Template for comments and secretariat observations

Date: 2009-04-17	Document: **ISO/DIS 10781**

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/Table/ Note** (e.g. Table 1)	**Type of com-ment**[2]	**Comment (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations** on each comment submitted
CA	Overall draft		Ge	Canada is pleased to vote Affirmative on this ballot, and is appreciative of the significant efforts of the HL7 EHR TC in responding to our earlier requests for refinement of the ballot and specification. It is important to note, however, that in the time frame for this ballot some significant changes have occurred in the Canadian context that make this standard increasingly important to our national objectives as well as to our international efforts in aligning on the expression of EHR functional requirements and the ability to test for conformance of solutions to those requirements. For this reason we have looked at the ballot with a fresh perspective and increased interest, which has resulted in additional comments, mostly technical, which are provided along with our affirmative response. We have provided these comments as they may be of interest to other ISO members, and they will form the foundation for a renewed interest and active participation by Canada in the HL7 EHR TC as it works on the next major iteration of the specification (R2). We appreciate HL7's commitment to moving forward with this iteration as evidenced in the disposition of many of the R1 comments & the committee members stated support during the disposition process. We know that the HL7 EHR TC appreciates the need to continue to evolve this specification, and Infoway recognizes the value of the current ballot to the ISO members. Given the manner in which healthcare services are provided at a national level by many of the member countries, Canada believes there is still work to be done in enhancing the components of the standard that address aspects such as the ability for EHR functions to work across organizational, regional, and even internationally boundaries in order to meet the needs of the citizens receiving those services as well the objectives of the varied health service delivery programs across countries.		(1) Overview, no action taken For purposes of reconciliation, the reviewers frequently use the disposition comment "Consider for future use'. The meaning of this phrase is defined immediately below: *Consider for future use: This reconciliation phrase is used where the comments will be further discussed in the development of the next version of the EHRS-FM. In addition, during those discussions, agreement will be reached on which comments will further enhance the FM or would be more appropriate as part of a profile (e.g. realm specific).*
CA	DC.1.1.1	Conformance Criteria 02	te	The system SHALL provide the ability to create a record for a	It is unclear what the is purpose of creating a record	(2) The workgroup has reviewed the question and answer from a

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				patient when the identity of the patient is unknown.	where patient identity is unknown. Does this mean that the system provides capability to create a placeholder for patient record and fill in appropriately at the time when those information become available?	point of clarification. Yes, the purpose is to ensure the system can support records for individuals who may be unidentifiable at time of admission (e.g hit by a car while walking and not carrying ID) see CC#4.
CA	DC.1.1.2	Conformance Criteria 06	te	The system SHOULD store historical values of demographic data over time.	The historical data must be available for auditing purposes in accordance with legislative regulation and system must ensure this capability is mandatory. Proposed wording: The system MUST provide the ability to store demographic data historical records for a period of time as required by legislative regulative / laws.	(3) Persuasive with Mod – the workgroup will add IN.2.1 to the See Also column of DC.1.1.2 (The comment is addressed in criteria #1 of IN.2.1 "The system **SHALL** provide the ability to store and retrieve health record data and clinical documents for the legally prescribed time.")
CA	DC.1.1.3.1	2 Conformance Clause	te		Criteria number 1 suggests that system SHALL provide capability to capture external data. Criteria 2 and 3 introduce condition clause "if … is received through an electronic interface" which does not appear in the remaining criteria. Why is that, and why only for lab results (and not for medications or diagnostic imaging for example)? Further. SHALL conformance (mandatory behaviour) is only applicable to lab test, whereas for other external data it is just a recommendation. Why is that?	(4) Not Persuasive – The workgroup has considered the comment but feel that Lab Results are considered essential base functionality.
CA	DC.1.1.4	Statement	te	Present a summarized review of a patient's comprehensive EHR, subject to jurisdictional laws and organizational policies related to privacy and confidentiality.	The summarized review should be provided within clinical care context. The description suggest it is comprehensive patient's EHR presuming provision of each and every health care episode summary and that should not be a case. Proposed wording: Present a summarized review of a patient's EHR relevant for one or more related health care delivery episodes, subject to jurisdictional laws and organizational policies related to privacy and confidentiality	(5) Persuasive with Mod – The workgroup will change the description as follows: "Present a summarized review of a patient's episodic and/or comprehensive EHR, subject to jurisdictional laws and organizational policies related to privacy and confidentiality." In response to your comments, see criteria #1 & 3, and also S.3.3.6.

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CA	DC.1.2	Conformance Criteria 02	te		The EHRS represents a centralized system that provides the capability to capture and share current and previous patient's history from multiple sources, including but not limited to EMRs, PHRs, practitioner office systems, etc. For that mater, all these various systems may be considered as the external sources, however the EHRS SHALL provide capabilities defined in Criteria 1.	(6) Not Persuasive – See Chapter 1 Overview, Sections 2.1 – "Notably, the EHR-S Functional Model does not address whether the EHR-S is a system-of-systems or a single system providing the functions required by the users."
CA	DC.1.3.1	Description	te	Capture and maintain patient and family preferences.	This information may be captured/ managed as part of comprehensive patient record (Patient Registry), along with demographic and other patient related information. Jurisdictions may extend patient record with multiple logical data sets, building patient record profiles to meet their own requirements.	(7) Considered – No Action Required Consider creating a profile if an extension of the record with logical data sets is needed.
CA	DC.1.3.2	2nd Conformance Clause	te		Suggested conformance criteria: System SHOULD store and present history of advanced directives. It should also allow for patients substitute decision maker / representative to provide advanced directives.	(8) Not Persuasive – 1) past discussions have determined that existing IN functions and criteria provide this capacity (IN.2.1 – CC #1 & IN.2.2 CC#15). 2) Not Persuasive – accommodated by existing CC #6.
CA	DC.1.3.3	Conformance Criteria 10	te	'The system SHOULD provide the ability to document the patient's personal representative's level of authority to make decisions on behalf of the patient.' The current statement suggests that the system should provide capability to determine / document / capture the level of substitute decision maker's authority in managing patients consent directives. In case it is not implemented, the substitute decision maker may have implied privileges to manipulate consent. This represents potential threat to privacy and security of the patient.	Rewording statement to SHALL (as mandatory clause) will provide more rigid control over SDM rights in managing patient's consent.	(9) Non-Persuasive – To be done in a profile, not at the model level
CA	DC.1.3.3	2nd Conformance Clause	te		Suggested conformance criteria: The system SHALL provide capability to override patient's consent to share information in cases where access to information may be critical for patient's health condition or treatment.	(10) Non-Persuasive – Existing See Also to IN.1.9 CC #10 "The system **SHALL** provide the ability to override a mask in emergency or other specific

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						situations according to scope of practice, organizational policy or jurisdictional law"
CA	DC.1.3.3	2nd Conformance Clause	te		Suggested rewording and consolidation of criteria 1 and 2: " System SHALL provide capability to capture and use patient's consent directive in appropriate clinical context. Directive may either 1) grant or 2) entirely or partially revoke consent / authorization for specific health care activity (example consent to view patient's drug usage history)	(11) Non-Persuasive – each criterion is created to stand by itself in orcer to support testing.
CA	DC.1.4.1	Statement	te	'Create and maintain patient specific allergy, intolerance and adverse reaction.' Suggestion: This whole statement may be aggregated as an extension / constituent part to Manage Patient's History function or generally patient's Health Record.		(12) Non-Persuasive – conformance criteria are unique for this function.
CA	DC.1.4.3	Statement	te		See 1.4.1	(13) Non-Persuasive - conformance criteria are unique for this function.
CA	DC.1.4.3	Conformance Criteria 10	te	'The system SHALL provide the ability to deactivate a problem.' System SHOULD provide capability to flag any type of health record as inactivate (logical delete) or deprecate (historical record)		(14) Considered for future use.
CA	DC.1.1.5 (DC.1.5)	Conformance Criteria 02	te	'The system SHOULD provide the ability to use standardized assessments where they exist.' Also, the system SHOULD provide capability to support assessment and provide recommendation based on captured medical condition data or information in patient's problem list (Clinical Decision Support).	The system SHOULD provide clinical assessment guides as means to standardize assessment process.	(15) Non persuasive. Support for the requested conformance criteria is in DC.2.1.1 and DC.2.1.2.
CA	DC.1.6.2	2 Conformance Clause	te		The system SHALL provide capability to create and manage automated workflows to support clinical health care planning and service delivery for patient, including but not limited to service referral, scheduling, alerts and notification functionalities.	(16) The link of the conformance criteria and function are not related. No action taken.
CA	DC.1.6.2	Conformance Criteria 01	te	'The system SHALL provide the ability to capture patient specific plans of care and treatment.'	Suggest merging criteria 1 and 2. Proposed Wording:	(17) Non-Persuasive – each criterion is a standalone to

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					The system SHALL provide the ability to capture patient specific plans of care and treatment utilizing locally or non-locally developed templates, guidelines, and protocols for the creation of patient-specific plans of care and treatment.	support testing.
CA	DC.1.7.2.2	Description	te		Suggestion: System SHOULD provide capability to send alert / notification prior to ordered diagnostic test, informing patient / practitioner about important prerequisites / instructions / reminders for test fulfillment. (NOTIFICATION)	(18) Non persuasive. This functionality exists in DC.1.9
CA	DC.1.7.2.4	Description	te		Suggestion: System SHOULD provide capability to send notification to sender once referral is accepted / completed with any additional information pertaining referral fulfillment. (NOTIFICATION)	(19) Consider for future use.
CA	DC.1.8.1	Conformance Criteria 01	te		What is the selection criteria used by system to compile medication list to be administered?	(20) Considered. No action required. This is not determined at the model level.
CA	DC.1.8.4	Description	te		The clinical measurement results should be captured in a context of an episode of care. Capturing / presenting results without context wrapper does not bring any value. This should be articulated or described as part of this function.	(21) Persuasive with mod. We have added the following to the description for clarification. **Description**: *Within the context of an episode care*, patient measures such as vital signs are captured and managed as discrete data to facilitate reporting and provision of care. Other clinical measures (such as expiratory flow rate, size of lesion, etc.) are captured and managed, and may be discrete data.
CA	Chapter 2 Conformance Clause pg 2		ge	Existing wording: 2. Conformance to the Functional Model is defined for functional profiles. An EHR-S does not directly conform to the Functional Model, rather it conforms to one or more functional profiles. **** Does this mean that for countries to make use of the		(22) The submitters question was considered. Either the realm specific profile or a universal profile would be utilized to carry out the detail of the comment.

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				conformance criteria for any certification that we would need to see a profile such as the Records Management and Evidentiary Support profile pass ballot as a universal profile or develop our own realm specific clinical and/or RM & ES profile?		
CA	DC.1.8.5	2 Conformance Clause	te		Suggested conformance clause: The system SHALL provide capability to persist and present history of document revisions / amendments / modifications	(23) Consider for future use. The workgroup feels this is handled impliciitly (rather than explicitly) through DC.1.8.5CC#9 and IN.2.2---however further discussion of 'persistance and history ' is needed.
CA	DC.1.9	Name	te	Generate and Record Patient-Specific Instructions Suggestion: Add clause's) pertaining to distribution of generated patient-specific instructions	Suggested wording: Generate, Record and Distribute Patient-Specific Instructions	(24) Consider for future use.
CA	DC.2.2.1.1	Conformance Criteria 04	te		Are we talking about variances pertaining to clinical decision or to local version of the guideline? Please clarify.	(25) For clarification, this function deals with standard care plans---and identifying the variances from the standard. Consider for future Use. Additional conversation as to whether this Function applies to Clinical Support and/or is appropriate to Direct Care or Supportive chapters.
CA	DC.2.2.4	2 Conformance Clause	te		The system SHALL provide capability to monitor actions / results provided by a patient and notify patient/health care provider in case where provided result are exceeding threshold boundaries or expected actions have not occurred (DC 2.6.3).	(26) Non persuasive. This criteria is located in DC.2.4.3 CC#1.
CA	DC.2.3.1.1	Statement	te	Identify drug interaction warnings time of medication ordering.	Proposed wording: Identify drug interaction warnings at the time of medication ordering.	(27) Persuasive. The change will be made as follows: **Statement**: Identify drug interaction warnings *at* time of medication ordering.

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CA	DC.2.3.1.2	2nd Conformance Clause	te		Suggested conformance clause: The system SHALL provide capability to capture patient's preference for medication usage and present it to practitioner at the time of medication ordering.	(28) Consider for future use.
CA	DC.2.3.2	Conformance Criteria 02	te		How does the system identify wrong patient?	(29) Considered. No action required. The FM is constrained to what and why, but not 'how'. This is an implementation issue. (Overview chapter, Section 2.1)
CA	DC.2.4.2	Conformance Criteria 02	te	The system SHALL present an alert at the time of order entry, if a non-medication order is missing required information.	Proposed wording: The system SHALL perform validation of the required data elements and raise an alert at the time of order entry, if a non-medication order is missing required information.	(30) Considered. No action required. The FM is constrained to what and why, but not 'how'. This is an implementation issue. (Overview chapter, section 2.1)
CA	DC.3.1.1	Conformance Criteria 05	te		Change SHOULD to SHALL	(31) Non persuasive. The workgroup has considered the request and has determined that 'SHOULD' is the appropriate constraint for this CC. Optionality can be elevated in a profile.
CA	DC.3.1.1	2nd Conformance Clause	te		Criteria 3 and 4 to be moved as conformance criteria in function DC 3.1.3, as they pertain to system capabilities to record and track a task status	(32) Consider for future use. The workgroup feels this could be persuasive.
CA	DC.3.1.3	Name	te	Clinical Task Tracking	Proposed wording: Clinical Task Status Tracking	(33) Consider for future use.
CA	DC.3.2.1	Conformance Criteria 01	te		Why limited to only verbal / phone call conversation. How about abstracts from email communication? There are also different verbs describing inclusion of various data and information as part of patient record (document , incorporate, transmit). Provide consistency of expression.	(34) Non persuasive. CC#3 and CC#4 cover email communication. Consider for future use: Review consistent use of action verbs.
CA	DC.3.2.1	Description	te		Missing concept of pub sub capabilities for inter provider communication. This concept is also applicable for other sections or functional definitions (D.C 3.2.2, DC 3.2.3, etc). There is a need to define a set of functional definitions to support pub sub capabilities (administrative, clinical, etc)	(35) Consider for future use

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CA	DC.3.2.2	Conformance Criteria 07	te		This should be common system capability for communication in EHRS not specific to provider - pharmacy user. Why not include this in DC 3.2.1	(36) Non persuasive. This is covered in DC.3.1.1 CC#5 and CC#6.
CA	DC.3.2.3	Description	te		Recommend to consolidate communication support functionalities (DC 3.2.1, 3.2.2, 3.2.3) as they have number of common criteria.	(37) Considered. No action required.
CA	DC.3.2.3	2nd Conformance Clause	te		Criteria 8 and 9 pertains to common Notification functionalities that should be described as part of EHRS FM document.	(38) Consider for future use. Will be added to glossary: notification, alert and reminder.
CA	Chapter 3 Direct Care Functions DC.3.2.3 pg 53		ge	Existing wording: CC 12. The system MAY provide the ability to support communication and capture documentation of communications between providers and patient groups. *** Is support for communication in more than one language, or using the language of preference, such as English and/or French, deemed to be feasible to include in the functional model or profile?		(39) Consider for future use. Suggest adding the phrase according to….. organizational policy and/or jurisdictional law. Also consider the technical implications of email or other type of communication.
CA	DC.3.2.5	Description	te		Suggested wording: The system should have capability to notify home device (telehealth device) user in case when communication between health care device and EHRS is interrupted or when feed is not registered at predefined intervals.	(40) Consider for future use.
CA	S.1.1	Statement	te		Criteria described here should be applicable for all centralized data registries (Patient, Provider, Organization, Health Services) and the system should provide capability to automate process of synchronization of centralized registry data from / to EMR applications. There should be a capability to administer registries.	(41) Consider for future use. Request specific details on: a. synchronization with registries and b. capability to administer registries. Depending on clarification, these may be included as MAY or SHOULD criteria in R2.
CA	S.1.2	Description	te		A few suggestions: Consent must be obtained for sharing sensitive information relevant for donations or receipt of organs/blood/ tissues etc... Most of the information pertaining to donor or receiver of donation may be tied to	(42) Persuasive with Mod. We will add DC.1.3.3 to the See Also column. Suggest adding the following to

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					Patient Record. Clinical information may be extracted from patient's health history or clinical case	the description: A consent or authorization includes patient authorization for redisclosure of sensitive information to third parties (*such as donor management)*
CA	S.1.3	Name	te	Provider Information	All S.1.3.X functionalities should support Provider Registry requirements. The Provider Registry may capture information including but not limited to, full name, address or physical location, location within facility, on-call practitioner indicator, etc Proposed wording: Provider Registry	(43) Consider for future use. S.1.3.1 performs the functions within your suggested comments. Will update the statement and description in the S.1.3 (H) as part of the R2 to incorporate the spirit of your comment.
CA	S.1.3.1	Conformance Criteria 01	te		Suggestions: 1. System SHALL provide consolidated, central registry of health care providers. 2. System SHOULD provide information (as part of the Provider registry) l for providers who have access to the system, indicating their access privileges	(44) Not persuasive. Different realms may implement registries in different ways. Some may have registries within the EHR and others outside the EHR. Nevertheless, S.1.3.1 provides for a registry. The criteria should remain optional. However different realms may choose to elevate the criteria to a SHALL. The second suggestion is handled by S.1.3.1 CC4. Note: we did not intend this criteria to provide access privilege information to providers.
CA	S.1.3.1	Conformance Clause 04	te		Proposed wording: The system **SHOULD** contain, in one or more directories, the information necessary to determine levels of access required by the system security functionality. A Provider Registry may be separate from a User Registry, where the latter may contain the EHRS role (or	(45) Persuasive. The wording will be changed to that proposed.

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					information necessary to…).	
CA	S.1.4.1	Name	te	Patient Demographics	Proposed wording: Patient demographic data synchronization	(46) Persuasive. The workgroup agrees with the proposed change. The name change better matches the description and criteria.
CA	S.1.4.3	Statement	te		This feature is predominantly built for EMR / hospital system and is not relevant for patient history in EHRS	(47) Not persuasive. The model is built for ambulatory and hospital setting. In a profile, one could choose not to select this function.
CA	S.1.5	Statement	ed	local requirements	"local" may be misconstrued. Proposed wording: applicable requirements	(48) Persuasive. The workgroup will change the wording from 'local requirements' to 'applicable requirements'.
CA	S.1.6	Description	te		Current conformance criteria are basic. The EHRS scheduling functionality should provide ability to orchestrate scheduling of selected health care services. Using pub / sub mechanism, EHRS retrieves confirmation from local health care organizations on availability. System provides capability to return confirmations to scheduling requestor and offer options from which one will be selected. Then EHRS monitors status and progress of the scheduled service. Scheduling service should also provide wait list capabilities. Once the resources / devices are available system notifies waitee about successfully booked health care event. These are few capabilities that should be elaborated for R2	(49) Not persuasive. We are unclear about what is meant by 'orchestrate scheduling' The current function and criteria already support accessing scheduling features.
CA	S.2.2.2	Description	te		Current conformance criteria cover some of the functional capabilities. It needs to support also research, trend analysis, and other statistical data anonymized. The system needs to provide functional capabilities to export data from various EHRS domains into dedicated data warehouse for analytical purposes. It may be a good idea to consolidate common conformance criteria of both report types (standard and ad hoc) under General Report Generation capability section.	(50) Considered for future use.

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CA	Chapter 4 Supportive Functions S.3.2.1 pg 19		te	Existing wording: CC 1 and 2 . . . Support coding of diagnoses, procedures, and outcomes based on . . .	Proposed wording: . . .support coding of diagnoses, procedures, outcomes, and other meaningful data using standard terminology code sets **** This may not be the exact wording, but the support for more than diagnoses, procedures, and outcomes seems appropriate given the wealth of data that can be codified using SNOMED CT, LOINC, etc. . . .	(51) Not persuasive. This level of detail may be best defined in a profile.
CA	IN.1	2nd Conformance Clause	te		"Following capabilities are not explicitly listed in the current document 1) - Security Administration: The system SHALL provide capability to administer and manage EHRS users, groups, access rules , etc. (create, update, manage, aggregate, dissolve) 2) Encryption - The system SHALL provide ability to manage encryption keys, to encrypt data fields, records, documents and messages as per jurisdictional P&S requirements 3) Anonymization - The system SHALL provide ability to protect a patient's privacy and security by ensuring thepatient's information used within the context of the EHRi system and outside the normal delivery of health care services (e.g. in planning, administration, and some forms of research) does not reveal the patient's identity to unauthorized users"	(52) Consideration: discuss with commenter, his/her intent related to inclusion in application or residing outside the application, data at rest. 1. Non persuasive. This is covered by IN.1.2.4 CC3 and CC4 and IN.1.2.5. 2. Consider for future use. Review IN.2.5 and IN.1.6.5 in R2. 3. Non persuasive. We have had a function for anonymization in the model but we do not have the ability to enforce what other systems use the data for once it leaves. As written, the suggested CC is not testable. We do not see a way to test that another system used the data for its intended purpose.
CA	IN.1				The following key functions appear to be missing from this document (and the whole set): - Malware detection - Hardening - Notification on privacy or security events such as an emergency override of masking or exceeding a threshold of failed access attempts	(53) Non persuasive. The FM is targeted at the application level. Malware and hardening are outside of the application level. Regarding Notification on Privacy and Security and the

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					- Audit log investigation and review functions	audit log comments---these are valid functions for R2 and will be considered during that work.
CA	IN.1.1	3rd Conformance Clause	te		Recommend removing this criterion because Chain of Trust agreements are highly variable based on the context (more variable than the notion of applicable laws). Alternatively, suggest changing "implement a Chain of Trust agreement" to "comply with any applicable Chain of Trust agreements"—unless the "a" in the former is intended to be generic.	(54) Consider for future use. This will be investigated more thoroughly in discussions related to R2. For R1.1 Persuasive with mod. The system SHOULD provide the ability to implement any applicable Chain of Trust agreement(s).
CA	IN.1.2	4th Conformance Clause	te		As worded it requires role-based access control (RBAC). RBAC is preferred over discretionary access control based on groups and user privileges, if this is not intended to enforce RBAC only, then the other aspects may be added.	(55) Non persuasive. CC#4 speaks specifically to roles. However, CC#3, CC#4 and CC#5 together cover the a breadth of authorization types which could include groups and other specific user privileges.
CA	IN.1.3	3rd Conformance Clause	te		Recommend "system and/or data access rules" instead of "system and data access rules"	(56) Non persuasive. The intent of the authors was purposeful in requiring data and systems access rules to be tied together. To allow each independently does not permit security.
CA	IN.1.3	4th Conformance Clause	te		Recommend "system and/or data access rules" instead of "system and data access rules"	(57) Non persuasive. The intent of the authors was purposeful in requiring data and systems access rules to be tied together.
CA	IN.1.3	Statement	ed		"prevent unauthorized use of a resource". Presume resource includes information. If not, this could be clarified.	(58) Persuasive with mod: We will change the statement to read: Verify and enforce access control to all EHR-S components, EHR information and functions for end-users, applications, sites, etc., to prevent

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						unauthorized use.. (we have removed the last words of the original statement)
CA	IN.1.4	Description and 1st Conformance Clause	te		The description refers to the ability of a patient to place restrictions on who can access their information, but the conformance clause refers to "managing a patient's access to his or her healthcare information". The Conformance criteria is not clear in this context.	(59) Consider for future use. Additional discussion needed regarding the need for additional conformance criteria or restriction of the description.
CA	IN.1.6	1st Conformance Clause	ge		This clause is not specific enough to be used for conformance (even within a profile). Recommend specific references be added to articulate the author's intent.	(60) Consider for future use.
CA	IN.1.6	3rd Conformance Clause	te		Recommend changing "obfuscate" to "encrypt" (or "encrypt or de-identify" if appropriate). Obfuscation may include Base64 encoding which is clearly insufficient.	(61) Not persuasive. The request is too prescriptive.
CA	IN.1.6	5th Conformance Clause	te		Recommend appending the words "in accordance with applicable regulations, policies and standards for the organizations concerned" to the clause. Ideally organizations have developed their own policies and/or standards regarding acceptable encryption algorithms (and parameters). e.g. RC2 is an encryption standard that one would not typically recommend today.	(62) Persuasive with mod. The criteria has been modified to read as follows: IF encryption is used for secure data exchange, THEN the system shall support standards based encryption in accordance with organizational policy or jurisdictional law.
		Statement	te		Recommend changing "known, registered, and authenticated" to "known and authenticated" since they are not all necessary. As per the Description, registration only refers to the static setup scenario, not the dynamic scenario.	(63) Consider for future use. Suggest adding a conformance criteria clarifying dynamic and static addresses including the requirement for registration.
CA	IN.1.9	7th Conformance Clause	te		Recommend changing "SHOULD" to "SHALL". Auditable records are a minimum requirement for privacy and security.	(64) Not persuasive. Not all systems may be able to do this and not all transactions may need to be audited. It is recommended that this criteria be elevated to a SHALL in a profile if needed.
CA	IN.2	2nd Conformance	te		Following capabilities are not explicitly listed in the current document: 1) Logging management -	(65) Consider for future use. 1. The workgroup felt that

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		Clause			The system SHALL provide capability to configure, capture, manage application, system, security and other types of logs. Log events will be triggered in execution of various services. These events, based on configuration parameters, will be recorded in an event log. The log could be persisted in a flat file, a relational database, a system event log repository etc. 2) - Exception Management - The system SHALL provide ability to capture, propagate and manage errors and other business level exceptions. Exceptions can range from system/application level exceptions to exceptions found as a result of corrupt or dirty data and other such conditions. 3) Configuration - The system SHALL provide ability to configure the EHRi. This could include configuration of the SHR data repository, the overall system, the metadata, the service components, schema support, security, session and caching mechanism etc. They offer an opportunity to centralise the mechanisms and processes used to configure and manage the parameters that affect the behaviour of separate pieces of an EHR Infostructure.	logging management is implied in our existing audit trails. There are concerns that this may be too prescriptive. The team will evaluate the apparent prescriptiveness in discussion of the future model. 2. The team will evaluate the apparent prescriptiveness in discussions of the future model 3. The team will evaluate the apparent prescriptiveness in discussion of the future model.
CA	IN.2.5.1	Description	te		With unstructured information there is a risk that it may not contain Personal Health Information 95% of the time, but does indeed contain PHI 5% of the time. That field, or document must be classified as Personal Health Information all of the time in order to ensure appropriate and consistent protection.	(66) Not persuasive. The description for this function is not present. The comment will be discussed as part of future use.
CA	IN.5		te		Following capabilities are not explicitly listed in the current document: 1) Mapping - The system SHOULD provide ability to map and translate a source document format to the destination format. This service can be used to map from XML to flat file and other formats and vice versa. 2) Queuing - The system SHOULD provide ability to support deferred communication and data exchange among various EHRS subsystems.	(67) Consider for future use. Discussion: Mapping and queuing may be technically too prescriptive. Examples would be helpful. Should the model support these at a higher level---but not so granular as to constrain. We have entries for WF mgmt, terminology mapping, business rules mapping --- please clairfy additional needs via examples.

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CA	IN.1.3	2nd Conformance Clause	te		Following capabilities are not explicitly listed in the current document: It is recognized that EHRS SHALL provide ability to uniquely identify, locate and supply links / references for retrieval of information related to key business entities involved in process of health care delivery via EHRS. DC and SF portion of EHRS FM describes functional capabilities pertaining to Patient / Provider registries. However, other key business entities such as Organization, Location, Health Service, Application, etc are not covered in this document. Unique identification of these entities and consistent linkage to information and relationship with other entities is crucial for successful heath care delivery. For example. Organization is an entity which needs to be registered and identified as health care delivery entity, which employees various providers, own infrastructure, deliver particular health care services, may establish relationship with other organizations or providers in health care programs to provide efficient and timely service in secure and professional manner. Therefore, the document must describe functional capabilities to support implementation of registries / directories for these key business entities.	(68) Consider for future use.
CA	IN.3	2nd Conformance Clause	te		It is not clear what securely means in this clause given the prior clause is exact same clause without the word “securely”. Given that authentication and authorization have been mandated elsewhere, is this supposed to mean “encrypt” too?	(69) Not Persuasive. The meaning of ‘Securely’ should be defined at the profile level. This may vary by realm.
CA	S.2	Statement	te		Following capabilities are not explicitly listed in the current document: 1) Data Warehouse Capabilities – The system must provide ability to aggregate and migrate health information data from multiple domains into DW designed to support efficient analytic and reporting tasks. These capabilities include, but are not limited to data manipulation, data transformation, aggregation rule configuration etc..	(70) Not Persuasive. Most data warehousing is done in a separate application. There is output capability to outside applications focused on datawarehousing through S.2.2.2 which supports the export of data for purposes such as reporting. Consider for future use. What is the opinion of other

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						countries e.g. NHS?
CA	S.3	Statement	te		Following capabilities are not explicitly listed in the current document: 1) Drug Adjudication 2) Insurance Coverage Verification	(71) 1. Consider for future use. Further discussion and input is needed with the commenter. 2. Non persuasive. This is covered in Function S.3 and S.3.3.2
CA	DC.1.1.2	1st Conformance Clause	te		Recommend appending: "but may store the demographic information (and other meaningful individual identifiers) separately from clinical data for identity protection purposes".	(72) Persuasive.with mod. The workgroup will add a conformance criteria: *CC #10: The system MAY store the demographic information (and other meaningful individual identifiers) separately from clinical data for identity protection purposes.*
CA	DC.1.7.2	2nd Conformance Clause	te		It is preferable to define functional capabilities for management of non-medication orders and referrals (Lab test, Diagnostic Imaging, etc…) with same level of conformance criteria details as it was done for Medication orders. For example, the system SHOULD provide specific details relevant for management of Lab Tests including: type of information captured, presumed constraints in capturing this information, follow up procedures requested for particular test, etc.. This document outlines detailed capabilities for medication order/referral management and it should be done for other recognized clinical domains as well (DI, Lab Test...). Even though FM is used as foundation to derive more specific functional profiles, this document should provide at least key functional capabilities for major constituent domains of EHRS.	(73) Consider for future use.
CA	DC.1	Statement	te		"Chronic Disease Management capabilities are not comprehensively covered in this document. Things like patient program or treatment plans, information about relevant subgroups of patients needing services, common "flow sheets" or templates used in diagnoses, monitoring, and treatment of CDM, Telehealth Assessments (real-time video and store & forward	(74) Not persuasive. The model was developed at a high level to accommodate both acute as well as chronic conditions. The model is designed to support both hospital as well as clinic settings. A profile could be

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					images), Remote Monitoring, access to specialist expertise, provider/patient education for CD are just few of the representative features that the system needs to provide.	developed to address a given diagnosis, chronic or otherwise.
CA	Chapter 5 Information Infostructure Functions All			1. Records Management & Evidentiary Support Functional Profile was balloted as universal, and to my knowledge remains without approval. 2. How will the referred and tracked items sent on to the EHR WG from RM & ES WG be added into the FM in the next release that are not included in R 1.1? If the FP is not approved, how can the FP be expected to be used for certification/conformance instead of the FM? 3. Is there any thought to having a base FM that includes the EHR-S FM & RM&ES FP (universal) functions combined as a single source and just use FPs for clinical specialty areas? The use of FP for conformance/certification and not the FM addes complexity and confusion. A single source for the base EHR-S and additional FPs for the clinical areas is complicated for anyone trying to use these tools to support their processes.		(75) The workgroup has reviewed the comment and offers the following responses: 1. The RM&ES profile passed ballot in January. 2. Persuasive. As part of the R2 review all registered profiles will be reviewed. 3. Considered by the workgroup but no change to be made for R1.1. The use of FP conformance to the FM is the framework and is not under consideration for change.
CA	Glossary Section T				Add Terminology Services definition as per 2008-09-22 Disposition Version V6.7 12/23; CA 3, 2.1 Submitted per disposition activities and listed as "done", but not added to glossary terms.	(76) Persuasive. The term will be added to the glossary.
CA	Comments Template				Referred and Tracked Items from ISO DIS 10781 HL7 EHR Functional Model, Release 1 to be included in future releases based on comments from Canada (CA 1, 5, 6, 11, 19, 25, 27, 28, 32, 37). Please refer back to Version 6.7 12/23 for input to Release 2. This note is for tracking only and not to be considered for R1.1. It is based on the December 2008 disposition version.	(77) Persuasive. The comments from the DIS ballot will be brought forward and considered for future use.
CA	Comments Template Pg 3			Existing wording on disposition of comments from R1 in ISO balloting was: CA 6 Non-Persuasive - alignment with HL7 and other ISO standards are part of realm or care specific profiles ** Is this applicable to universal profiles, such as Records	Please confirm answer to this question.	(78) Yes. Alignment with realms or care settings would still be required of a derived profile.

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				Management and Evidentiary Support?		
DE	Whole		Ed	Please take the ISO/IEC Directives "Internal regulations – part 3: rules for the structure and Drafting of International Standards (PNE-Rules)" into account (only one document, structured as described in the rules)		(79) Referred and tracked. We understand the comment but offer that the submitted documents, though in several chapters, were approved for submission to the ISO DIS ballot. This will be referred to the ISO Secretariat and JIC.
IT			ge	Abstention due to lack of answers.		(80) Comment reviewed but could not be addressed.
NO			ge	This document is not according to ISO rules for standard documents. This makes the separation between normative and informative text unclear.	Reformat the document according to ISO rules. Use notes for informative comments in normative text.	(81) Referred and tracked. We understand the comment but offer that the submitted documents, though in several chapters, were approved for submission to the ISO DIS ballot.
NO			ge	This document contains a large number of functional requirements that should be fulfilled. However, since the profiling process may modify these requirements they are no longer absolute requirements as stated.	Make the chapter concerning profiling the only part of this DIS document. Move the detailed lists of requirements to a separate ISO TS.	(82) Not persuasive – Per the FM, Chapter 2, the functions are not an absolute requirement. Conformance is only allowed to a profile.
NO			ge	The title is misleading as there is no model involved.	Propose “Electronic Health Record System – Functional Requirements” for the part containing the detailed requirements.	(83) Not persuasive – Per the FM, Chapter 2, the functions are not an absolute requirement. Conformance is only allowed to a profile.
NO	DC.1.3.2		ed	Patient Advance directives is a specific American term.	Provide a generic description of this function.	(84) Persuasive with Mod. The workgroup will provide a formal Glossary term and definition.
NO	DC.2.1.4		ed	This clause duplicates DC.1.3.1.	Delete	(85) Not persuasive. DC.1.3.1 is designed to capture information. DC 2.1.4 actuallly uses the information.
NO	DC.2.2.1		ed	Not part of direct care functions.	Move to another chapter.	(86) Not persuasive. This function is considered part of

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						direct care. Consider adding a scenario describing how these functions are appropriate to the chapter.
NO	DC.2.2.2		ed	Not part of direct care functions of an EHRS.	Delete or move to another chapter.	(87) Not persuasive. These functions are considered part of direct care. Consider adding a scenario describing how these functions are appropriate to the chapter
NO	DC.2.2.3		ed	These requirements are not specifically related to Clinical Decision Support.	Move to DC.1.	(88) Non persuasive. Clinical Decision Support has a role in research. Clinical Decision Support was intended to be part of Direct Care as it is to assist the practiioner with his/her job. Consider adding a scenario describing how these functions are appropriate to the chapter
NO	DC.2.3.1.2		ed	We would expect to find genetic disposition as a main factor for dosage evaluation.	Add “genetic disposition”.	(89) Persuasive with mod. The description will be enhanced to read: Additional patient parameters, such as age gestation, Ht, Wt, BSA, *genetic disposition*, shall also be incorporated.
NO	DC.2.6		ed	Not part of direct care functions of an EHRS.	Delete or move to another chapter.	(90) Not persuasive. These features are intended to support of the patient and is a tool for the health care provider. Consider adding a scenario describing how these functions are appropriate to the chapter.

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NO	DC.2.7		ed	Not part of direct care functions of an EHRS.	Delete or move to another chapter.	(91) Not persuasive. These features are intended to support of the patient and is a tool for the health care provider. Consider adding a scenario describing how these functions are appropriate to the chapter
SE			Ge	We are happy to see that many of our comments to the previous version have been accepted. The comment below on interchange standards (IN 5.1) has been overlooked and we submit a proposal of how to formulate that paragraph.		(92) The workgroup will address this comment as part of the resolution of the comment on IN.5.1 (see comment 2 lines below.)
SE	title		ge	The name of the organisation behind a standard should not be reflected in the name of the standard.	Rename the standard to *System functional model*	(93) Not persuasive
SE	IN.5.1	3rd paragraph	te	As this is an international ISO standard other international and recognised standards should be mentioned as well, e.g. EN ISO 13606.	"Representation of EHR content is transmitted in a variety of interchange formats such as: ISO 13606 extracts, HL7 Messages, Clinical Document Architecture (CDA) and other HL7 Structured Documents, X12N healthcare transactions, and Digital Imaging and Communication in Medicine (DICOM) format."	(94) Persuasive. We will add the proposed verbiage to the description.
UK	General		te	Though the document is laudable and in many respects well written (other than the customary lack of clear definitions and referencing seen in HL7 documents) it has one major flaw. Conformance claims (encouraged by Chapter 2) are entirely dependent on Functional Profiles constructed according to the purely informative How-to Guide. As "the intent [is] to enable consistent expression of system functionality" this omission of normative conformance requirements seems to render any pretence of "conformability" pointless. To use it as the basis of self-created self-attested and uncontrolled (though possibly registered) functional conformance profiles without any test of validation criteria appears at best pointless, and at worst potentially misleading. A pity, because as a survey of functional components of an EHR it is interesting - just not a standard as currently drafted.	Either: 1. Amend structure to provide meaningful conformance requirements – cooperation with EuroRec might be useful in this regard? Or 2. Replace "shall" statements with "should" and publish as TR. Maybe then work to achieve (1)?	(95) Not persuasive. As set out in Chapters 1 and 2, specific…..the standard was specifically designed to allow vigorous conformance testing of the profile against the model. The workgroup will enhance in Chapters 3, 4 and 5 what is normative and what is informative.
Ch 1 - Overview						

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UK	General		te	In this document sections 2 and 3 are designated as normative. A normative section should be constructed from normative statements to which users are expected to conform. However these sections 'discuss' the concepts without any 'shall' or 'may' statements.	Make this whole document informative	(96) Non persuasive. As set out in Chapters 1 and 2, specific…..the standard was specifically designed to allow vigorous conformance testing of the profile against the model. The workgroup will enhance in Chapters 3, 4 and 5 what is normative and what is informative.
UK	General		ed	The document is well written and comprehensive and worthy of DIS status.		(97) Thank you.
UK	Introduction	RM-ODP		Will require a formal reference		(98) Non persuasive. The model is designed at the application level. As such, General architectural concepts are not individually referenced in the document.
UK	P6.	Ref 3. Smith and Kalra	gen	Update, and preferably remove from here and put in bibliography		(99) Consider for future use. The location of the reference is not clear to the work group.
UK	3.11 &3.30	'clinical' not = 'health'	ed	Not synonyms		(100) Consider for future use. The workgroup recognizes the need to normalize terms within the document.
UK	3.28/ 3.32/3.33		ed	Inconsistent use of 'healthcare' and 'health care'		(101) Consider for future use. The workgroup recognizes the need to normalize terms within the document.
UK	4.1.1	Bullets..	ed	e.g.' identifying and avoiding increased risks'		(102)
UK	General		ed	'technically, structurally and semantically interoperable'		(103)
UK	General		ed	General worry about the all or nothing 'apparent conformance' and the certainty that no system will meet all these business		(104) Not persuasive – Per the FM, Chapter 2, systems are not

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				requirements in the foreseeable future.		expected to be conformant with the entire model..
Ch 2 - Conformance						
UK	General			A standard must have a normative section early in the document which precisely defines the terms which are used in the normative sections. There is a 'glossary' section which does contain definitions but this is informative. The aim of the normative definitions is that the definition can replace the term wherever it is used.	Provide a normative section with definitions of terms	(105) Considered for future use. Making the accomodations for handling what appear to be ISO format requirements will be reviewed as part of the next release. This may also be considered in JIC discussions.
UK	2.1		te	There are no normative conformance statements in this section	Make informative	(106) Considered for future use. Making the accomodations for handling what appear to be ISO format requirements will be reviewed as part of the next release. This may also be considered in JIC discussions.
UK	General		ed	Please make plain within the scope of the diagrams the meanings of the abbreviations, e.g. DC 1.1 and IN4.2		(107) Persuasive.. Additional description will be added to both of the diagrams.
UK	6.2		te	I am unclear as to whether it is permissible to have a mixture of both parent and leaf types as children of a particular node	Add explanatory text	(108) Consider for future use. Replace the word 'leaf with child. Will contact the original author.
Ch 3 – Direct Care Functions						
UK	General			This seems very thorough although the presentation is unusual for an ISO Standard. I do wonder is some of the 'shalls' are a little too strong (i.e. demoted to 'should'). For example, ■ family preferences for language, religion, etc. ■ advance directives	None	(109) Considered. No change made.
UK	Row 323 + 324		te	These rows present 'shalls' and relate to: The system **SHALL** provide the ability to access the standard assessment in the patient record.	Convert to 'should'– particularly as national / local guidance could tighten, but not release, these constraints.	(110) Non persuasive. The SHALL statements exist as these were seen as required up front in any profile development. The standard assessment is not

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				The system **SHALL** provide the ability to access to health standards and practices appropriate to the EHR user's scope of practice. I am unclear as to what: - are the standards which are being used here - how to classify the user's scope of practice.		defined in the model as what is standard may vary from locale to locale or country to country. Scope of practice would be defined as part of each profile. Consider for future use. The workgroup will develop examples that further clarify scope of practice, organizational policy and jurisdictional law.
UK	Rows 365 - 372		te	This section on 'context sensitive care plans, guidelines, protocols leave me somewhat perplexed. For example: The system **SHALL** provide the ability to access care and treatment plans that are sensitive to the context of patient data and assessments. This 'context' could be interpreted at a variety of levels from adolescent female to a much more complex set of factors such as health, ethnic, biological and social information. Is the user allowed to choose their own interpretation of context?	Clarify– particularly if "sensitive" means "context-sensitive", and not "clinically or socially sensitive" – or something else.	For clarification the user is allowed to choose his/her own interpretation of context as a part of developing a profile
UK	Rows 397 - 423		te	Experience with systems shows that users tend to demand that such a facility is deactivated. Is there a suggestion that the system should provide these facilities despite user preferences?	Clarify	(111) Considered for future use. The model has not explicity addressed selectiive enabling and/or disabling user preferences. This would also require additional audit and logging requirements.
Ch 4 – Supportive Functions						
UK	Row 38		te	Providing a facility to provide information about the location of a patient when receiving ancillary services is probably going too far.	Demote to 'should'	(112) Not persuasive. Since this criteria only applies if the person has an assigned location, by default, it would not need to be used for ancillary services.

1 **MB** = Member body (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

NOTE Columns 1, 2, 4, 5 are compulsory.

1	2	(3)	4	5	(6)	(7)
MB[1]	**Clause No./ Subclause No./ Annex** (e.g. 3.1)	**Paragraph/ Figure/Table/ Note** (e.g. Table 1)	**Type of com-ment**[2]	**Comment (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations** on each comment submitted
Ch 5 – Information Infrastructure Functions						
UK	various			The mandatory requirements concerning the coded representation of clinical data and the ability of systems to equate or map these representations is likely to be onerous, especially when exchanging information between systems. I wonder how conformance should be judged. Full conformance may preclude many systems	Clarify conformance criteria	(113) Conformance will be more detailed or more context sensitive in updated or revised conformance criteria in a profile. The intention is not to conform to the functional model Consider for future use.

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