

HL7 Newsletter Article for Sep 2018

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Healthcare IT Computable Interoperability Strategy Among HL7 Product Lines and Product Families

HL7 Newsletter Article, ~1k words, **Title/Abstract submitted** Wed Jun 13, **Article due** Mon Jul 9
HL7 (CIC, PHER, EHR, CQI, CDS, CIMI, STRUCDOC, VOCAB, SOA) Workgroups, Steve Hufnagel, editor

REQUESTED ACTION: Technical Verification, Clinical Validation and Suggestions for improvement.

Is the article easy to understand (clear, complete, concise, correct, consistent)?

Affiliate (international) participation is particularly desirable.

2018-06-22 WORKING DRAFT

INTRODUCTION

As a global authority on interoperability in healthcare, HL7 is a critical leader and driver in the healthcare standards arena, in the U.S. and internationally. The HL7 product lines and product families – including the widely adopted and rapidly evolving HL7 FHIR®, Consolidated CDA (**C-CDA**) and Version 2 message (**V2**) product line standards - provide the underpinnings for connected, patient-centered health care on a global scale and an information highway for improving patient safety, advancing research into improved treatments, and achieving ambitious visionary programs such as precision medicine. CIMI logical models have been added as an HL7 product line. HL7 is comprised of members from over 50 countries and is integrally involved in global standards policy, regulation and harmonization. HL7's clinical goal is to help people live the healthiest lives possible by enabling a "Learning Health System" supporting areas such as, but not limited to Clinical Decision Support, Population Based Medicine, Genomics and Research. "*Data quality is the lynchpin of patient safety.*" Our Healthcare IT objective is to make quality data available when, where and how it is needed across different platforms with computable semantic-interoperability.

This is a follow-on article to "*Healthcare IT Computable-Interoperability Strategy --- Methodology to manage data-quality risk by standardizing data In accordance with 21st Century Cures Act, TEFCA and USCDI*", HL7 Newsletter, May 2018, P16-18, http://www.hl7.org/documentcenter/public/newsletters/HL7_NEWS_20180523.pdf.

- The May 2018 article discussed HL7 supporting the US National and International Common Data Interoperability (**USCDI**) agendas across US Office of the National Coordinator (ONC) Trusted Exchange Framework Common Agreement (**TEFCA**) among Qualified Health Information Networks (**QHINs**).
- This Sep 2018 newsletter article discusses emerging HL7 harmonization technologies, processes and methodologies to improve computable semantic-interoperability across HL7 product lines and product families in support of USCDI, TEFCA and QHINs.

MISSION

HL7 Structured Documents and Vocabulary Work Groups (**WGs**) are spearheading the HL7 Terminology Authority (**HTA**) and Universal Terminology Governance (**UTG**) harmonization processes. CIMI WG is collaborating with stakeholder WGs and Health Services Platform Consortium (**HSPC**) to spearhead computable semantic-interoperability with Integrated Information Models and Tools (**IIM&T**), processes and products. HL7 workgroups and

product line management groups' objective is to improve healthcare IT data quality across implementation paradigms with consistent and requirements traceable HL7 FHIR, CDA and V2 artifacts. Developers and users want "faster" and "cheaper" approaches. CIMI is developing efficient and effective methodologies to add "better" to the value proposition. The result is improved Healthcare IT value (patient-safety, care-quality, reduced-cost). HL7's balloted FHIR Structure Definition (**FSD**) language is emerging as the canonical HL7 specification language describing underlying data structures, data types, resources, templates, messages, extensions and profiles bound to controlled vocabularies, value sets and code sets. CIMI-compliant standards, methodologies and Domain Analysis Models (**DAMs**) can empower Seamless Model Driven Development (**MDD**) tools to produce CIMI-compliant requirements traceable logical Detailed Clinical Models (**DCMs**), which may be specified as FSDs. HL7 tools can then transform FSDs into consistent V2 messages, FHIR profiles, C-CDA templates, implementation guides (**IGs**), Application Program Interfaces (**APIs**), reusable-components, reference implementation code, controlled value and code sets.

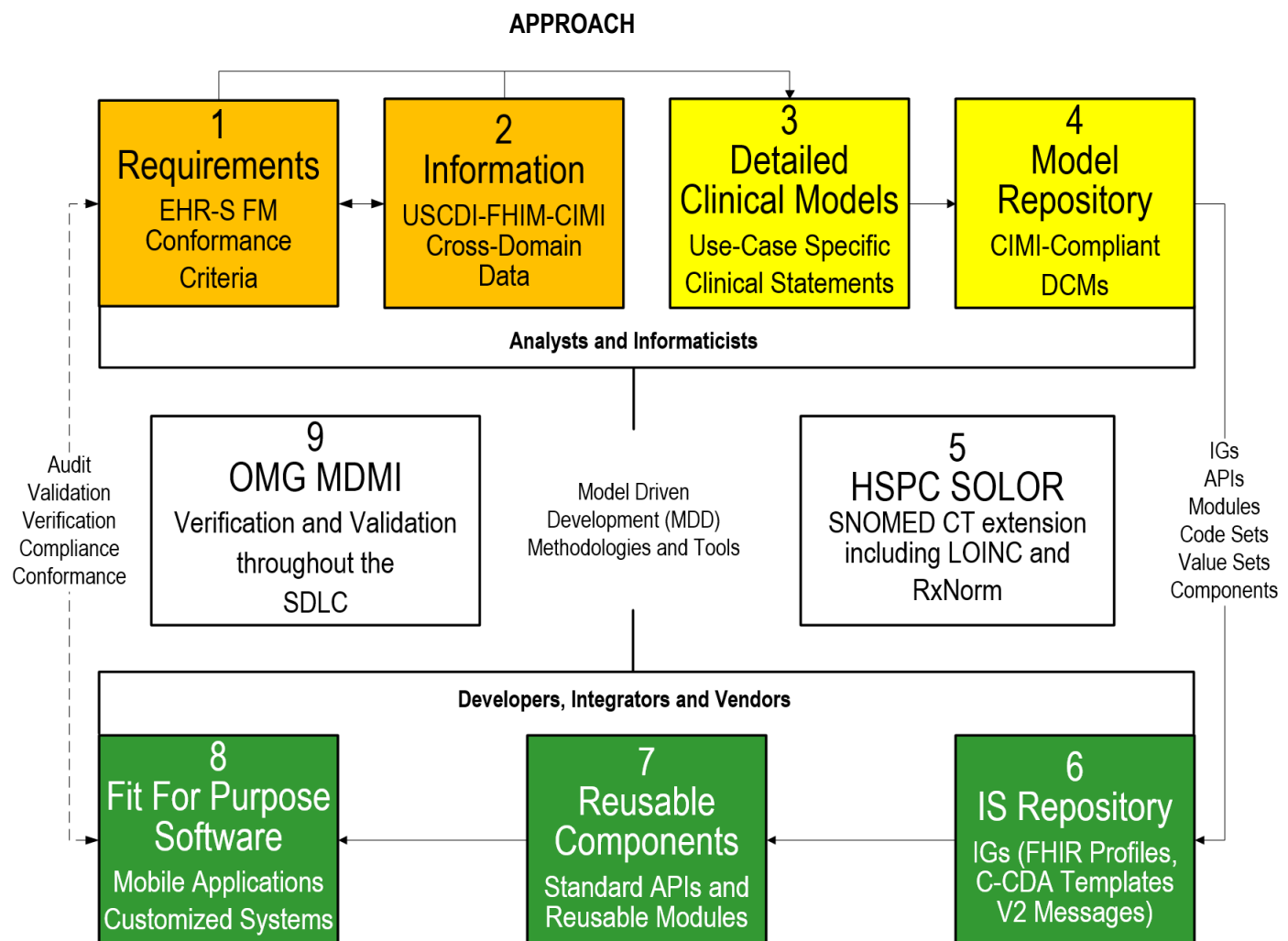


Figure 1: Software Development Lifecycle (SDLC) Storyboard

In Figure 1, clinical analysts and informaticists can start a project with 1: EHR System Functional Model (**EHR-S FM**) clinical-requirements stated as conformance criteria, mapped to 2: CIMI-FHIM multi-domain data requirements. This domain data is constrained to 3: CIMI-compliant sub-domain reference archetypes, patterns and clinical statements (aka observations with explicit functional context DCMs) specified as 4: logical DCMs Interoperability Specifications (**ISs**). HL7 WGs are collaborating to ballot FHIR, CDA and V2 profiles, templates and extensions. ISs can be bound

to 5: SOLOR (SNOMED CT extension for LOINC and RxNorm) terminology to specify 6: Implementation Guides (IGs) for interoperable FHIR profiles, C-CDA templates and V2 artefacts.

In Figure 1, developers can start a project with 6: IGs for *consistent* FHIR profiles, C-CDA templates or V2 messages to create or use 7: standard APIs and reusable code modules for the construction of 8: custom mobile applications and custom software systems. *This separation of concerns is a big deal!*

CIMI methodology supports:

- Rigorous development of DCMs by seasoned clinical professionals (steps 1-5)
- Faster, better and cheaper software development by IT developers (Steps 6-8)
- SDLC consistency can be verified by Model Driven Message Interface (MDMI) tools (Step 9)
- Value (patient safety, care quality, reduced cost) can be improved for QHIN users.

RDAM SDLC includes:

1. Requirements: The Electronic Health Record System Function Model (**EHR-S FM**) Release 2 offering a comprehensive set of functions and criteria partitioned by clinical domain. The work is informed by industry advances/directions, regulatory changes, learning from work from functional profiles, and participation by the international community. The work is also balloted through six standards organizations including: ISO, CEN, IHTSDO, CDISC, GS1 and HL7. The RDA project is mapping CIMI-FHIM data to EHR-S FM functions. Any issues found or recommended changes will be referred to the appropriate workgroup for consideration.
2. Information: The CIMI-FHIM offering a comprehensive set of common data elements and classes (modules) partitioned by clinical domain. The work is informed by industry advances/directions, regulatory changes, learning from work from federal agencies and commercial and professional organizations. Although US centric in its origin, FHIM is international in its intent and core content. The RDA project results in an object-oriented domain specific software system architecture, which may be referenced by specific project IGs, using Model Driven Development (**MDD**) tools and CIMI-compliant methodology. These RDA reference domain analysis model profiles can empower MDMI tools to verify and validate EHR-S FM system functions (behaviors) to CIMI-FHIM compliant DCMs and resultant HL7 implementation artefacts.
3. Model Repositories: MDD tools can be used to specify steps 3 DCMs, which may be published in a step 4 repository as ADL AND/OR FSD models. In step 5 these logical models are bound to terminology, value sets and code sets constrained to specific project implementation needs, such as FHIR, C-CDA templates, V2 message profiles or extensions.
4. Interoperability Specification (IS) Repositories: MDD tools can be used to specify Fig 1 step 6 IGs for FHIR, C-CDA and V2 message profiles and extensions.
5. Reusable Components: The key to data quality is reuse of thoroughly vetted and tested common data elements and reusable components, such as those resulting from the work being done by the HSPC Smart on FHIR initiative and ONC USCDI and TEFCA initiatives in support of the 2016 US 21st Century Cures Act.
6. Fit for purpose Software: faster and cheaper fit for purpose enterprise software from best-of-suite reusable and thoroughly tested software components and sub-systems, result in efficient and effective context optimized workflows meeting the diverse needs across locations, facilities, clinics and ancillary services.

CONCLUSION

The emerging CIMI compliant methodology, products and tools can enhance patient value. HL7 user and developer value proposition is that HL7 (HTA, UTG, IIM&T, RDA) and HSPC (CIIC, SOLOR) initiatives are working together to

holistically harmonize across and within standards for faster, better and cheaper FHIR, C-CDA and V2 implementation artefacts, increasing patient value (safety, quality, cost) and thereby benefiting all healthcare stakeholders. Harmonization, governance and configuration management work remains to be done to operationalize the the emerging HL7 CIMI Product Line.

ENCLOSURE: CIMI Technical Deep Dive

CIMI Compliance includes conformance to the CIMI Reference Model, containing:

- L1 BMM* Core Reference Model: Primitives and core datatypes
- L2 BMM Foundational Reference Model: Classes aligned with ISO 13606 and OpenEHR reference model that defines the top level classes from which all CIMI BMM Level 3 clinical models are derived.
- L3 BMM Clinical Reference Model: Clinical class hierarchy aligned with FHIM that define the Reference and stable structural Foundational-pattern Archetypes for DCMs. Non-clinical domains are supported by FHIM, e.g., finance, admin., logistics, which can have analogous BMM level 3 Reference and Foundational pattern archetypes defined, as needed.
- L4 Foundational Archetypes: Reference and Foundational Pattern hierarchy, represented in ADL, with progressively tightened constraints on the CIMI BMM level 3 Reference and Foundational Pattern archetypes.
- L5 Detailed Clinical Models (DCMs): leaf level archetypes that support interoperable clinical information exchange can be bound to SOLOR specified value sets and code sets and can be operationalized with terminology servers, such as VSAC or HAPI FHIR.

*BMM is Basic Meta Model, currently represented in UML; where, the *preferred* CIMI Reference model representation is Fig 2 level 1-3 BMM and Fig 2 level 4-5 ISO 13606 Archetype Description Language (**ADL**) constraint language. The Fig 2 levels 1-3 BMM is a CIMI balloted artefact intended for use by informaticists. Clinicians should be able to use tools, which "hide" the model representations to produce Figure 1 step 6 interoperability specifications balloted by appropriate workgroups. Alternate DCM representations, e.g., FSD, UML, ideally have bi-directional mappings to the preferred Fig 1 step 4 CIMI repository BMM-ADL representation; where, CIMI ADL tools can automatically verify CIMI reference model compliance and HL7 FSD tools can create the Fig 1 Step 6 developers' IS repository.

Figure 2 shows how analysts, informaticists and MDD tools can define clinical statements by starting with a core set of CIMI-FHIM reference archetypes, constraining them into logical CIMI DCMs, which can be expressed as FHIR FSD. Using HL7 tools, FSDs can then be transformed into consistent and requirements-traceable FHIR profiles, C-CDA templates and V2 messages. CIMI follows the Pareto 80/20 rule, Sub-domain or project DCMs may require additional attributes, aka extensions, which are not in the core CIMI reference model. Additionally, mapping to FHIR, C-CDA or V2 messages may necessitate additions or changes resulting from current disjoint data elements, data types, code sets and value sets across HL7 product lines and product families; where, this mapping step is a data quality risk. In addition to the HTA and UTG, the HSPC SNOMED with LOINC and RxNORM extension (**SOLAR**) project and Clinical Information Interoperability Council (**CIIC**) are addressing data-quality risks discussed in the referenced May 2018 HL7 Newsletter article. HL7 management groups will address these types of issues.

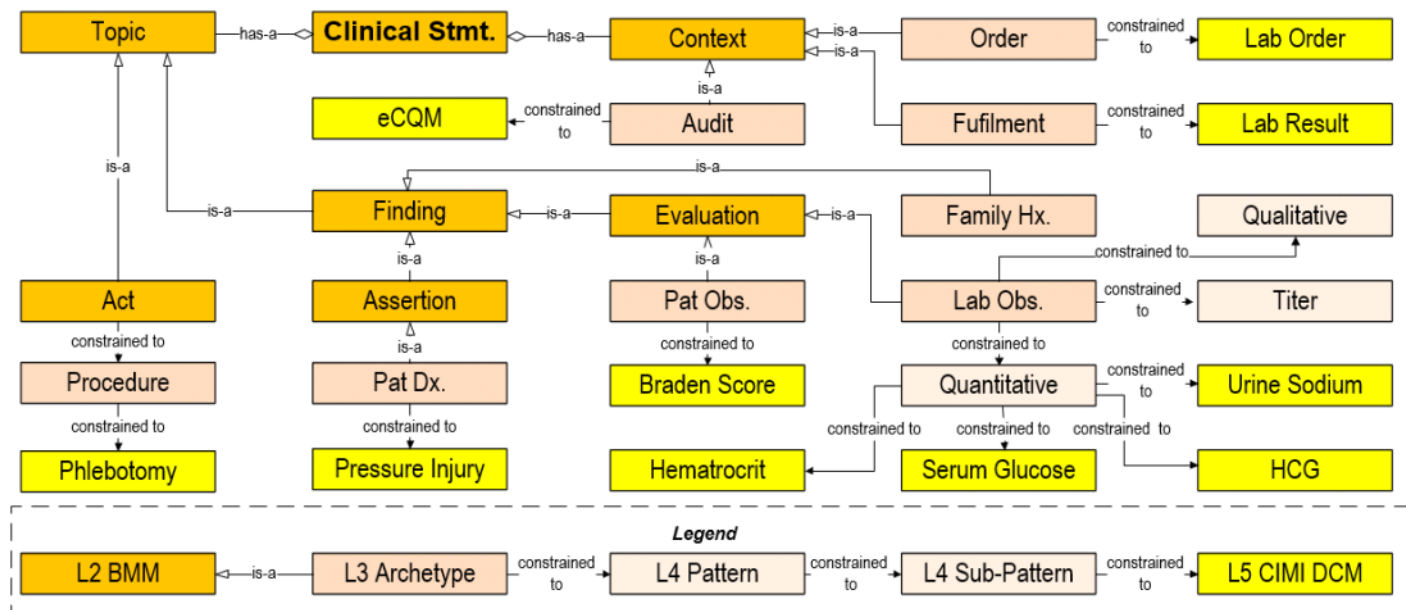


Figure 2: Notional Example of CIMI Compliant Clinical Statement DCMs

POC: Contact Stephen.Hufnagel.HL7@gmail.com for details.

Timeline:

- **2018-09-29** to 2018-10-05 HL7 Workgroup Meeting. Baltimore, MD, USA
- **2018-07-09** Article due
- **2018-06-13** Title and Abstract submitted
- **2018-06-01** (Andrea Ribick) Call for Story Ideas for HL7 September 2018 Newsletter

Attachment: Published HL7 May 2018 Newsletter Article

Healthcare IT Computable-Interoperability Strategy

“Methodology to manage data-quality risk by standardizing data”

In accordance with 21st Century Cures Act, TEFCA and USCDI

HL7 (CIC, PHER, EHR, CQI, CDS, CIMI) Workgroups, Steve Hufnagel facilitator

The ‘2016 *21st Century Cures Act* provides the healthcare IT (HIT) industry with definitions for “interoperability” and “information blocking”. It outlines a penalty system for those who fail to ensure the free flow of patient healthcare data. “*Computable interoperability*” implies improved patient value (safety, quality, cost) from consistent quality-data available to learning health systems.

In January 2018, Health and Human Services (HHS) Office of the National Coordinator (ONC) released the Trusted Exchange Framework and Common Agreement (TEFCA) and U.S. Core Data for Interoperability (USCDI) draft policy documents. They promise profound impact on the activities and priorities of Health Information Networks (HINs), provider organizations that participate in HINs and HIT vendors and service providers. TEFCA and USCDI will define US policy for interoperability, when finalized around December 2018.

- TEFCA strives to establish a single Healthcare Information Exchange (HIE) “on-ramp” to enable providers, hospitals and other healthcare stake-holders to join within the nationwide health information exchange (NHIN). TEFCA establishes “Qualified HINs” (QHINs) as a vehicle to facilitate a standardized methodology for NHIN connectivity. This methodology is managed by a Recognized Coordinating Entity (RCE).
- USCDI begins with the Common Clinical Data Set (CCDS) required by ONC’s 2015 Certification Criteria; where, USCDI adds classes (data modules) for structured-and-unstructured Clinical Notes

and for Provenance (who, what, when, where, why, how). USCDI outlines a roadmap to include additional classes and data elements categorized as

- mature, where, established standards exist, that become USCDI inclusion candidates.
- Immature, where, terminology, controlled vocabularies and code sets are evolving.

The problem is clinicians prefer pre-coordinated EHR data entry terminology forms while analysts prefer post-coordinated EDW analytic terminology forms. There is an Electronic Healthcare Record (**EHR**), Enterprise Data Warehouse (**EDW**) and HIE data-quality conundrum. The conundrum is that data must be optimized for clinician data entry, EDW analytics and HIE exchanges with bidirectional mappings, without loss of information. Data quality mapping risk is exasperated by

- clinical findings that have multifaceted workflow context, provenance and intended use and
- differing terminology granularities and ontology-categorizations across-and-within standards.

HL7 workgroups and product-line management-groups are striving to address this data quality conundrum with standards, technologies, methodologies and Model Driven Development (**MDD**) tools. MDD tools are intended to efficiently-and-effectively specify interoperable HL7 V2 messages, FHIR profiles, C-CDA templates, etc. with consistent implementation guides, APIs, components, controlled vocabularies and code sets.

Figure 1 summarizes an emergency-response scenario, where, healthcare data moves with the patient. Disaster management requires computable-interoperability among ad-hoc partners collaborating with heterogeneous systems, during patient-movement episodes across disparate continuums-of-care. Figure 1's "ABC Stabilization and Decon." refers to emergency responders' essential steps of airway, breathing, and circulation stabilization plus biological and chemical decontamination.

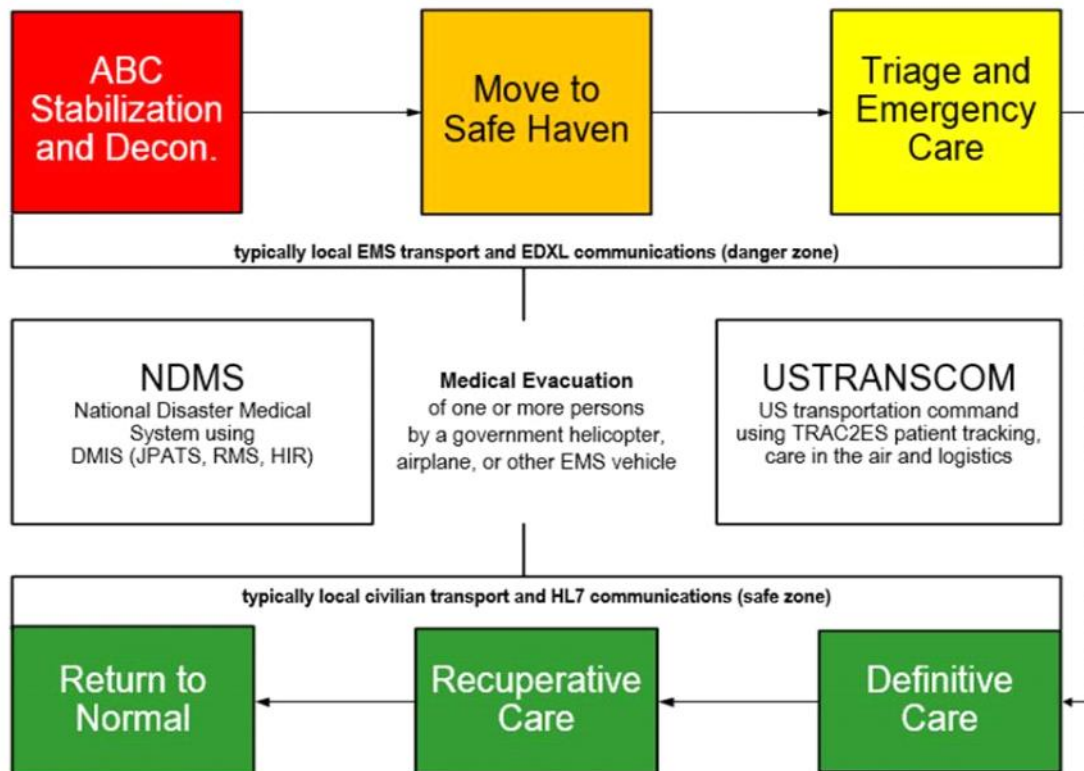


Figure 1: Emergency-Response Patient Movement Continuum-of-Care Scenario

1. Emergency responders inform hospitals using the OASIS EDXL-TEP/HL7 XML standard containing patient condition, treatment and physical tracking information.
 - TEP uses NEMESIS/HL7 data elements transformable into HL7 ADT messages.
 - OASIS EDXL-Distribution Element (**DE**) "envelope" wraps-and-routes data packages, like NIEM Information Exchange Package Documentation (**IEPD**), across a continuum-of-care
2. Hospitals' inform emergency responders using the OASIS EDXL-HAVE/HL7 XML standard

containing hospitals' resource availability information.

3. NDMS coordinates among federal agencies using NIEM IEPDs.

Example: pre/post-coordinated data representation forms.

1. In a pre-coordinated clinical entry form, multiple concepts are brought together into one term. Here, entry order is relevant for disambiguation of concept relationships. For example,
 - Clinicians text notes: "closed displaced-fracture of the right leg at the neck of the femur"
 - ICD-10-CM billing form: femur fracture type III
2. In a post-coordinated data analytic form, concepts are broader and searched with Boolean operators.
 - A post-coordinated representation might be "fracture AND femur AND neck AND displaced AND right AND closed", where, order is irrelevant.
 - SNOMED CT analytic form: fracture (morphologic abnormality), structure of neck of femur (body structure), right (laterality), plus primary procedure (qualifier value), etc.

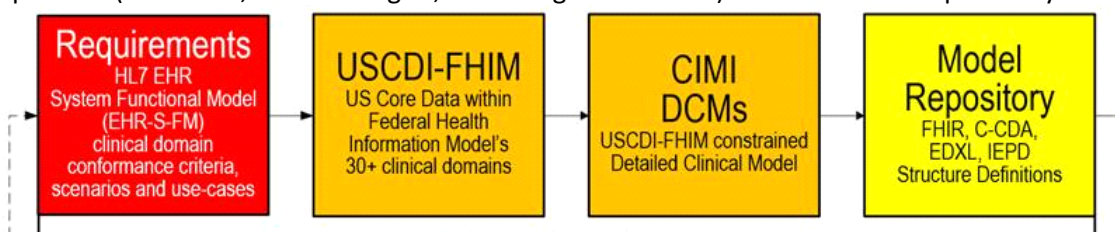
Recommendation: The 21st Century Cures Act's Health Information Technology Advisory Committee (**HITAC**) suggest that the RCE methodology align standards, technologies, tools and RCE Certification Criteria by including USCDI, FHIM, DCM and SOLOR stewardship, governance, configuration management and standardization processes to achieve efficient-and-effective MDD computable-interoperability including bidirectional pre/post coordinated mappings, without loss of information; where,

- **FHIM** is Federal Health Architecture's (**FHA**) Federal Health Information Model
- **DCM** is HL7 Clinical Information Model Initiative's (**CIMI**) Detailed Clinical Models
- **SOLOR** is US Realm SNOMED CT extension including LOINC and RxNorm

TEFCA-USCDI should build upon areas of agreement, in a decentralized way that percolates consensus up, gradually extending and scaling data-use agreements and data-interoperability conformance criteria, as consensus and standards mature. Vendor system conformance testing should be voluntary and QHIN compliance certifications should have periodic updates. This is key to evolving standards adoption and enhanced QHIN interoperability on the path to learning healthcare systems. The success metric is scalability among healthcare domains, sub-domains and stakeholder uptake. Figure 2, shows a suggested RCE methodology; where, product use-case scenarios are

1. Organized into EHR-S FM clinical-domain functional conformance-criteria
2. Aligned with USCDI-FHIM clinical-domain architypes and patterns for findings, orders, procedures, etc.
 - a. Where, USCDI data elements and classes are harmonized within FHIM
3. Constrain FHIM architypes and patterns into logical DCMs, which specify
 - V2, FHIR and C-CDA, etc. structure-definitions bound to
 - SOLOR vocabularies and code sets
4. Resulting in interoperable OASIS, HL7, NIEM etc. implementation guides, APIs, components & services.
5. Used for data sharing among learning systems' analytics, reasoning and decision support.

This suggested RCE methodology has no impact on deployed EHR systems. It positively impacts inconsistent Extraction, Transfer and Load (**ETL**) processes that put QHIN data at risk. Federal Agencies, partners, QHINS, venders and contractors should incorporate these modern best-practice (standards, methodologies, technologies and tools) to enhance interoperability.



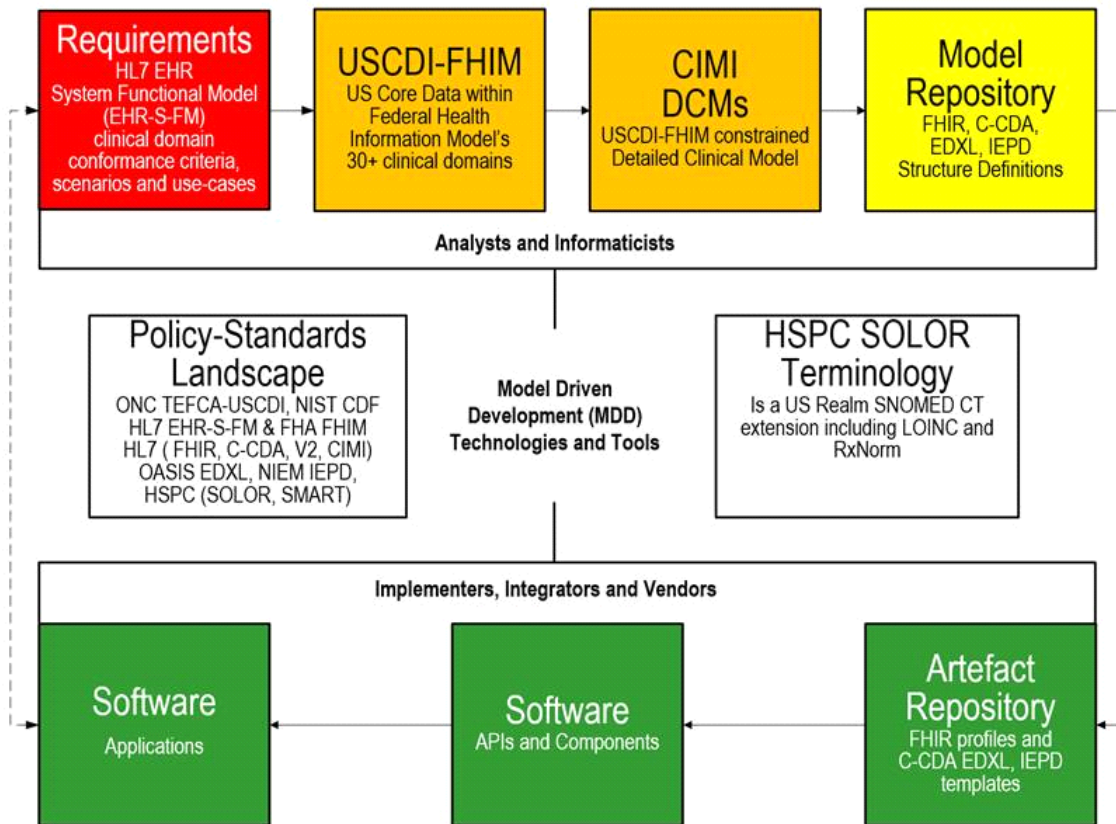


Figure 2: Suggested RCE Interoperability Methodology.

Conclusion: Computable interoperability among QHINs ensured by the suggested RCE methodology and certification processes can positively influence NHIN patient-value (safety, quality, cost), by empowering better learning healthcare systems' analytics, reasoning, decision support and outcomes measurements.

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