/riskcalc/app/index.html#!/baseline-risk.]]

- <obtain> Patient's 10-Year Cardiovascular Disease Risk

4. History and Physical

[Technical Note: For this documentation template, the following information should be included, if available.]

- <obtain> History, Brief - describing symptoms, HPI
- <obtain> History of prior cardiac evaluations (e.g., prior hospitalization or evaluations for: chest pain, rule/out MI, angina, heart failure, etc.)
- <obtain> Results of prior cardiac diagnostic procedures performed (resting ECG, echocardiogram, stress testing (echo, nuclear, MRI), CCT or angiography
- <obtain> Physical Exam, Pertinent Positive and Negative Findings
- <obtain> Details of previous invasive diagnostic procedures and resulting interventions (e.g., angiography, PCI/Stents, or CABG)

5. Treatment Provided

[Technical Note: For this documentation template, the following information should be included, if available.]

- <obtain> Pharmacologic Therapy

- <obtain> Other Pertinent Therapy

6. Laboratory Studies

[Technical Note: For this documentation template, the following information should be included (latest value within the past 2 years), if available.]

- <obtain> Basic Metabolic Profile Lab Result
- <obtain> Complete Blood Count Lab Result
- <obtain> Lipid Profile Lab Result
- <obtain> Thyroid Function Testing Lab Result
- <obtain> Troponin Lab Result
- <obtain> Brain Natriuretic Peptide Lab Result
- <obtain> D-dimer Lab Result

7. Imaging and Diagnostic Studies

[Clinical Note: Images and diagnostic studies older than one year are not considered for inclusion in this documentation template.]

[Technical Note: For this documentation template, the following information should be included, if available from the prior 1 year.]

[Technical Note: Image and result text should be attached automatically if they are is provided for the 12-Lead Electrocardiogram Interpretation field.]

- <obtain> resting 12-Lead Electrocardiogram Interpretation
- [Attach or link Images: 12-Lead Electrocardiogram]

[Technical Note: Results should be attached automatically if text is provided for the Stress Electrocardiography Interpretation field.]

- <obtain> Stress Electrocardiography Interpretation
- [Link Images: Stress Electrocardiography]

[Technical Note: Results should be attached automatically if text is provided for the Resting Echocardiogram/Doppler Interpretation field.]

- <obtain> Resting Echocardiogram/Doppler Interpretation
- [Link Images: Resting Echocardiogram/Doppler Electrocardiography]

[Technical Note: Results should be attached automatically if text is provided for the Stress Echocardiogram Interpretation field. This includes treadmill and dobutamine stress echo.]

- <obtain> Stress Echocardiogram Interpretation
- [Link Images: Stress Echocardiogram]

[Technical Note: Results should be attached automatically if text is provided for the Stress Myocardial Perfusion Imaging (MPI) Interpretation field.]

- <obtain> Stress MPI Interpretation

- [Link Images: Stress MPI]

[Technical Note: Results should be attached automatically if text is provided for the Rest/Stress MRI Interpretation field.]

- <obtain> Rest/Stress MRI Interpretation

- [Link Images: Rest/Stress MRI]

[Technical Note: Result text should be attached automatically if it is provided for the Chest/Coronary/Cardiac CT Angiography (CTA) Interpretation field.]

- <obtain> Chest CT or Coronary/Cardiac CTA Interpretation

- [Link Images: Chest CT or Coronary/Cardiac CTA]

[Technical Note: Result text should be attached automatically if it is provided for the X-Ray Chest Interpretation field.]

- <obtain> X-Ray Chest Interpretation

- [Link Images: X-Ray Chest]

8. Link to Order set

[Activate order set]

[End Document Template.]

9. Evidence

Bibliography

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Chapter 4. Order Set

1. Knowledge Narrative

[See Clinical Context.]

2. Clinical Stability

[Section Prompt: This order set is not applicable for use with patients who are unstable based on clinician judgement. Examples of unstable patients include, but are not limited to, patients with chest pain pattern suggestive of ACS (e.g., those with new onset resting CP, CP with minimal exertion, new unstable angina pattern, ST-segment elevation, non–ST-segment elevation myocardial infarction on ECG, or suspected aortic dissection), and patients with any of the following symptoms or findings:

1. Ongoing resting chest pain for > 20 minutes with ST elevation or depression on ECG

2. Onset of new resting chest pain episodes within the past week

3. New onset, recurrent chest pain with minimal exertion over the past 2 months.

4. Previously stable exertional angina now occurring with minimal activity over the past 2 months.

Consider transferring unstable patients to the nearest emergency department immediately.]

3. Consults and Referrals

[Section Prompt: Cardiology consult order.]

[Technical Note: Consider other consult modalities which might be available (e.g., e-consult or other rapidly iterative consult method. A simple consult is included here as the overarching clinical intent.]

- □ referral to cardiology to evaluate chest pain (routine)

[Section Selection Behavior: Only one may be selected. At least one must be selected.]

[Section Prompt: Reason for cardiology consultation.]

- □ typical angina
- □ atypical chest pain
- □ progressive angina symptoms in a stable patient with known CAD (if the patient is unstable based upon clinical or test results, direct physician-to-physician communication is required)

[Technical Note: If other is selected, the reason must be obtained.]

- □ other: <obtain>Reason for cardiology consultation

[Section Prompt: Specific goal of the cardiology consultations (e.g., cardiology to manage patient, cardiology to risk stratify and recommend management, etc.).]

- goal of cardiology consultaion: <obtain> goal of cardiology consultation

4. Imaging and ECG

Electrocardiogram/Chest X-ray

[Section Prompt: Consider ordering prior to the cardiology consultation. Resting 12-lead electrocardiogram is required if it has not been obtained within the past two months.]

[Section Selection Behavior: More than one may be selected. Optional]

- ☐ resting 12-lead electrocardiogram to evaluate chest pain (routine)
- ☐x-ray chest to evaluate chest pain(routine)

Coronary CTA

[Section Prompt: Consider ordering prior to the cardiology consultaion.]

[Technical Note: Coronary CTA (cCTA) is included for completeness, but its availability will be facility dependent.]

[Section Selection Behavior: Optional]

- ☐ coronary CTA angiogram (cCTA) chest to evaluate chest pain (routine)

Echocardiogram

[Section Prompt: Consider for patients with suspected pericarditis, myocarditis, hypertrophic cardiomyopathy, or pulmonary hypertension.]

[Section Selection Behavior: Optional]

- ☐ Resting echocardiogram to evaluate chest pain (routine)

5. Laboratory Tests

[Section Prompt: Consider the following tests to be completed prior to the cardiology consultation.]

[Section Selection Behavior: More than one may be selected. Optional]

- ☐ basic metabolic profile (routine)
- ☐ complete blood count (routine)
- ☐ lipid profile (routine)
- ☐ thyroid function testing (routine)
- ☐ brain natriuretic peptide (routine)

6. Cardiac Risk Stratification

[Section Prompt: For stable patients, these orders may assist in cardiac risk stratification.]

[A link to the ACC/AHA clinical practice guideline for stress testing (Gibbon 2002) should be made available to ordering providers: http://circ.ahajournals.org/content/106/14/1883.long.]

[Section Prompt: Assess for contraindications to stress testing such as: Acute CHF, acute MI or unstable angina, severe aortic stenosis, unstable rhythm, aortic aneurysm/dissection, endocarditis, acute pericarditis, acute pulmonary embolus/infarction, acute systemic illness/infection, severe hypertension, inability to cooperate, Inability to exercise (<5 METs), LBBB, etc.]

Exercise Stress Testing. [Section Prompt: Consider for patients with no known or prior coronary artery disease, low probability for coronary artery disease, ability to exercise, normal electrocardiogram, and heart rate > 60 beats per minute.]

[Section Selection Behavior: Optional.]

- ☐ exercise ECG (routine)

Stress Testing with Echocardiography. [Section Prompt: Consider for patients with no known or prior coronary artery disease, low to intermediate probability for coronary artery disease, ability to exercise, and no evidence of significant regional wall motion abnormalities or conduction abnormalities (IVCD/bundle branch block or pacing) of 12-lead electrocardiogram.]

[Section Selection Behavior: Optional.]

- ☐ exercise echocardiography (routine)

Dobutamine Stress Testing with Myocardial Perfusion Imaging (MPI). [Section Prompt: Consider for patients with no known or prior coronary artery disease, intermediate probability for coronary artery disease, inability to exercise, and normal electrocardiogram.]

[Section Selection Behavior: Optional.]

- ☐ dobutamine stress myocardial perfusion imaging (routine)

Exercise Stress Testing with MPI. [Section Prompt: Consider for patients with known or prior CAD, ability to exercise, and normal ST-T.]

[Section Selection Behavior: Optional.]

- ☐ exercise stress myocardial perfusion imaging (routine)

Vasodilator Stress Testing with MPI. [Section Prompt: Consider for patients with known or prior CAD and abnormal electrocardiogram/PPM. This subsection should also be made available to the provider for patients with known or prior CAD, abnormal electrocardiogram, and history of prior myocardial infarction or regional wall motion abnormalities.]

[Section Selection Behavior: Only one should be selected. Optional.]

- ☐ regadenoson (Lexiscan) stress myocardial perfusion imaging (routine)
- ☐ adenosine stress testing myocardial perfusion imaging (routine)
- ☐ dipyridamole stress testing myocardial perfusion imaging (routine)

Dobutamine Stress Testing with Echocardiography or MPI. [Section Prompt: Consider for patients with known or prior CAD, inability to exercise, normal electrocardiogram, and no prior myocardial infarction. Only one should be selected.]

[Section Selection Behavior: Only one should be selected. Optional.]

- ☐ dobutamine stress testing echocardiography (routine)
- ☐ dobutamine stress testing myocardial perfusion imaging (routine)

Coronary CT Angiogram. [Section Prompt: Consider for patients with no known coronary artery disease, low or intermediate probability for coronary artery disease, especially in presence of a history of prior inconclusive or discrepant diagnostic testing, recurrent symptoms or significant family history of CAD/multiple risk factors in young patients. Additional postprocessing (CT-FFR) or CTA stress perfusion may be ordered where available.]

[Section Selection Behavior: Optional.]

- ☐ coronary CT angiogram (routine)

7. Medications

[Section Prompt: Based upon clinical judgement, consider initiating a new order for one or more of the following medications prior to the cardiology consultation, if not otherwise contraindicated.]

[Section Selection Behavior: More than one category may be selected. Only one from each category may be selected. Optional.]

- □ Antianginal Therapy
-
  - □ metoprolol tartrate 25 mg tablet oral twice daily (routine)
  - □ metoprolol tartrate 25 mg tablet oral twice daily (routine)
  - □ metoprolol tartrate 50 mg tablet oral twice daily (routine)
  - □ amlodipine 5 mg tablet oral daily (routine)
  - □ nitroglycerin 0.4 mg tablet sub-lingual every 5 minutes as needed for chest pain; maximum 3 tablets (routine)
- □ Antiplatelet Therapy
-
  - □ aspirin 81 mg enteric coated tablet oral daily (routine)
- □ Risk Factor Reduction
-
  - □ atorvastatin 20 mg tablet oral daily (routine)
  - □ atorvastatin 40 mg tablet oral daily (routine)
  - □ simvastatin 20 mg tablet oral daily (routine)
  - □ simvastatin 40 mg tablet oral daily (routine)
  - □ rosuvastatin 5 mg tablet oral daily (routine)
  - □ rosuvastatin 10 mg tablet oral daily (routine)
  - □ rosuvastatin 20 mg tablet oral daily (routine)

8. Evidence

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Appendix A. Appendix: Existing VA Artifacts

These artifacts consist of screenshots from the Portland VA cardiology, chest pain/coronary artery disease consult set.

Figure A.1. Cardiology - General

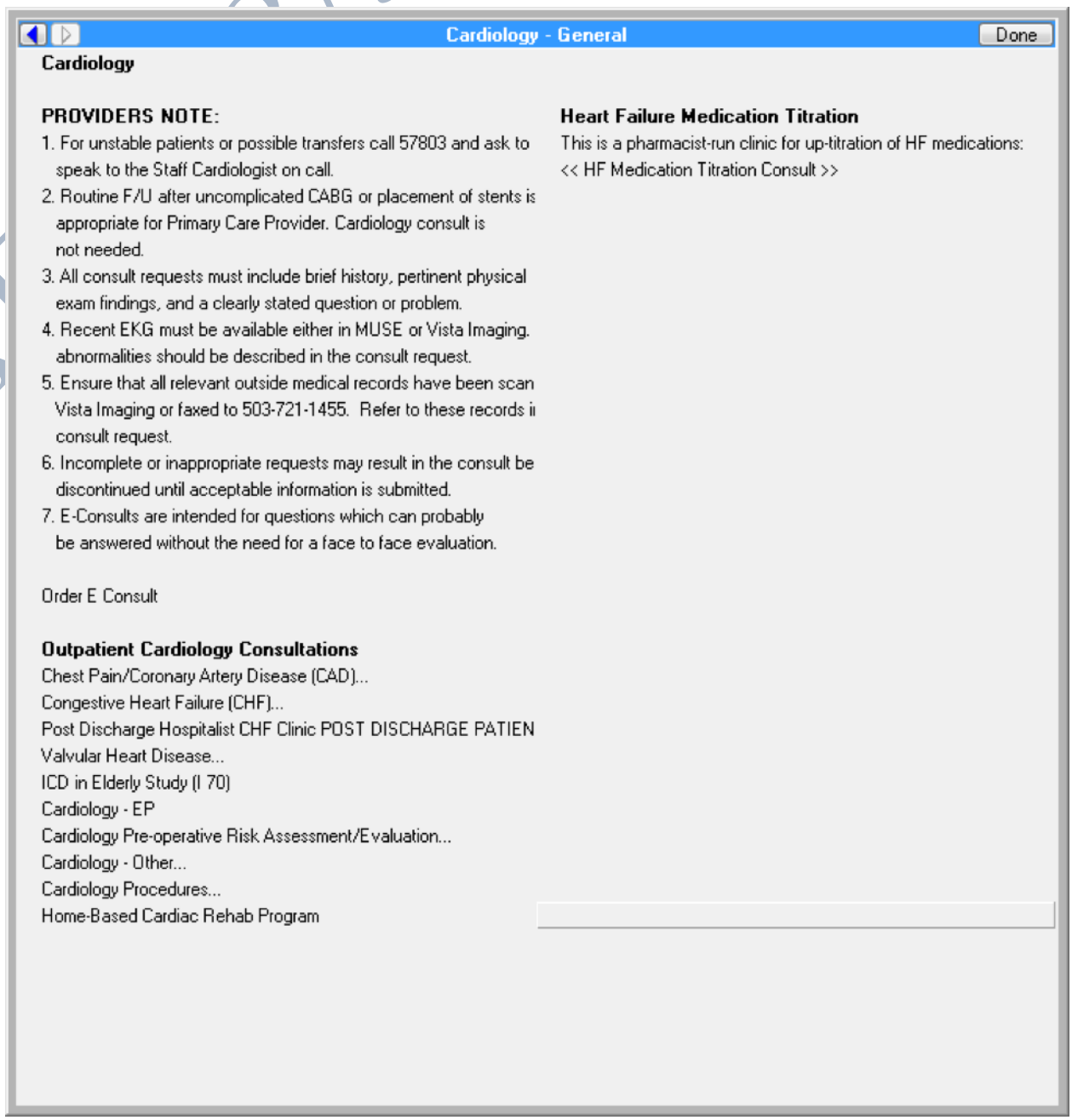

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Figure A.2. Chest Pain (CP)/Coronary Artery Disease (CAD) Screenshot

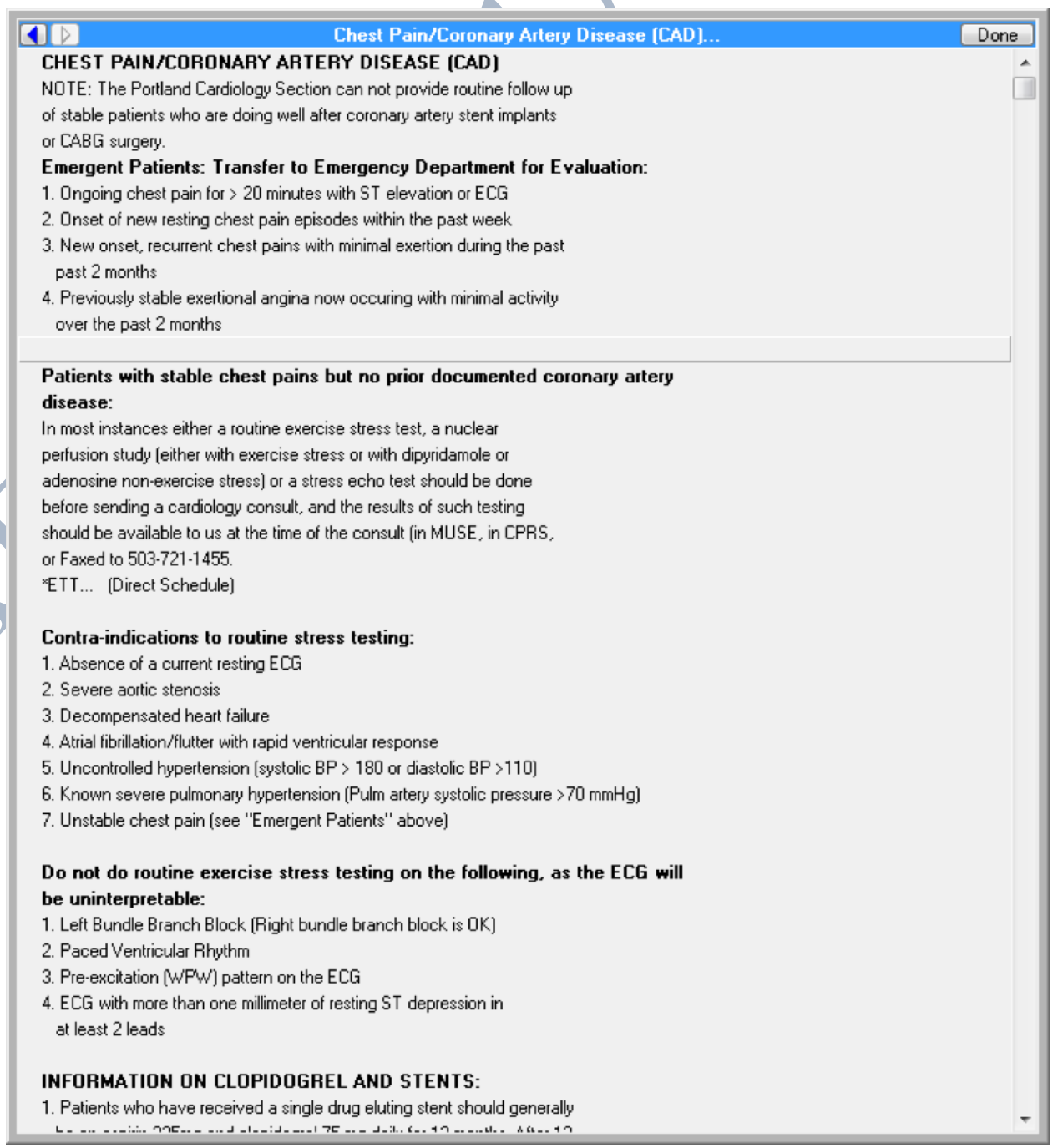

Figure A.3. Chest Pain (CP)/Coronary Artery Disease (CAD) Screenshot with Contraindications

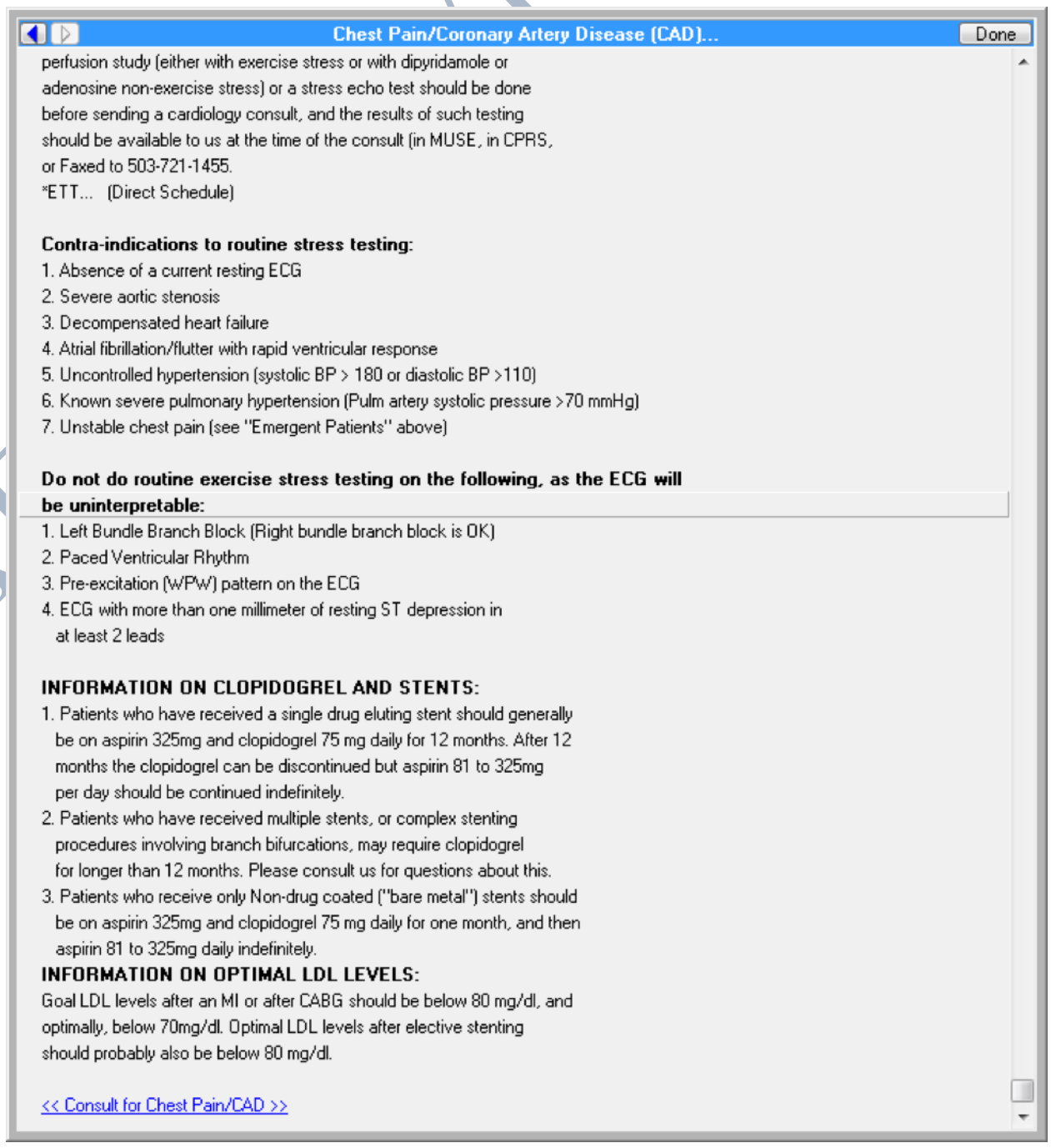

Figure A.4. Cardiology ETT Procedure

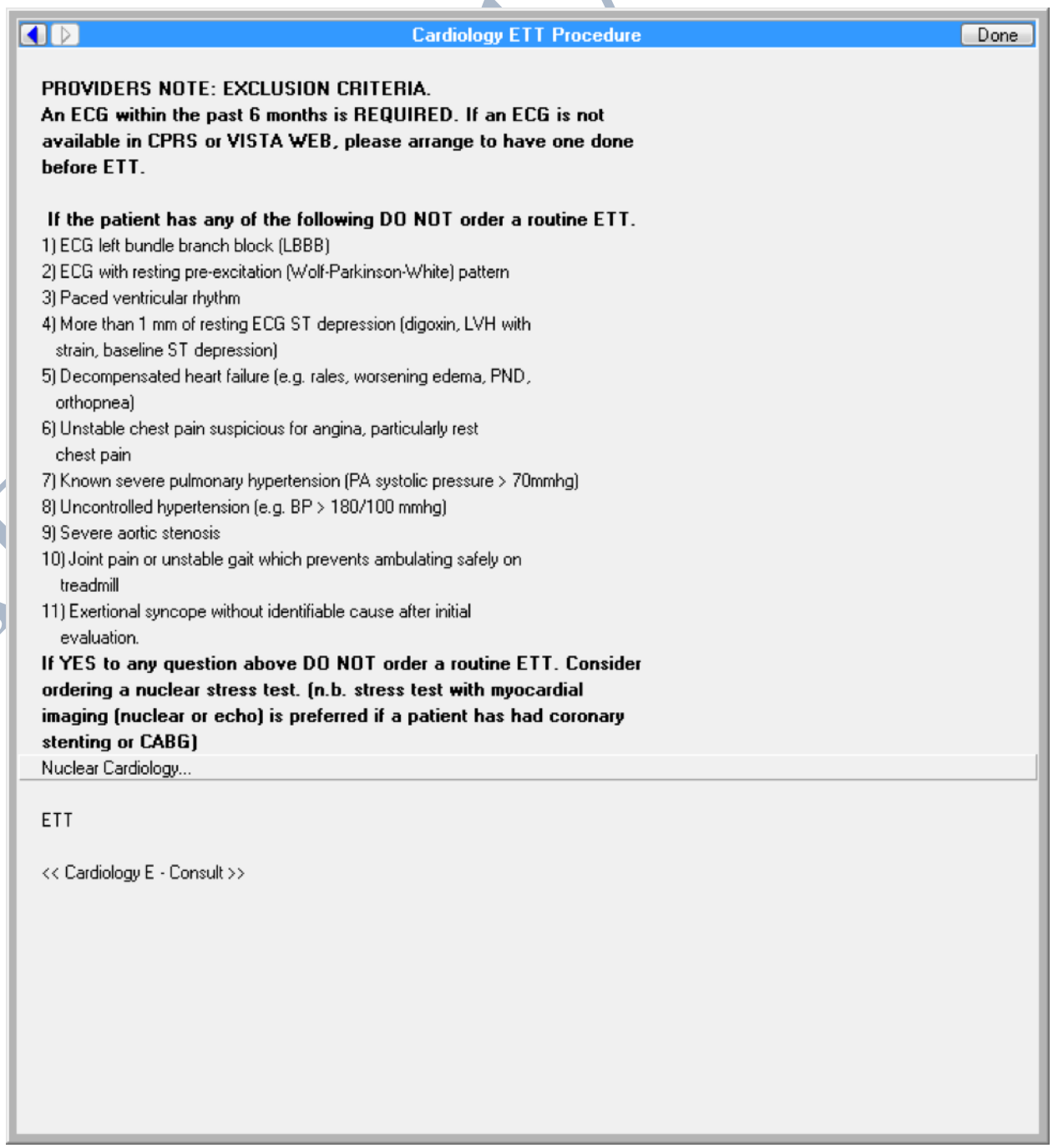

Figure A.5. Order a Procedure

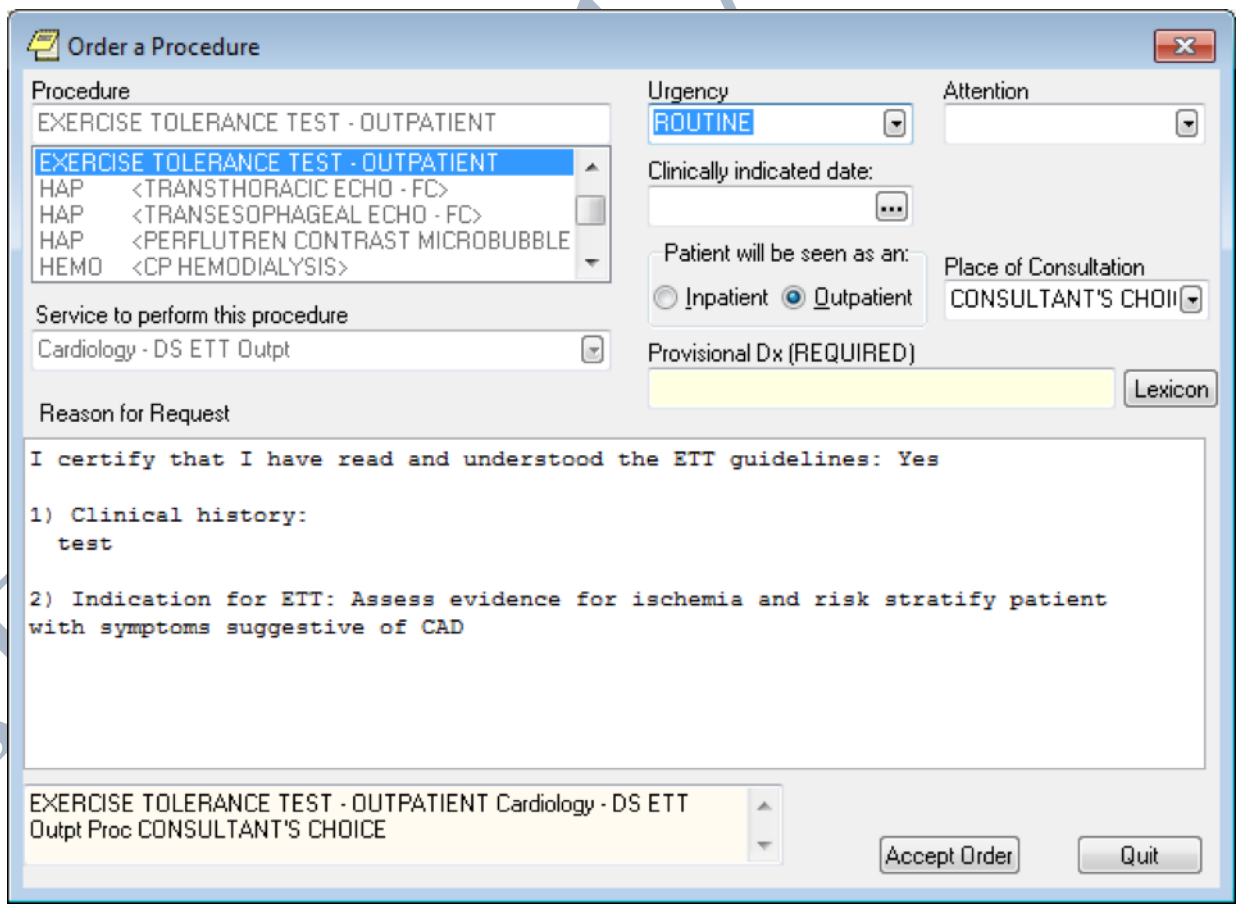

Figure A.6. ETT Request Screenshot

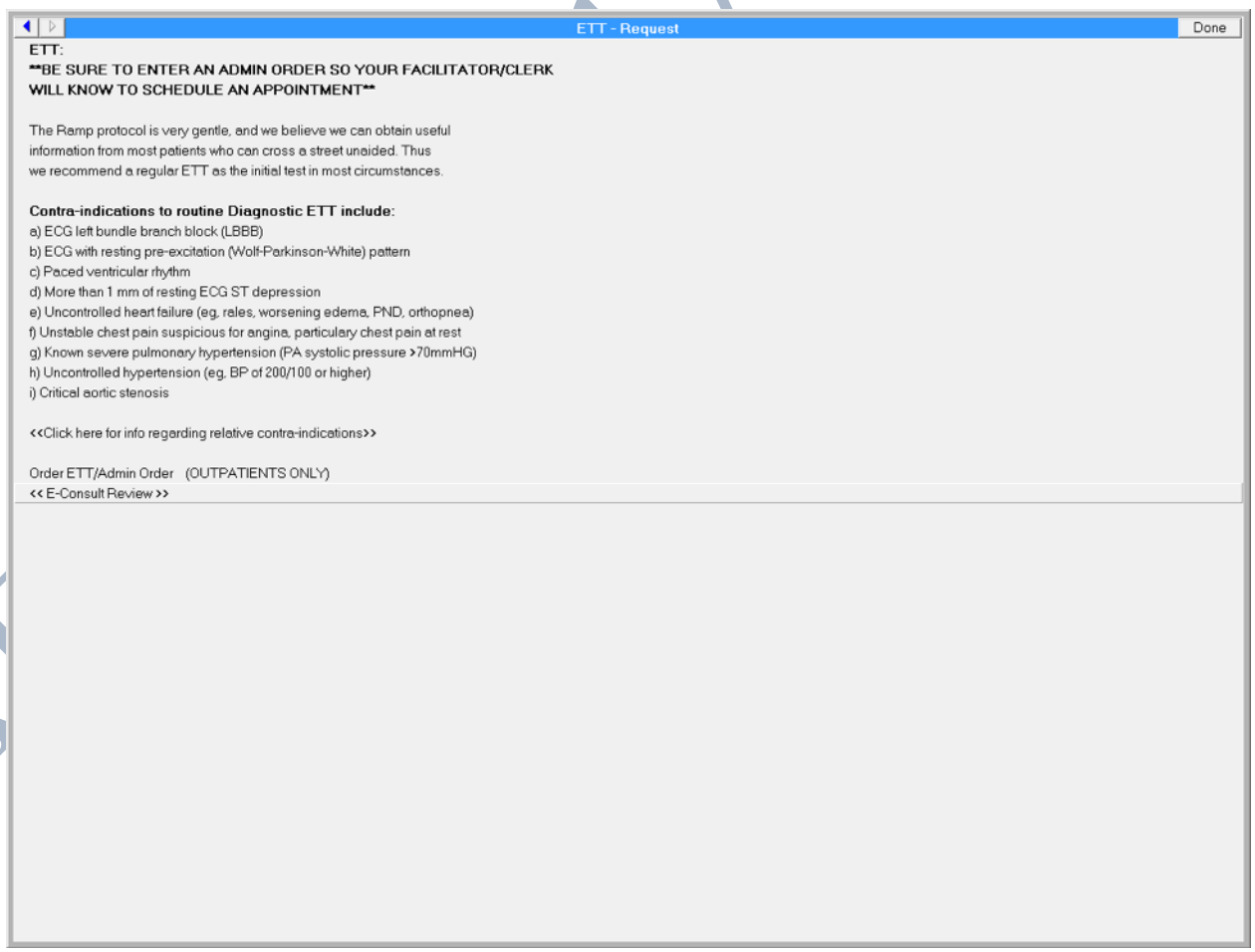

Figure A.7. Reason for Request: Cardiology - General Output

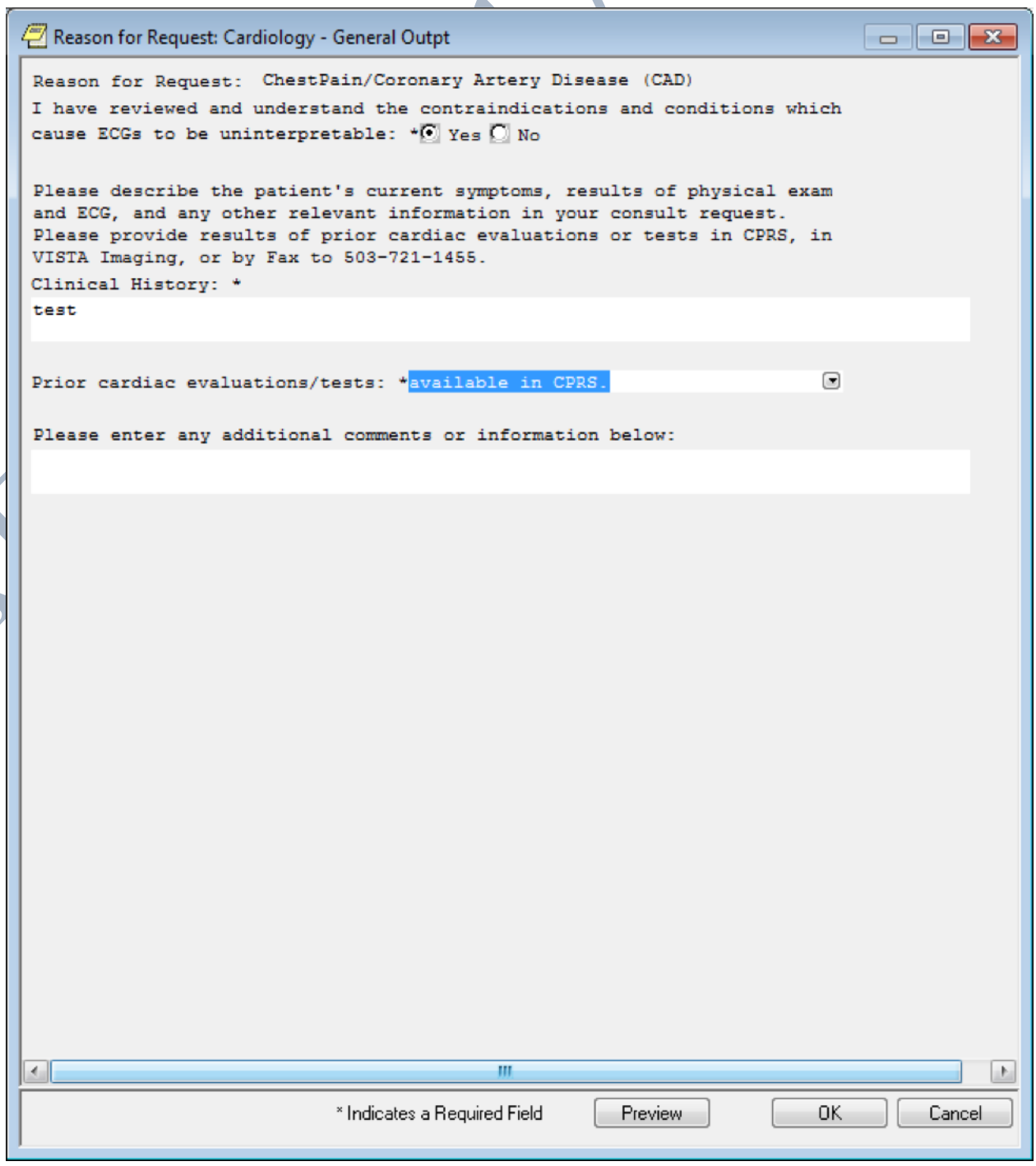

Figure A.8. Order a Consult Screenshot for Cardiology

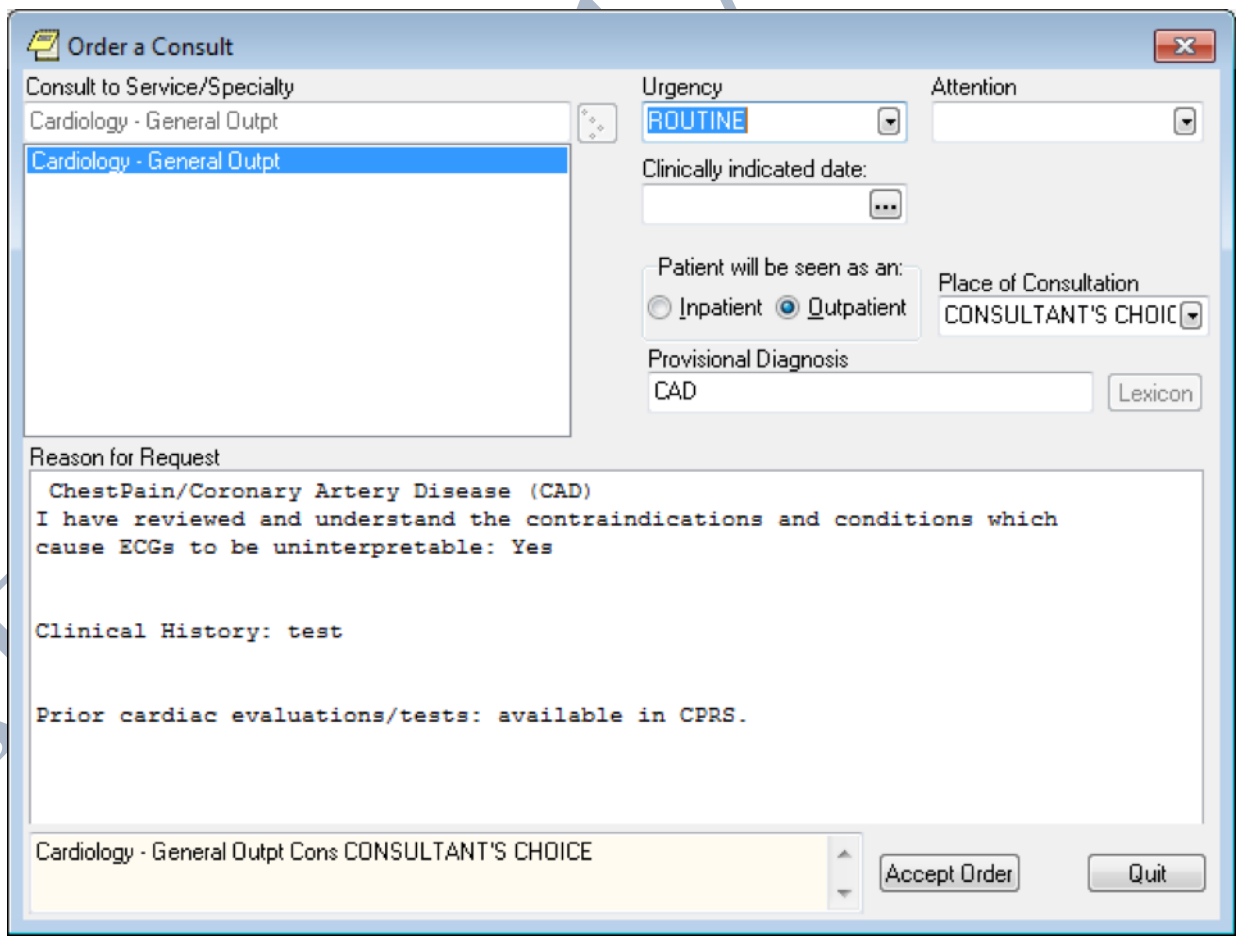

Figure A.9. Consult to Service/Specialty Screen