

Guidelines for Expressing Conformance Criteria
An initial assessment of the HL7 EHR-S Functional Model

Draft, not intended for application

Draft, not intended for application

Lynne S. Rosenthal
NIST, 100 Bureau Drive, Stop
8970
Gaithersburg, MD 20899-8970
(301)975-3353,
fax (301)948-6213
lynne.rosenthal@nist.gov

Introduction:

As part of an effort to advance a conformance strategy for the EHR-S DSTU Functional Model and to facilitate testing and certification activities by others, NIST staff members recently volunteered to draft a set of example conformance statements for a sample (incomplete, partial) draft subset of the DSTU Functional Model. Though the sample set of conformance statements created by NIST is a rough draft – a work-in-progress – we believe it demonstrates a reasonable, quality approach for creating conformance criteria.

Process and results:

As a side benefit, this conformance creation exercise also resulted in a list of observations concerning the DSTU, such as the existence of confusing terminology, the presence of inconsistencies, and the identification of challenges associated with “rolled-up” functions (namely, those related functions that were combined into an associated parent function).

For example, NIST team members observed that:

- a. Some functional statements may be easily converted into conformance statements by inserting the words “The system shall...”
- b. There is a need for a glossary (in association with a set of Style Guidelines) to assure consistent use of “shall”, “may”, “should”, etc., even if the glossary initially consists of the small set of words that will support the writing phase of the conformance statement development cycle.
- c. The associated conformance statement for a given functional statement may be better represented as a “set of conformance statement choices” (because the function they define may, in fact, represent a set of application options in the real world). Conversely, a conformance statement for a function that represents a set of workflow tasks may become technically unsound if, for instance, a given task is omitted from what is actually a set of workflow tasks.

As a side note, by examining NIST’s list of observations, the EHR TC may be in a good position to address pending, potentially troublesome issues – and do it sooner rather than later.

The EHR TC can use NIST’s sample subset of draft conformance statements and the observations recorded during the conformance statements’ creation to:

- a. Identify functions (or parts of functions) that are “required” versus those functions which may be “optional”.
- b. Examine the consistency of the DSTU’s functionality.
- c. Provide a sound basis for articulating specific features of the various functions.

Table Structure:

Conformance Statements (labeled a,b,c..) were created from the Function Statement and Function Description. Conformance statements that are derived from 'a,b,c..' are labeled with a double letter (aa). Labels (a, b, c) in Dependencies and Questions/Comments correspond to conformance statements with the same label.

Terminology:

SHALL: (mandatory) to indicate a requirement to be followed (implemented) in order to conform

Should: (optional) to indicate a recommendation that is particularly suitable, without mentioning or excluding others.

May: (optional) to indicate a permissible action.

May indicates an optional, permissible action. We included these for several reasons (1) you can have conformance statements for options. If the option is exercised, then one would conform to the statement. (2) Other groups, profiles, etc. may want to make this option a requirement, thus they could use this agreed upon statement. (3) to let the EHR TC decide what to do with these statements (always easier to delete), including changing a 'may' statement a 'shall'.

General Questions and Comments

1. Managed vs Maintained. Maintain is being used to indicate passive actions – such as store, preserve. Managed is more active – such as modify, update, retrieve.

2. Over time: Is this an instance of time (e.g., start, point in time, end) or can it be an interval of time (e.g., over course of a visit or stay). Both are indicated in functions (instance: DC1.1.3.2; interval DC 1.1.3.1; both: DC1.1.5 (date or date-range))

3. Is there an explicit requirement for small ambulatory EHRs to have connectivity with any system outside of their practice? The functions to support HC interoperability specs are mandatory; however they could still be used within the systems of the practice and still have no outside connectivity. Specifically, 'order diagnostic tests' generally makes the assumption that there is connectivity. In terms of the conformance statements, it would be good to know if connectivity outside of the EHRs (or practice) is required.

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
DC1.1	Health information capture, management, review		<p>a) The system SHALL achieve data capture using standardized code sets or nomenclature or as unstructured data.</p> <p>b) The system should keep track of date and actor for all data entries.</p>	ISO 18308 Requirements for EHR Arch; ASTM E 1769 Properties of EHR and Record Systems	<p>a) This really says nothing, since data capture MAY be done anyway desired, these are just suggestions</p> <p>b) a SHOULD is also a suggestion</p>
DC1.1.1	Identify and maintain a patient record	Identify and maintain a single patient record for each patient	<p>a) The system SHALL create a single patient record for each patient</p> <p>b) The system SHALL associate (store/link) key identifier information with each patient record</p> <p>c) The system SHALL maintain static and dynamic data elements for each record</p> <p>d) Using the key identifying information, the system SHALL identify the unique patient record.</p> <p>dd) Using key identifying info, the system SHALL identify corresponding record. If multiple records are identified, an alert is issued?</p>	b) key identifier info can be enumerated by others for more specificity	<p>a) is 'store and link' required or is this a specific technique? Need both?</p> <p>c) does this refer to the record?</p> <p>d) Desc not account for finding duplicates and how to handle it.</p> <p>dd) alternative. This adds new information, i.e., alert</p>
DC1.1.2	Manage patient demographics	Capture and maintain demographic information. Where appropriate, the data should be clinically relevant, reportable and trackable over time	<p>For the following, demographics to include at least: address, phone, DOB, sex.</p> <p>a) The system SHALL capture and maintain demographic information.</p> <p>b) The system SHALL provide ability to report demographic information</p> <p>c) The system should keep track of demographic information over time</p>	<p>a) additional demographics can be enumerated by others</p> <p>c) over time needs more specificity</p>	<p>Managed vs maintained</p> <p>c) should or shall?</p> <p>c) clinically relevant is vague and since this is 'should' – ignored this requirement.</p>
DC1.1.3	Manage summary lists	Create and maintain patient-specific summary lists that are structured and coded where appropriate	<p>a) The system SHALL create and maintain a summary list for each patient.</p> <p>b) The system SHALL be capable of including structure and codes.</p> <p>c) The system SHALL display summary list in a summary format.</p> <p>d) The system should include at least the following in the summary list: problem list,</p>	<p>b) need to specify more on structures and codes; and where/when appropriate</p> <p>c) summary format can be made explicit by others</p>	<p>a) Manage vs maintained</p> <p>b) is this really a requirement, it is very vague</p>

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
			medication list, allergy and adverse reaction list.		
DC1.1.3.1	Manage Problem list	Create and maintain patient-specific problem lists	<p>For testing purposes, suggested problem lists to include: chronic conditions, diagnoses, or symptoms, functional limitations, visit or stay-specific conditions, diagnoses, or symptoms.</p> <p>a) The system SHALL create and maintain patient specific problem lists</p> <p>aa) The system SHALL create a problem list for every patient.</p> <p>b) The system SHALL manage problem lists over time</p> <p>bb) The system SHALL be able to create, modify, retrieve problem lists for a specified time interval.</p> <p>c) The system SHALL maintain (store?) problem specification, prioritization and/or resolution dates for when noted, diagnosed, and changed d) The system may use time stamps to indicate time of event</p> <p>e) The system SHALL display available problem list history.</p>	Vocabulary group to clarify?	<p>a) Managed vs maintained</p> <p>c) removed ‘pertinent’, since it is untestable and will need to be defined for testing</p> <p>aa) Does every patient have a problem list (may be a null list) or system capable of creating list for every patient? (corey)</p> <p>bb) specified time interval is catch-all for managing lists for a visit (instance of time), stay (interval of time) or life of patient. Deleted specified # patients (corey)</p> <p>“allowing documentation of historical info and tracking the changing character of problems and their priority” is covered by bb), c), e). This isn’t a requirement per se, but an explanation.</p>
DC1.1.3.2	Manage Medication List	Create and maintain patient-specific medication lists	<p>a) The system SHALL manage medication lists over time</p> <p>aa) The system SHALL be able to create, modify, retrieve med list for a specified time interval.</p> <p>b) The system SHALL maintain (store?) medication ordering dates of start, modify and end</p> <p>c) The system SHALL display available medication history</p> <p>d) The system SHALL allow for functions</p>	Vocabulary group to clarify? a) Medication lists can be enumerated by others (can test without it)	<p>Managed vs Maintained</p> <p>b) removed ‘pertinent’ since it is untestable.</p> <p>d) functions are vague, is it possible to provide a list of functions? (corey)</p>

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
			entries by actors other than prescriber		
DC1.1.3.3	Manage allergy and adverse reaction list	Create and maintain patient-specific allergy and adverse reaction lists	<p>a) The system SHALL be able to handle allergen, immunizations and substance identity and codes</p> <p>b) The systems SHALL manage patient specific allergy and adverse reaction lists over time.</p> <p>bb) The system SHALL be able to create, modify, retrieve allergy/adverse reaction lists for a specified time interval and number of patients</p> <p>c) The system SHALL be able to modify descriptions of allergy and adverse reactions over time.</p> <p>d) The system SHALL record and maintain allergy and adverse reaction event dates</p> <p>e) The systems SHALL display allergy history</p> <p>f) The system SHALL be capable of including drug reactions not classified as true allergy, dietary intolerances or environmental triggers.</p> <p>g) The system SHALL indicate (via notation) the actor reporting the event.</p>	a) specific codes can be enumerated by others	Managed vs Maintained
DC1.1.4	Manage Patient History	Capture, review, and manage medical procedural/surgical, social and family history including the capture of pertinent positive and negative histories, patient-reported or externally available patient clinical history.	<p>a) The system SHALL capture, store, report, and allow modification to patient history.</p> <p>b) The system SHALL capture past medical/surgical problems, diagnoses, procedures, family history and social history.</p> <p>c) The system should be able to capture both positive and negative history formats</p> <p>d) The system SHALL allow multiple data capture methods, including either electronic or non-electronic methods or both</p> <p>e) The system SHALL allow for documentation other than locally captured.</p> <p>f) The system SHALL display patient history.</p>	c) specific data capture methods can be enumerated and mandated by others	<p>Doesn't manage include the ability to review? If so, it doesn't need to be explicitly called out in Statement</p> <p>d) Are any of the listed methods more than suggested examples?</p> <p>f) other functions use 'display' this uses 'presented' We assume these are the same.</p>
DC 1.1.6	Manage clinical documents and notes	Create, addend, correct, authenticate and close, as needed, transcribe or directly-	a) The system SHALL be able to create, addend, correct and close clinical documentation and notes.	b) Authentication function I1.1 and standards	<p>a) what is 'close'?</p> <p>c) This should be a requirement – are both</p>

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
		entered clinical documentation and notes.	b) The system SHALL be able to authenticate all clinical documentation and notes. c) The system should be able to provide both free text and structured documents. d) The system may provide templates for capturing data.		required or at least one of them required? c) structured documents? (corey)
DC.1.2.1	Present care plans, guidelines, and protocols	Present organizational guidelines for patient care as appropriate to support order entry and clinical documentation.	a) The system SHALL contain organizational care plans, guidelines and protocols. b) Organizational care plans may be site-specific, community or industry-wide standards. c) The system SHALL present care plans, guidelines and protocols at appropriate points in the order-entry functions. d) The system SHALL present organizational care plans, guidelines and protocols as appropriate as part of the system's clinical documentation functions. e) The systems SHALL track and present implementation or approval dates of specific content for the organizational care plans, guidelines and protocols. f) The system SHALL provide the capability to modify organizational care plans, guidelines and protocols and reflect change in e) above. g) The system SHALL delineate care plans, guidelines and protocols by relevancy to specific domains or context	a) Note that DC.2.2.1.3 is not in this list, meaning that while the function to contain organizational guidelines exists, a function to provide alerts when going against the norm is not mandated. b) Should DC.1.4.1 also be a dependency since that is a type of 'order entry'?	a) Organizational care plans are defined by others. b) The description statement "They may need to be managed across one or more providers" is unclear. Does this mean 'providers as users' of one EHR-S, or does this mean across multiple EHR-Ss? c) The term 'order entry' is rather vague. Can specific functions of the 'order entry' type be listed? g) The logic to determine relevancy is provided by others.
DC.1.3.1	Order medication	Create prescriptions or other medication orders with detail adequate for correct filling and administration. [The following statement not included in mandatory: Provide information regarding compliance of medication orders with formularies.]	a) The system SHALL provide for the creation of prescription or other medication orders with detail adequate for correct filling. b) The system SHALL provide for the creation of prescription or other medication orders with adequate administration or patient instructions. c) The system SHALL make available administration and patient instruction content		Content for prescription administration and patient instructions is provided by others.

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
			to be selected by the ordering clinician or the system SHALL facilitate the creation of such instructions. c) The system SHALL generate and use appropriate time stamps for all medication related activity generated. d) The system SHALL be capable of generating a series of orders that are part of a therapeutic regimen.		
DC.1.4.1	Place patient care orders	Capture and track orders based on input from specific care providers.	a) The system SHALL be able to capture orders (that request actions or items) based on input from specific care providers. b) The system should capture, for each orderable item, appropriate detail including at a minimum, order identification and instructions. c) The system SHALL be able to track orders over the life of the order from capture to fulfillment. d) The system SHALL communicate the order to the correct recipient if appropriate.	DC1.3.1 - This dependency creates the implicit requirement that medication orders are also tracked – does this make sense?	b) ‘appropriate detail’ is determined by others c) Does the system use the ‘order identification’ to track orders? c) Should the order be tracked beyond fulfillment? d) this conf stmt implies that the system has connectivity outside the EHRS – or the act of printing order for manual fulfillment suffices?
DC.1.4.2	Order diagnostic tests	Submit diagnostic test orders based on input from specific care providers.	a) The system SHALL have the capability for care providers to submit orders for diagnostic tests. b) The system SHALL provide, for each orderable item, the appropriate detail and instruction for the ordering care provider to complete. c) Orders SHALL be either: c1) transmitted to the correct destination for completion, or c2) generate appropriate requisitions for communication to the relevant resulting agencies.	I.1.2	b) the criteria to determine “appropriate” detail and instruction is determined by others. c) If the EHRS does not have connectivity with respect to ordering tests, would producing paper output to be hand carried by the patient meet the conformance stmt?
DC.1.4.5	Manage results	Route, manage and present current and historical test results to appropriate clinical personnel for review, with the ability to filter and compare	a) The system SHALL manage test results. b) The system SHALL present current and historical test results in an easily accessible manner to the appropriate care provider. c) An easily accessible manner may include,	The phrase “appropriate care provider” implies access control or privilege.	The sentence “Documentation of notification is accomodated” is unclear. b) ‘easily’ is subjective,

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
		results.	but is not limited to, flow sheets, graphs or other tools to show or uncover trends over time. d) The system SHALL be able to filter and compare results. e) The system SHALL be able to route results to other appropriate care providers. f) The system may route results to patients electronically or in the form of a letter.		suggest removal from Description c) Is the ability to route a requirement? Would email with an attachment satisfy the conf. stmt? c) these are techniques for accomplishing b) “accessible manner”
DC.2.1.1	Support for standard assessments	Offer prompts to support the adherence to care plans, guidelines, and protocols at the point of information capture.	a) The system SHALL offer prompts, based on information captured during the assessment process, to support adherence to care plans, guidelines and protocols.		a) Appropriate logic used to determine when/content of prompts based on captured information is determined by others. a) Should the language of this function be consistent with DC.1.2.1?
DC.2.2.1.1	Support for standard care plans, guidelines, protocols	Support the use of appropriate standard care plans, guidelines and/or protocols for the management of specific conditions	a) The system SHALL present standard care plans, protocols and guidelines when requested. b) The system may support site-specific considerations. c) The system SHALL delineate standard care plans, guidelines or protocols based on specific conditions.		a) Should the language of this function be consistent with DC.1.2.1?
DC.2.3.1.1	Support for drug interaction checking	Identify drug interaction warnings at the point of medication ordering.	a) The system SHALL identify and provide drug interaction warnings during the medication ordering process. b) The system SHALL provide warnings regarding drug-drug, drug-allergy and drug-food interactions at a level appropriate to the health care entity.	DC.1.3.1 – Partial language is mandatory for ordering medication.	a) The drug info and logic/algorithms for the warnings are determined by others. b) The determination of ‘appropriate’ level to the health care entity is determined by others.
DC.2.4.2	Support for result interpretation	Evaluate results and notify provider of results within the context of the patient’s clinical data.	Within the context of the patient’s clinical data, system SHALL: a) automatically evaluate results b) notify provider of actual results c) notify provider of corresponding standard	Needs standard sets of normal result ranges for such evaluations.	System automates <i>evaluation</i> and leaves actual <i>interpretation</i> to recipient?

Draft Guidelines for expressing Conformance Criteria

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
			evaluations	May need standards formats for results.	Evaluate? (corey)
DC.2.5.1	Present alerts for preventive services and wellness	At the point of clinical decision making, identify patient specific suggestions/reminders, screening tests/exams, and other preventive services in support of routine preventive and wellness patient care standards.	-System SHALL support clinical decisions at time of encounter by presenting alerts for patient-specific: a) suggestions and reminders b) screening tests and exams c) other services supporting routine preventive and wellness patient care standards	Items (a-c) – specific EHR-S applications can specify which preventive standards are included	
DC.2.7.1	Access clinical guidance	Provide relevant evidence-based information and knowledge to the point of care for use in clinical decisions and care planning.	System SHALL provide evidence-based information and knowledge (a) to the point of care (b) for use in clinical decisions and care planning.	Must characterize “relevant” in some way.	
DC.3.1	Clinical workflow tasking	Schedule and manage tasks with appropriate timeliness.	System SHALL manage clinical workflow by: (a) creating finite-duration workflow tasks (b) scheduling tasks (c) starting tasks at time of request (d) monitoring and ensuring progress of tasks toward their on-time completion (e) ending and removing each task properly	Range of functions must exist to support electronically any workflow previously dependent upon physical artifacts (paper chart, paper phone message).	
DC.3.2.1	Inter-provider communication	Support secure electronic communication (inbound and outbound) between providers to trigger or respond to pertinent actions in the care process (including referral), document non-electronic communication (such as phone calls, correspondence or other encounters) and generate paper message artifacts where appropriate.	-System SHALL support inter-provider clinical communication via: (a) secure inbound and outbound electronic communication between providers (b) triggers or responses to pertinent actions in the care process (including referrals) (n) (b) documentation of non-electronic communication (d) generation of paper messages where appropriate (n)		Item (b) might mention real-time, as per description column?

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
DC.3.2.4	Patient, family and care giver education	Identify and make available electronically or in print any educational or support resources for patients, families, and caregivers that are most pertinent for a given health concern, condition, or diagnosis and which are appropriate for the person (s).	-System SHALL identify and provide in electronic or printed format educational or support resources for patients, families, and caregivers. (n) -System selected education materials SHALL be those most pertinent for a given health concern, condition, or diagnosis and which are appropriate for the person (s).(n)	Uses health concern classifications and diagnoses categories for actual conformance testing?	<i>Appropriateness</i> for person will need refinement (some classifications, etc.?).
S.1.3.1	Provider demographics	Provide a current directory of practitioners that, in addition to demographic information, contains data needed to determine levels of access required by the EHR security system.	System SHALL provide a directory of practitioners that: (a) has demographic information on providers (b) contains data needed to determine levels of access required by the EHR security system (c) allowing updating of provider demographics	-Inherits additional stipulations from parent S1.3 -(a) input will include defined formats or codes for demographics and related information Related to access authen: I1.1 and I1.2	Likely to take a very <i>ad hoc</i> form initially reviewed & manually entered by EHRS credentials officer?
S.1.4.1	Patient demographics	Support interactions with other systems, applications, and modules to enable the maintenance of updated demographic information in accordance with realm-specific recordkeeping requirements.	System SHALL maintain patient demographics directory via: (a) interactions with other systems, applications, and modules (b) the minimum demographic data set must include updates of current entries required by realm-specific laws governing health care transactions and reporting. (c) may also include patient death status information.	-Inherits additional stipulations from parent S1.4 - (a) Status codes to be determined for system realm specific requirements	Does 'patient demographics directory' make sense? This is derived from S1.4 Patient Directory – current directory of patient information.
S.1.5	De-identified data request management	Provide patient data in a manner that meets local requirements for de-identification.	System SHALL: (a) provide de-identified data in a manner that meets applicable local requirements (b) maintain an audit trail of all requests and de-identified information exports (c) re-identification keys may be added to the data	(a) stipulations for de-identification to be determined as per local constraints.	(c) for internal clinical auditing

Draft Guidelines for expressing Conformance Criteria

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
S.2.2	Report Generation	Provide report generation features for the generation of standard and ad hoc reports.	System SHALL provide generation features for (a) standard reports (b) ad hoc reports	Definition details needed for standard and ad hoc reports.	
S.2.2.1	Health record output	Allow users to define the records and/or reports that are considered the formal health record for disclosure purposes, and provide a mechanism for both chronological and specified record element output.	System SHALL: (a) allow users to define the records or reports that are considered the formal health record for disclosure purposes (b) provide a mechanism for output of both chronological and specified record element.		System provides hardcopy and electronic output that fully chronicle the healthcare process, support selection of specific sections of the health record, and allow healthcare organizations to define the report and/or documents that will comprise the formal health record for disclosure purposes.
S.3.3	Administrative transaction processing	Support the creation (including using external data sources, if necessary), electronic interchange, and processing of transactions listed below that may be necessary for encounter management during an episode of care	System SHALL support the following transaction when necessary for encounter management during an episode of care: (a) the creation (b) electronic interchange, and (c) processing	The EHR system captures: 1. patient health-related information needed for administrative and financial purposes including reimbursement. 2. episode and encounter information to pass to administrative or financial processes. (c) To S3.3.6	(c) Define episode of care?
S.3.4	Manage Practitioner/Patient relationships	Identify relationships among providers treating a single patient, and provide the ability to manage patient lists assigned to a particular provider.	System SHALL (a) identify relationships among providers treating a single patient (b) provide the ability to manage patient lists assigned to a particular provider.	Concerns ability to access and update information about caregivers and care recipients. The relationship among	Could get quite complex.

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
				providers treating a single patient will include any necessary chain of authority/responsibility.	
S.3.5	Subject to Subject relationship	Capture relationships between patients and others to facilitate appropriate access to their health record on this basis (e.g. parent of a child) if appropriate.	System SHALL capture relationships between patient and others to facilitate appropriate access to patient health record on this basis, (e.g. parent of a child patient) as needed.	Each patient has different types of relationships to others.	[Clarify description] A user may assign the relationship of parent to a person who is their offspring.(?)
S.3.5.2	Related by insurance	Support interactions with other systems, applications, and modules to provide information of Related by insurance (domestic partner, spouse, and guarantor).	System SHALL support interactions with other systems, applications, and modules to provide information on those persons related-by-insurance (domestic partner, spouse, or guarantor) to the patient.		
I1.1	Entity Authentication	Authenticate EHR-S users and/or entities before allowing access to an EHR-S	<p>a) System SHALL provide at least one of the following:</p> <ul style="list-style-type: none"> --the ability to authenticate users prior to accessing an application -- the ability to authenticate applications prior to accessing EHR information from other applications or remote EHR-S <p>b) System SHALL prevent access to EHR-S to all non-authenticated users and non-authenticated applications</p> <p>c) System may provide authentication using username/password, digital certificate, secure token or biometrics</p>	Authentication standards (e.g., Kerberos, PKI, DSS, RBAC)	
I.1.2	Entity Authorization.	Manage the sets of access-control permissions granted to entities that use an EHR-S (EHR-S Users). Enable EHR-S security administrators to grant authorizations to users, for roles, and within contexts. A combination of the	<p>System SHALL manage the sets of access-control permissions granted to entities that use an EHR-S (EHR-S Users).</p> <p>System SHALL enable EHR-S security administrators to grant authorizations:</p> <ul style="list-style-type: none"> (a) to users (b) for roles 	<p>See I1.1.</p> <p>Legal requirements</p>	<p>Combos of conformance items (a-c) are not obligatory because the DSTU employs “may” text.</p> <p>(d) Want “may” on authorization levels?</p>

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
		authorization levels may be applied to control access to EHR-S functions or data within an EHR-S, including at the application or the operating system level.	(c) within contexts. Optionally, (a-c) may be used in combination. (d) Authorization levels may be applied to control access to EHR-S functions or data within an EHR-S, including at the application or the operating system level.		Description is explanatory material and contains no requirements, thus no conformance statements created from the Description
I.1.3	Entity Access Control	Verify and enforce access control to all EHR-S components, EHR information and functions for end-users, applications, sites, etc., to prevent unauthorized use of a resource, including the <i>prevention or use of a resource in an unauthorized manner.</i> (c→)	System SHALL (a) verify users and/or applications and (b) enforce access control for all EHR-S resources—at component, application, or user levels— whether local or remote.	Can look at (a) and (b) separately.	DSTU suggests identity lookup of users or application for any <i>operation</i> [resource?—data too] that requires it and <i>enforce</i> [ment of] system and information access rules that have been defined. (c) [Statement, col. 2] ”,including the <i>prevention or use of a resource</i> in an unauthorized manner”: does this text mean <i>denial of a resource</i> ?
I.1.5	Secure Data Exchange	Secure all modes of EHR data exchange.	a) System SHALL secure all modes of EHR data exchange. b) System SHALL provide capability to do data obfuscation and destination/source authentication. c) If encryption performed, System SHALL establish connection and be cryptographically synchronized with the remote or external system. cc) System SHALL have encryption and decryption functionality	Encryption standards, etc. Coordination, compatibility with other systems	b) does data obfuscation == encryption. Requires system has connectivity outside the EHRs, and be interoperable. Expresses need for overall coordination regarding information exchange among EHR-S entities and how exchanges should occur. Policies applied at different locations must be consistent or compatible with each other to ensure that information is protected as it crosses entity

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
					boundaries within or without an EHR-S.
I.1.6	Secure Data Routing	Route electronically exchanged EHR data only to/from known, registered, and authenticated destinations/sources (according to applicable healthcare-specific rules and relevant standards).	System SHALL route electronically exchanged EHR data only to and from (a) known, (b) registered, and (c) authenticated sources and destinations. (d) System SHALL route EHR data according to applicable healthcare-specific rules and relevant standards.	(d) Exchange standards.	[included as extra; not requested as part of trial conformance text markup]
I.1.8	Enforcement of Confidentiality	Enforce the applicable jurisdiction's patient privacy rules as they apply to various parts of an EHR-S through the implementation of security mechanisms.	a) System SHALL enforce the applicable jurisdiction's patient privacy rules. b) System SHALL include security mechanisms, including authentication, authorization, and access control. (I1.1, 1.2, 1.3)	See I1.6, 1.5, etc. for related entries. Jurisdiction requirements	Description is explanatory information, with no conformance requirements
I.2	Health record information and management	Manage EHR information across EHR-S applications by ensuring that clinical information entered by providers is a valid representation of clinical notes; and is accurate and complete according to clinical rules and tracking amendments to clinical document. Ensure that information entered by or on behalf of the patient is accurately represented.	a) System SHALL manage EHR information across EHR-S applications ensuring clinical information entered by providers is a valid representation of clinical notes b) System SHALL provide the ability to access, manage, and verify accuracy and completeness of EHR information c) System SHALL provide the ability to audit the use of and access to EHR information	a) Need to incorporate clinical rules and tracking amendments c) Access and Audit standards	b) Does this need to relate specifically to clinical notes?
I.2.1	Data Retention, Availability and Destruction	Retain, ensure availability, and destroy health record information according to organizational standards. This includes: > Retaining all EHR-S data and clinical documents for the time period designated by	a) System SHALL provide for the storage and retrieval of health record data and clinical documents for legally proscribed time b) System SHALL retain source documents (to health records) as originally received (unaltered) for legally proscribed time c) System SHALL provide the ability to retrieve and present information in	a) length of time= c) others to provide manner to retrieve information d) others to provide destruction policy and retention periods.	a) is retain and availability same as store and retrieve? c) need better words than semantically intelligent and useful – this is untestable.

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
		<p>policy or legal requirement; >Retaining inbound documents as originally received (unaltered); >Ensuring availability of information for the legally prescribed period of time; and >Providing the ability to destroy EHR data/records in a systematic way according to policy and after the legally prescribed retention period.</p>	<p>semantically intelligent and useful manner d) System SHALL provide the ability to identify specific EHR data/records for destruction and review and confirm destruction before it occurs. d) System SHALL be capable of destroying EHR data/records so that all traces are removed and unrecoverable, and according to policy and legal retentions periods.</p>	<p>d) Others to indicate methods for destruction – e.g., number of erase overwrites.</p>	
I.2.2	Audit trail	<p>Provide audit trail capabilities for resource access and usage indicating the author, the modification (where pertinent), and the date and time at which a record was created, modified, viewed, extracted, or deleted. Audit trails extend to information exchange and to audit of consent status management (to support DC.1.5.1) and to entity authentication attempts. Audit functionality includes the ability to generate audit reports and to interactively view change history for individual health records or for an EHR-S.</p>	<p>System SHALL provide audit trail capabilities for resource access and usage events indicating (a) viewer or author of change, (b) any modifications (where pertinent) (c) time of day and date when a record was created, modified, viewed, extracted, or deleted.</p> <p>System audit trails SHALL extend to (d) information exchange (e) audit of consent status management (to support DC.1.5.1) (f) entity authentication attempts.</p> <p>EHR-S audit functionality SHALL include the ability to (g) generate audit reports (h) view change history interactively for individual health records or for an EHR-S.</p> <p>System SHALL provide audit trails for the following events: (i) Loading new versions of, or changes to, the clinical system; (j) Loading new versions of codes and knowledge bases;</p>	(e) see DC1.5.1	<p>Audit trail settings should be configurable to meet the needs of local policies.</p>

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
			(k) Changing the date and time where the clinical system allows this to be done; (l) Taking and restoring of backup; (m) Archiving any data; (n) Re-activating of an archived patient record; (o) Entry to and exiting from the clinical system; (p) Remote access connections including those for system support and maintenance activities		
I.2.4	Extraction of health record information	Manage data extraction in accordance with analysis and reporting requirements. The extracted data may require use of more than one application and it may be pre-processed (for example, by being de-identified) before transmission. Data extractions may be used to exchange data and provide reports for primary and ancillary purposes.	(a) System SHALL manage data extraction in accordance with analysis and reporting requirements. (b) An EHR-S must support data extraction operations across the complete data set that constitutes the health record of an individual (c) An EHR-S must provide an output that fully chronicles the healthcare process.	(a) requires analysis and reporting specifics (b) See I.5.1	
I.4	Health Informatics and Terminology Standards	Ensure consistent terminologies, data correctness, and interoperability in accordance with realm specific requirements by complying with standards for health care transactions, vocabularies, code sets, as well as artifacts such as: templates, system interfaces, decision support syntax and algorithms, and clinical document architecture. Support reference to standard and local terminologies and their versions in a manner that	(a) System SHALL ensure consistent terminologies, data correctness, and interoperability in accordance with realm specific requirements by complying with standards for health care transactions, vocabularies, code sets, as well as artifacts such as: templates, system interfaces, decision support syntax and algorithms, and clinical document architecture. (b) System SHALL support reference to standard and local terminologies and their versions in a manner that ensures comparable and consistent use of vocabulary, such as the Common Terminology Services specification.	EHR-S uses consistent terminology sets, such as LOINC, SNOMED, applicable ICD, CPT and messaging standards such as X12 and HL7. Vocabularies may be provided through a terminology service internal or external to an	

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
		ensures comparable and consistent use of vocabulary, such as the Common Terminology Services specification.		EHR-S.	
I.4.2	Mapping local terminology, codes, and formats	Map or translate local terminology, codes and formats to standard terminology, codes, and formats to comply with health informatics standards.	System SHALL map or translate local terminology, codes and formats to standard terminology, codes, and formats to comply with health informatics standards.	Standard terminology, codes and formats (TBD).	
I.5	Standards-based Interoperability	Provide automated health delivery processes and seamless exchange of key clinical and administrative information through standards-based solutions.	System SHALL provide (a) automated health delivery processes (b) seamless exchange of key clinical and administrative information through standards-based solutions.	Interoperability standards (TBD) enable an EHR-S to operate as a set of applications.	More philosophical than anything else: gives scope and objective
I.5.1	Interchange Standards	Support the ability to operate seamlessly with complementary systems by adherence to key interoperability standards. Systems may refer to other EHR-S', applications within an EHR-S, or other authorized entities that interact with an EHR-S.	(a) System SHALL support seamless operation with complementary systems by adhering to key interoperability standards. (b) An EHR-S SHALL adhere to standards for connectivity, information structures, and semantics ("interoperability standards"). An EHR-S, which may exist locally or remotely, must support seamless operations between complementary systems. (c) An EHR-S must support realm specific interoperability standards (d) An EHR-S must support multiple interaction modes to respond to differing levels of immediacy and types of exchange.	Scope: System may interact with other EHR-Ss, applications within an EHR-S, or other authorized entities that interact with an EHR-S. (a) Actual standards TBD for applications and conformance tests (b) examples: HL7 Messages, Clinical Document Architecture (CDA), X12N healthcare transactions, Digital Imaging	(b) What does "seamless operations" mean and how test for it? (d) Example: <i>messaging is effective for many near-real time, asynchronous data exchange scenarios but may not be appropriate if the end-user is requesting an immediate response from a remote application.</i> [?If not shared-memory, how get other than messaging?]

Draft Guidelines for expressing Conformance Criteria

ID	Name	Statement	Conformance Statement	Dependencies	Questions/comments
				and Communication in Medicine (DICOM).	

Draft, not intended for application