

Document name: Comment and Review In Advance of 2019 "ISA Reference Edition" Publication.

Critical - - indicates non-concurrence with the document until the comment is satisfactorily resolved; convincing support for critical comments must be provided.

Substantive - - indicates that a section in the document appears to be or is potentially unnecessary, incorrect, misleading, confusing or inconsistent with other sections; requires convincing support.

Administrative - - corrects what appears to be a typographical, format or grammatical error.

Page # or Section VI Question #	Section	Name of "Interoperability Need"	Name of Standard Implementation Specification	Comment type (C, S, A)	Rationale
I-A	Allergies & Intolerances	Representing Patient Allergies and Intolerances; Food Substances	SNOMED CT	S	Additional information that could be provided under Limitations, Dependencies, and Preconditions for Consideration: SNOMED CT may be sufficient for food substance allergens as there are 63 child codes for Food allergen (substance).
I-A	Allergies & Intolerances	Representing Patient Allergies and Intolerances; Environmental Substances	SNOMED CT	S	Additional information that could be provided under Limitations, Dependencies, and Preconditions for Consideration: SNOMED CT may be sufficient for environmental substance allergens as there are child codes listed that cover many environmental substances from the Allergen class (substance).
I-J	Medications	Representing Patient Medications		S	A potential addition as an interoperable standard: The IPO is interested in knowing if there has been consideration for standardizing Medication Routes/Routes of Administration as an interoperability standard using Value Set: HL7 Table 0396.
I-O	Procedures	Representing Dental Procedures Performed	CDT	S	Additional information that could be provided under Limitations, Dependencies, and Preconditions for Consideration: CDT licensure has to be purchased to have this terminology in its entirety making it difficult for organizations to use as a standard. Are there additional 'workarounds' that the ONC has recognized that could assist organizations with this potential setback?
I-O	Procedures	Representing Medical Procedures Performed		A	Typo under Limitations, Dependencies, and Preconditions for Consideration: procedures is captured as this: srocedures.
I-P	Race and Ethnicity	Representing Patient Race and Ethnicity		S	A potential addition as an interoperable standard but it may need its own section if considered: The IPO is interested in knowing if there has been consideration for standardizing 'Patient Relationship or Next of Kin' standards using Value Set: Role Code (OID 2.16.840.1.113883.5.111)?
I-Q	Research	Representing Analytic Data for Research Purposes	CDISC	S	Additional information that could be provided under Limitations, Dependencies, and Preconditions for Consideration: The CDISC Terminology is freely available without any licensing restrictions.
				S	Please add a new section (or Appendix) to list the latest US Core Data For Interoperability (USCDI) and associated definitions. If too early to list draft USCDI, list prior 2015 Common Clinical Data Set (CCDS)
I-E	Health Care Providers	Representing Health Care Providers	SNOMED CT	S	Consider adding a section to represent 'Provider Specialty' with a reference to SNOMED.
I-E	Health Care Providers	Representing Provider Role in Team Care Settings		S	Consider updating 'Representing Health Care Providers' to 'Identifying Health care Providers' - NPI is appropriate as identifier here. Remove NUCC.
I-T	Tobacco Use (Smoking Status)	Representing Patient Tobacco Use	SNOMED CT	S	Please correct the SNOMED names provided since they are incorrect. 77176002 is smoker NOT "Smoker, current status unknown"
I-V	Vital Signs	Representing Patient Vital Signs		S	Title of table states 'Applicable Security Patterns for Consideration'. Please update to 'Applicable Value Set(s) and Starter Set(s)'
Section II	Admission, Discharge and Transfer	Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers	Standard	S	The link points to the generic v2.5.1 web page; it is not clear how this is directly helpful, since none of the profiles listed at the lower part of the page are ADT - they are for Lab etc. The kind of information that is more directly useful is published by e.g. integration engine vendors, such as: https://corepointhealth.com/resource-center/hl7-resources/hl7-adt/ , blogs such as https://datica.com/academy/hl7-201-the-admission-discharge-transfer-adt-message/ etc. Also, v2.3 ADT messages are probably in use, but are not represented here.
Section II	Care Plan	Sharing Quality Measure Artifacts for Quality Reporting Initiatives	FHIR CQF on FHIR	A	link out of date (replace with redirect location on FHIR site)
Section II	Care Plan	Documenting and Sharing Care Plans for a Single Clinical Context	Emerging Standard - FHIR STU 3	C	The link is just to the FHIR home page; presumably it should be to something specific.
Section II	Care Plan	Documenting and Sharing Care Plans for a Single Clinical Context	Emerging Impl. Spec. - HL7 Resource Care Plan	A	Presumably should read 'HL7 FHIR Resource CarePlan'.
Section II	Care Plan	Documenting and Sharing Care Plans for a Single Clinical Context	Implem. Specs x 3	S	Unclear how these 3 specific standards relate to general purpose shared care plans mentioned elsewhere.
Section II	Care Plan	Sharing Patient Care Plans for Multiple Clinical Contexts	Emerging Implem. Spec. IHE DCP	S	It is not clear why a different Care Plan spec would be proposed for sharing versus 'single clinical context'. Care Plans are almost by their nature going to be used across contexts.
Section II	Clinical Decision Support	Provide Access to Appropriate Use Criteria	Emerging Implem Spec x 2 rows	A	Both rows contain old URLs that result in HL7 FHIR site redirects.
Section II	Clinical Quality Measurement and Reporting	Sharing Quality Measure Artifacts for Quality Reporting Initiatives	All rows.	S	8 standards are listed, but in reality it appears that there is HL7v3 QMF (eMeasure), and the new CQL, embedded within HL7v3 (still in use?) or FHIR. The last two rows, from a quality measure point of view probably don't constitute separate standards.
Section II	Clinical Quality Measurement and Reporting	Reporting Patient-level Quality Data for Quality Reporting Initiatives	CDA R2	S	The reference is just to the CDA standard. It is unclear whether this is mandated or used in any way for Quality Data reporting. The Adoption level surely does not relate to this, but just to CDA use generally in the US.
Section II	Laboratory	Identify Linkages Between Vendor IVD Test Results and Standard Codes	LVD/LOINC	A	This would seem to belong in Section I - it appears to be terminology-related, not data-related.
Section II	Diet and Nutrition	Exchanging Diet and Nutrition Orders Across the Continuum of Care	HL7v3: Diet and nutrition	S	HL7v3 probably has to be regarded as a legacy standard today, but there is nothing to indicate this status in the entry for it.
Section II	Drug formulary and benefits	The Ability for Pharmacy Benefit Payers to Communicate Formulary and Benefit Information to Prescribers Systems	NCPDP Formulary and Benefits v3.0	S	The link points to the generic NCPDP web page, rather than to a useful specific location. (This may all that is possible, since NCPDP standards are closed).
Section II	Electronic Prescribing	All		A	Presumably the FHIR prescription resources should be included as Emerging Standards on some of these. E.g. one would expect that FHIR MedicationRequest would be included for 'Allows a Prescriber or a Pharmacy to Request a New Prescription' - http://build.fhir.org/medicationrequest.html
Section II	Healthy Weight	Sending Healthy Weight Information		A	HL7 FHIR Observation should probably be listed as an emerging standard - http://build.fhir.org/observation.html

Section II	Healthy Weight	Sending Healthy Weight Information	HL7v2.5.1 Standard	A	Link should probably be named HL7 v2.5.1 Lab result and point here: http://www.hl7.org/Implement/standards/product_brief.cfm?product_id=279
Section II	Patient Identification Management	Patient Demographic Record Matching	(missing)	S	Would expect to see OMG HDTF EIS/IXS - https://www.omg.org/spec/IXS/About-IXS/
Section II	Patient Identification Management	Patient Demographic Record Matching	Implementation Guide for Expressing Context in Direct Messaging	A	Link points to raw HTML in google docs ; replace with correct link. Label does not indicate publishing org.
Section II	Patient Preference/Consent	Recording Patient Preferences for Electronic Consent to Access ...	HL7 FHIR Contract Resource	A	It is not clear why this is here, other than it being referenced by the HL7 FHIR Consent resource, listed above. This is unnecessary; users of the Consent resource will find the Contract resource if they need it by the usual means.
Section II	Public Health Reporting	Reporting Antimicrobial Use and Resistance Information to Public Health Agencies	HL7 CDA r2	S	The standard referenced is just generic CDA r2; the fact that CDA r2 is the basis for some specific standards is clear from the other rows - CDA2r does not constitute a separate standard in this space. The adoption level of CDA2 does not apply specifically to the CDAs for Public Health reporting, which appear to be in early adoption.
Section II	Public Health Reporting	Reporting Cancer Cases to Public Health Agencies	HL7 CDA r2	S	as above
Section II	Public Health Reporting	Case Reporting to Public Health Agencies	Emerging implem spec: HL7 CDA R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.0 - US Realm	A	Link does not correspond to the named standard.
Section II	Public Health Reporting	Sending Health Care Survey Information to Public Health Agencies	All rows.	S	As for other entries in the ISA, there is a row for generic CDA, which is not useful, and multiple versions (1.0, 1.1, 1.2) of a specific CDA implem guide for HealthCare Surveys. All rows could be reduced to just this one implem standard, indicated as being based on CDA2 and existing in 3 minor versions.
Section II	Public Health Reporting	Exchanging Immunization Data with Immunization Registries	All rows.	S	as above
Section II	Public Health Reporting	Reporting Birth and Fetal Death to Public Health Agencies	Standard - row 1	A	It is unclear why the first row is marked 'Standard' when it is an Implementation specification.
Section II	Research	Submission of Clinical Research Data to FDA to Support Product Marketing Applications		A	It is unclear why this subsection heading indicates it is for Study -> FDA, and for Marketing. Other than the row for CDISC questionnaires, the other rows appear to be applicable for all the usages of CDISC, i.e. probably any kind of clinical trial and any receiver.
Section II	Research	Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements		A	As above: most of the rows in this entry are generic standards that are not specific to the heading, which itself is probably over-specific.
Section II	Research	Data Segmentation of Sensitive Information	FHIR Consent2Share (row 3)	A	The link is not to a standard but to a gForge location with working documents. If a FHIR resource is to be pointed to, it should be the FHIR consent page - https://hl7.org/fhir/2018Jan/consent.html
Section II	Summary Care Record	Support a Transition of Care or Referral to Another Health Care Provider	CDA2 (row 1)	S	As for many other entries, the inclusion of a row for generic CDA2 is not useful.
Section III	Consumer Access/Exchange of Health Information	Remote Patient Authorization and Submission of EHR Data for Research	FHIR STU 3	S	The reference is just to FHIR STU3, which is generic. As far as I know there is no FHIR specification for this purpose. There is probably no standard to include here; consider removing this subsection; note also the existing comments - possibly the AMA comment indicates an entry that can be used in this subsection.
Section III	Consumer Access/Exchange of Health Information	Push Patient-Generated Health Data into Integrated EHR	FHIR STU 3	S	Firstly it is unclear how 'push patient-generated data into EHR' fits under the subsection heading Consumer Access/Exchange, since writing data into the EHR is a completely different function. Secondly, the entry just indicates FHIR STU3, rather than any specific FHIR resource/profile/guide for writing data to the EHR. As far as we know, FHIR is not even designed to perform such an operation, since its fundamental design concept is retrieval of data fragments from (generally opaque) systems.
Section III	Consumer Access/Exchange of Health Information	Patient Exchanging Secure Messages with Care Provider	FHIR STU 3	S	Here again FHIR STU3 is listed, but with no indication as to what part of FHIR is applicable, or even if there is one, or any roadmap intention for this area. As far as we know, there is no released standard within FHIR for this purpose.
Section III	Healthcare Directory, Provider Directory	Listing of Providers for Access by Potential Exchange Partners	FHIR US Core Implem Guide	S	It is unclear why the FHIR US core is included in this entry, for provider directory service(s).
Section III	Query	Data Element Based Query for Clinical Health Information	FHIR DSTU2, STU3	S	The first row points to FHIR DSTU 2, which has no querying standard. Not clear why this is here. The 3rd row points to FHIR STU 3, also not a querying standard. In any case, both links are out of date and result in redirects. A relevant reference might be to 'Using GraphQL with FHIR' - https://hl7.org/fhir/2018Jan/graphql.html
Section III	Clinical Decision Support Services	All		S	Missing: OMG HDTF CDSS standard - https://www.omg.org/spec/CDSS/
Section III	Clinical Decision Support Services	All		S	Missing section: Terminology services. Should include at least OMG HDTF CTS2 - https://www.omg.org/cts2/index.htm
Section III	Healthcare Directory, Provider Directory	Listing of Providers for Access by Potential Exchange Partners		S	Missing: add a reference to OMG HDTF ServD - https://www.omg.org/servd/index.htm

I	T	Tobacco Use (Smoking Status)	SNOMED	S	<p>The VHA HEALTH INFORMATICS KNOWLEDGE BASED SYSTEMS (KBS) Terminology team is currently conducting a terminology mapping project. The ONC value set for tobacco use is shown below. Their description (in red) for the concept 77176002 [Smoker (finding)] is not consistent with the official SNOMED description. "Current smoker" (SNOMED) has been changed to "current status unknown" (ONC). I believe the ONC term may be based on CDC requirements (?), but the terms are not synonymous, and this can have implications for whether and how this code is used in a patient's record. This value set has many use cases – patient problem lists, clinical quality measures, HL7 FHIR, clinical decision support, etc. – so it is important that the meaning of these terms is clear and (I think) should reflect the original terminology standard.</p> <p>SNOMED CT ID SNOMED CT FSN SNOMED Synonym ONC Term 8517006 Ex-smoker (finding) Past tobacco smoker Former smoker 77176002 Smoker (finding) Current smoker Smoker, current status unknown 266919005 Never smoked tobacco (finding) Never smoked tobacco Never smoker 266927001 Tobacco smoking consumption unknown (finding) Tobacco smoking status unknown Unknown if ever smoked 449868002 Smokes tobacco daily (finding) Daily tobacco smoker Current every day smoker Current every day smoker 428041000124106 Occasional tobacco smoker (finding) Current some day smoker Current some day smoker 428061000124105 Light tobacco smoker (finding) Current light tobacco smoker Light tobacco smoker</p>
II	K	Images	DICOM	S	<p>How about structured reports in DICOM? There is macular thickness mapping based on optical coherence tomography of the retina. There is the visual field SOP class, which is not really an image – more of a report. https://www.dicomstandard.org/wgs/wg-09/. DICOM imaging is of course lots of specialties including eye care, not just radiology.</p>
II			CCDA	S	<p>How about encounter based CCDA for progress note documentation of the patient visit? We have an eye care document in trial implementation in IHE for this purpose.</p>
2	I-A	Representing Patient Allergies and Intolerances: Medications		S	<p>Consider adding MED-RT as an emerging standard for representing medication classes for medication allergies in addition to SNOMED CT</p>
4	I-B	Representing Patient Medical Encounter Diagnosis		S	<p>ISA only contains Encounter Diagnosis, it does account for Encounter Type. ISA should account for encounter type by adding standard CPT4/HCPCS as a in-use federally required standard</p>
24	I-U	Defining a Globally Unique Device Identifier		S	<p>There is no difference between the standards recommended for representing UDIs and defining UDIs. Propose referencing UMLS- SNOMED CT/ Global Medical Device Nomenclature (GMDN) to define a UDI (or Medical Device)</p>
7	I-F	Representing Imaging Diagnostics, Interventions and Procedures		S	<p>VA is still using CPT4/HCPCS to transmit radiology reports. Add to standards list in this section listing lower adoption level!</p>
Entire document	Entire document	Entire document		S	<p>Consider creating a new standard type classification of 'Interim' or 'Sunsetting' to indicate a standard is being phased out/replaced</p>
19-22	I-S	Entire section		S	<p>Consider adding 'Representing Religious Affiliation' as data domain using HL7 Religious Affiliation Codes</p>
19-22	I-S	Entire section		S	<p>Consider adding 'Representing Marital Status' as data domain using HL7 Marital Status Codes</p>
2--26	Section I			S	<p>Consider creating a data domain for Orders or creating data elements under the current relevant domains to represent "medication orders", "laboratory orders" etc - and indicating the relevant standard specification for each. Example: Medication Order: RxNorm Lab Order: LOINC Radiology Order: LOINC or CPT4/HCPCS</p>
10	I-J	Representing Patient Medications		S	<p>Recommend removing MED-RT and NDF-RT as standards for 'Representing Patient Medications'. They are used to represent medication allergen classes - not for representing general medication classes.</p>



ONC Interoperability Standards Advisory (ISA)

CONTENT REVIEW by Thomas Beale, BookZurman

Executive Summary

The ISA resource is well-conceived, and the site is generally easy to use. Our review of specifics has led to various suggestions and recommendations, including:

- **Adjust the column and row structure** to better:
 - Distinguish implementation guides/standards from underlying generic standards (e.g. IHE profile for lab from generic HL7v2.5.1)
 - Make clearer where the multiple entries are successive minor versions of the same standard.
- Improve the quality of the **adoption-related information** so that it relates to the specific standard/guide of the entry, and distinguishes types of adoption e.g. large organization, academic research etc.
- **Remove rows that just mention a generic standard** or technology, such as CDA or FHIR – these obscure the useful information in the ISA, which is specific standards / implementation guidelines.
- **Adjust major section structure** to better separate out APIs, device communications standards, content models, and functional profiles.
- **Better search capability.**

We believe that a modicum of work on the site could improve an already very useful resource, making it a definitive e-health standards advisory for the US.



ONC Interoperability Standards Advisory (ISA) CONTENT REVIEW by Thomas Beale, BookZurman

ISA Site – General Review

The current structure of the Interoperability Standards Advisory (ISA) at HealthIT.gov is clear and highly usable.

Nevertheless, we make the following suggestions.

Add Reference information for Content (section II)

A significant number of entries in the ISA site are classified as ‘Emerging Standard’ or ‘Emerging Implementation Specification’. Examples can be found under Care Plan in Section II. Some of the ‘standards’ referred to are quite immature, and not directly usable in their current state of development. In order for standards users to make better use of such information, it is suggested that throughout Section II, rows be added (or another table on each page) containing references to related content/structure specifications that constitute more mature scholarship and/or other efforts in the relevant space.

For example, for Care Plans, such references might include:

- A row pointing to the HL7 Care Plan DAM (2014)
- A row pointing to the VA FHIM Care Plan (based on the HL7 DAM)
- A row pointing to related non-US specifications, e.g. ISO 13940 (Concepts for Continuity of Care), openEHR archetypes / CKM and so on.

These resources are all significantly more advanced than the current FHIR Care Plan resource. For all standards, it would be very useful to have the underlying content specification indicated. For example, most IHE specifications are based on an underlying HL7v2, v3, CDA or FHIR content specification, DAM or something similar – but one must look inside each IHE spec to discover which. Including this information directly in the ISA site would enable users to see that (in some cases) multiple standards are just variants on some core content specification (e.g. an HL7 DAM).

Distinguish Content Standards from API/transaction standards

In some places, for example the Care Plan sub-sections of Section II, the standards referred to are content standards such as FHIR Care Plan resource. Arguably, as per above, content specifications such as HL7 DAM, FHIM etc. should also be referred to.

However, in other sub-sections, such as [Sharing Patient Care Teams for Care Planning in Multiple Clinical Contexts](#), the referred to standard is a transactional API, in this case, the HIS Dynamic Care Team Management (DCTM) specification. This is a different category of standard, and probably should be marked in a different way. Separate tables for content and service interface standards would be one way to make things clearer; although it is not clear why the DCTM standard is not in Section III.

Adoption Level

It is not clear how accurate the Adoption Level column could be, or how useful. If there were mid-level adoption of an emerging standard in academic or research programs for example, it is not clear whether this really constitutes meaningful adoption for a large federal agency such as the VA or DoD.



ONC Interoperability Standards Advisory (ISA) CONTENT REVIEW by Thomas Beale, BookZurman

Nevertheless, the Adoption Level is probably the information item most likely to be used by users to think about ‘choosing’ standards. If it is not accurate or does not correspond well to the kind of adoption contemplated by an organization, it is misleading at best.

It is suggested that known reference sites / projects / products be included where known to improve the utility of this item.

General v Specific Standards

In some cases (ex: [Reporting Patient-level Quality Data to Quality Reporting Initiatives/Reporting Patient-level Quality Data for Quality Reporting Initiatives](#)), there is a mixture of completely general standards and ones specific to the subject are (here: CDA in standard and two versions of CDA quality reporting document). It is unclear why the non-specific form is included, since presumably its adoption and use do not relate to this specific area.

It might be better to add another column to the tables to indicate whether a standard is merely a general one that *could* be applied to the topic area, or a dedicated standard designed for that use. In addition, the Adoption Level needs to relate to its use in that area, not generalized use.

A more radical approach might be clearer: convert the single column ‘Standard / Implementation Specification’ into two columns:

- Implementation Specification;
- Underlying Standard.

This would reduce the uninformative rows that simply indicate generic CDA, v2.5.1, FHIR etc., while indicating more clearly for IHE-like standards what the underlying standard really is.

Multiple Versions of the Same Standard

Many of the tables contain multiple versions of the same standard. Usually it would be assumed that the direction of adoption by those who use the earlier one will progress to the next version, if available.

It might therefore be clearer to indicate multiple versions as sub-rows of a single standard.

An example is in Section II / Public Health Reporting / Sending Health Care Survey Information to Public Health Agencies: there is a row for generic CDA, which is not useful, and multiple versions (1.0, 1.1, 1.2) of a specific CDA implementation guide for HealthCare Surveys. All rows could be reduced to just this one implementation standard, indicated as being based on CDAR2 and existing in 3 minor versions.

Legacy and Sunset Standards

Certain standards, notably HL7v3, are regarded in most of the industry as legacy today, and new projects or products would not use them. The ISA site contains references to HL7v3 standards (and probably other legacy standards) but does not indicate their real status; indeed the ‘Standards Process Maturity’ column says, ‘Balloted draft’, which is literally true, and might give the impression of a standard that is appropriate to adopt. Note that the ‘Adoption level’ column value being low does not help – new standards that are likely to be better choices will also typically have a low adoption value for some period of time.



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CONTENT REVIEW by Thomas Beale, BookZurman

Recommendation: provide a way to indicate that a standard or family of standards is legacy, in a sunset phase or otherwise not in current use.

[Advanced Search](#)

We were unable to make the search function work produce any results. It is however an important feature of the site to have working.



ONC Interoperability Standards Advisory (ISA) CONTENT REVIEW by Thomas Beale, BookZurman

Specific Content

Most comments relating to specific content are included in the accompanying spreadsheet.

Model Representation and Tooling

One major section that appears to be completely missing relates to model representation and tooling. These are specifications that define how content and other models are created from underlying information models ('resources' in the case of FHIR). Relevant standards include:

- ISO 13606-2 - Health informatics -- Electronic health record communication -- Part 2: Archetype interchange specification ([ISO site page](#));

This is the standard in use by HL7 CIMI, openEHR, and countries including Norway, UK, Russia, Australia, Slovenia, Canada, Brazil, China and others. Numerous tools are available. The HL7 FHIR equivalent of this appears to be Structure Definition.

FHIR

FHIR is the subject of much industry hype and is routinely and automatically proposed as the solution for any interoperability or other healthcare information system need. The ISA guide falls prey to this attitude to a certain extent, and includes numerous entries for 'FHIR', often simply in its generic form, for use cases for which there is a) no released FHIR offering at all; b) no release, but work underway, c) no offering intended and d) where the use case only approximately matches the FHIR offering. In order to be useful, the ISA guide should limit entries to post v1.x standards / specifications releases. One odd example is in Section III / Consumer Access/Exchange of Health Information / Push Patient-Generated Health Data into Integrated EHR. Here generic FHIR 3 is included as an emerging standard for pushing data into the EHR, a purpose for which FHIR is not designed, and for which it has no specific offering. This does not appear to be a useful thing to do. In general, the industry knows that HL7 and FHIR are 'interested' or 'working on' standards / implementation guides for nearly everything in e-health; it adds no useful information to the ISA site to repeatedly add rows for 'FHIR' (or CDAR2 for that matter) to try and indicate this general state of affairs. We suggest that the ISA resource is far more useful if it reports only:

- Released standards, developed for the specific topic area;
- Work underway for the specific topic area, within a standards organization, that is nearing release – i.e. proto-standards.

Section III

Section III appears to be a mixture of protocol related entries, e.g. to do with 'Push' exchange, PUBSUB, technology entries, e.g. FHIRpath, and entries for specific API services. It is recommended that generic technology items be separated out into other section(s), and that Section III be used for APIs.



ONC Interoperability Standards Advisory (ISA)

CONTENT REVIEW by Thomas Beale, BookZurman

Medical Device Real-time Communication

It may make sense for medical device real-time communications standards to have their own major section, since this type of communication typically does not correspond to the typical API model but of message or packet definitions.

Section IV: Models and Profiles

This section contains two different items: HL7 EHR Functional Model profiles, and two very specific information models.

It is recommended to separate these items into two sections. The EHR FP profiles are primarily intended to be used for procurement and high-level non-technical conformance evaluation. The information models are something else entirely, although it is not clear what the intended purpose is here, given that only Diet & Nutrition Orders and Behavioral Health models are included. Clearly there are numerous information models at the domain level, including:

- HL7 DAMs
- VA FHIM and other VA models
- HL7 FHIR resource profiles, and some resources
- Specialized CDAs
- HL7 CIMI archetypes
- International archetypes

At the data representation level, there are also various models:

- HL7 v2 and v3 message representation
- HL7 FHIR – generic resources
- CDA R2
- HL7 CIMI Reference Model
- Various models used in OMG HDTF specifications
- International sources – e.g. openEHR EHR Reference Model

If a more representative Information Models section is contemplated, it would probably need to include some of the above.