HITSP Foundations Committee

Proposed Harmonization Process
(DRAFT Nov 28, 2007)

1 Executive Summary

HITSP Foundations is recommending to the HITSP Panel that the HITSP Foundations Harmonization Subcommittee be charged with the ongoing oversight of individual harmonization projects led by various harmonization working groups.

The HITSP Foundations Harmonization Subcommittee will be comprised of representatives from each HITSP-recognized Standards Development Organization, HITSP Foundations co-chairs, and other interested parties.

Principles by which the HITSP Foundations Harmonization Subcommittee will operate are outlined in section *3 Harmonization principles*. Processes by which the HITSP Foundations Harmonization Subcommittee will operate are detailed in section *4 Harmonization Process*.

The proposed process has 5 major stages:
- **Initiate:** Proponent of a harmonization project will present to HITSP Foundations Harmonization Subcommittee, after which a harmonization working group will be formed.
- **Build:** The harmonized artifact is built by the harmonization working group.
- **Approve:** The harmonized artifact is subjected to an approval process.
- **Publish:** Approved artifacts are published.
- **Evaluate:** The harmonization process is evaluated, and streamlined where possible.

Principles and Processes are being iteratively tested via a "small scale harmonization project", further described in section *5.1 Small Scale Harmonization Project*.

2   HITSP Foundations Harmonization Subcommittee

The HITSP Foundations Harmonization Subcommittee is a subgroup of the HITSP Foundations committee charged with overseeing individual harmonization projects led by various harmonization working groups.

HITSP Foundations Harmonization Subcommittee will attempt to address these components of the HITSP Foundations Terms of Reference:

- Context/Information Model - establishing a **common reference information model** (and subordinate models) to support clinical, public health, financial, and administrative healthcare functions.
- Terminology/Content Definition - establishing **common reference terminology** models and data content specifications that are integrated with the information model(s).
- Methodology- establishing a **common methodology/process** that all standards organizations and code set maintainers will follow to achieve standards harmonization.

HITSP Foundations Harmonization Subcommittee is comprised of:

- Representatives from each HITSP-designated Standards Development Organization (SDO).
- HITSP Foundations co-chairs.
- Other interested parties.

Principles by which the HITSP Foundations Harmonization Subcommittee will operate are outlined in section *3 Harmonization principles*.

Processes by which the HITSP Foundations Harmonization Subcommittee will operate are detailed in section *4 Harmonization Process*.

3   Harmonization principles

Harmonization principles that guide the HITSP Foundations Harmonization Subcommittee include:

- **Where prior or current parallel harmonization efforts are identified, there shall be a coordinated alignment of efforts**
    o Support and build upon Consolidated Health Informatics (CHI) recommendations.
    o Support and build upon the ANSI process and HITSP foundational principles.
    o Work with NCI, NLM, and others towards common machinery for value set maintenance.
    o Draw upon existing SDO standards development frameworks for the creation of model-based standards.
    o Support and build upon HIPAA requirements.

- **Alignment of harmonized value sets and information models is not restricted to point-to-point interactions.**
    o Alignment of harmonized value sets and information models can span the spectrum of care, from data origination in an electronic health record, to point to point communication, to data reuse, etc.

- **There is expected participation from SDOs whose content is being harmonized.**

- o An SDO will appoint representation for those domains they have content they want considered in a harmonized artifact.
- o SDOs will ensure an ongoing harmonization and the use of harmonized products in their own specifications.
- o All SDOs will have an equal opportunity to participate in standards harmonization efforts.
- o SDOs will encourage changes to HITSP charter to acknowledge the Foundations processes and harmonization products.
- o The intent is for SDOs to adopt and use harmonized artifacts, as opposed to using local codes and/or models with mappings or translations. QA of mappings or translations are the responsibility of the SDO maintaining local codes and/or models.
- o If an SDO does not support all the values, while another SDO does – if there is mapping between two standards, the SDOs must determine the rules for values not supported by both.

- **The overhead potentially incurred by cross-SDO collaboration will be minimized.**

- **For HITSP-recognized harmonized artifacts:**
  - o There should be a single point where change requests can be submitted.
  - o There should be a single point of reference to obtain / view harmonized artifacts.
  - o There should be a single consensus process for each artifact type.
  - o There should be a common representational form and style guide for each artifact type.
    - There should be a common framework for reference terminology models and a common representation of value sets. There should be semantic coherence across code systems in the common framework.
  - o Artifacts that participating SDOs have agreed to harmonize will become HITSP-recognized US national artifacts.

- **Harmonization processes:**
  - o HITSP Foundations Harmonization Subcommittee should minimize divergence or change from existing value sets and information models when building harmonized artifacts.
  - o Codes for a value set should be drawn from a standard reference terminology.
  - o HITSP Foundations reserves the right the add values into value sets prior to the code being added into the source code system. These would be contained in an interim US national code system (with the expectation that the interim codes are replaced once adopted by the source code system).
  - o Representation of **NULL** and **OTHER** will not be addressed on a per value set basis, but may be addressed as harmonization topics themselves.
  - o Extensibility (e.g. whether or not local codes can be included in an instance in addition to harmonized codes) is outside the scope of HITSP Foundations, and is a decision left to the SDO and the HITSP TCs.
  - o Dynamic vs. Static considerations (e.g., whether or not an instance can include codes from a value set that were added after the relevant specification was balloted) is outside the scope of HITSP Foundations, and is a decision left to the SDO and the HITSP TCs.
  - o There will be a uniform policy for versioning harmonized artifacts, based on a predictable frequency. The frequency may vary depending on the artifact type.

- **Work will be prioritized in various ways. The end result will be a HITSP roadmap for harmonizing information and terminology standards across SDOs.**
  - o Driven by HITSP.
  - o Driven by AHIC.
  - o Driven by CCHIT.
  - o Driven by NHINs.
  - o Driven by SDOs.
  - o Constrained by available resources.

- ▪ **HITSP Foundations is not a Standards developer.**
  - o HITSP Foundations Harmonization Subcommittee is developing a process to harmonize work done within and among SDOs.

4 Harmonization Process

This section describes the harmonization process used by the HITSP Foundations Harmonization Subcommittee. Harmonization processes are tightly coupled with harmonization principles – the two are iteratively reviewed and revised as processes are tested and refined over time.

The intent is to define harmonization processes such that they can serve as a template for a project plan for any harmonization project. All HITSP Foundations Harmonization Subcommittee harmonization projects will be tracked with a project plan built from said template.

4.1 Initiate project (i.e. create Harmonization Working Group)

Requests for new harmonization projects or for revisions to existing harmonization artifacts shall be presented to HITSP Foundations Harmonization Subcommittee, who will then assist in the creation of a Harmonization Working Group. The real harmonization work is carried out by the Harmonization Working Group, following the process defined by HITSP Foundations Harmonization Subcommittee. All Harmonization Working Groups are open, and the artifacts they produce will be subject to approval by HITSP-member SDOs.

NOTE: While anyone can propose a harmonization project, there are logistical factors that often determine whether or not a Harmonization Working Group will be formed. In particular, there needs to be an identifiable working group leader, and there needs to be sufficient direct participation from the affected SDOs.

NOTE: HITSP Foundations Harmonization Subcommittee is not a standards developer. Identified terminology or information model gaps should be communicated to the SDOs. In order to ensure that identified gaps don't wind up being implemented differently by different SDOs, HITSP Foundations Harmonization Subcommittee could be a forum / model for pre-reconciliation.

- ▪ Project coordination will be managed by HITSP staff
- ▪ Sponsor of proposed harmonization project will present a draft description to HITSP Foundations Harmonization Subcommittee, including:
  - o Overview of project, including high level scope and need being addressed.
  - o Existing code sets, if known.
  - o Existing collaboration/harmonization efforts, if known.
  - o Suggested actions.
  - o Forward / backward compatibility issues if this is a proposed change to an existing harmonized artifact.
- ▪ HITSP Foundations Harmonization Subcommittee will formally notify all HITSP members (all SDOs, non-SDO stakeholder organizations, governmental bodies, consumers) of an intent to harmonize and call an organizational meeting.
- ▪ The organizational meeting will be held to identify level of interest and participants. Presuming sufficient interest and SDO participants, a Harmonization Working Group will be formed. The Harmonization Working Group will further clarify the objectives and harmonized artifacts to be built.
- ▪ The Harmonization Working Group will operate under standard HITSP committee guidelines. All meetings will be announced in advance. Key discussions, decisions and attendance will be documented. All decisions will be by consensus or failing that by two-thirds vote of members.
- ▪ The Harmonization Working Group will identify a project lead (to collect use cases, to manage the project template, etc).

- The Harmonization Working Group, once formed, will report back to HITSP Foundations Harmonization Subcommittee before proceeding on to the next step.

4.2 Harmonization Working Group

4.2.1 Determine project scope

- The Harmonization Working Group will further clarify the scope and objectives, identify use cases to be supported, and define the harmonized artifacts to be built.
    - o Review relevant HITSP use cases.
    - o Review relevant SDO use cases.
- The Harmonization Working Group will record their work in a HITSP Foundations Harmonization Subcommittee project plan template.
- The Harmonization Working Group will report back to HITSP Foundations Harmonization Subcommittee before proceeding on to the next step.

4.2.2 Perform background research

- In accordance with the ONC Contract, HITSP Foundations Harmonization Subcommittee will start with, and give priority to, the CHI recommendations.
- Review existing HITSP referenced standards and value sets.
- Identify HIPAA requirements
- Review prior and current parallel efforts
- Identify existing mappings and collaborative activities
- Assess broad impact of various options to the SDOs.

4.2.3 Build harmonized artifact

4.2.3.1 Establish baseline decisions

- For value sets, determine if you're building a code system, a value set drawn from one or more existing code systems, or enhancing an existing code system or value set.
    - o What is/are the code system(s)?
    - o What cross-mappings will be built?
    - o Enumerated vs. Criteria-based? (see section *5.4 Definitions* for definitions)
    - o Versioning requirements?
    - o Display name requirements? (HITSP-recognized value sets typically harmonize on codes rather than display names. Display names from the code system(s) are typically shown with the value set, but SDOs are not bound to them. In some cases, there may be a need to harmonize both on the codes and the display names).
- Populate "Baseline Decisions" tab in HITSP Foundations Harmonization Subcommittee project plan template.
- The Harmonization Working Group will report back to HITSP Foundations Harmonization Subcommittee before proceeding on to the next step.

4.2.3.2 Create metadata

Metadata is drawn from USHIK/CaBIG (ISO 11179)
[http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/cadsr/ISO11179])

NOTE: HITSP Foundations anticipates that metadata will evolve over time, as the number of harmonized artifacts grow, in order to support discoverability.

- HITSP Foundations assigns OIDs to artifacts (or registers pre-existing OIDs).
  - HITSP OID: 2.16.840.1.114443.
  - HITSP Foundations OID: 2.16.840.1.114443.1.
  - HITSP Foundations sex structure value set OID: 2.16.840.1.114443.1.1
  - HITSP Foundations marital status value set OID: 2.16.840.1.114443.1.2
- Populate "Metadata" tab in HITSP Foundations Harmonization Subcommittee project plan template.

4.2.3.3 Build the artifact
- The actual harmonized artifact is built.
- Update "Metadata" tab in HITSP Foundations project plan template.
- The Harmonization Working Group will report back to HITSP Foundations Harmonization Subcommittee before proceeding on to the next step.

4.2.3.4 Create cross-mappings or translations
Per principles, these are the responsibility of the SDO. The repository will be able to hold cross-mappings.

4.3 Approve harmonized artifact
In the process outlined below, approval of harmonized artifacts is occurring without a full membership ballot of any of the affected SDOs. This raises some logistic issues, which are addressed partially in this section, and partially in section *5.2 Facilitating SDO adoption of harmonized artifact*.

It is recognized that changes to information model fragments can have a more significant structural impact on an SDO (e.g. may require a formal vote of the SDO in order to approve incorporation of said changes into their standard), and therefore this section lays out a general approval process, along with special considerations for different artifact types.

- Upon completion of the steps outlined in section *4.2 Harmonization Working Group*, HITSP Foundations Harmonization Subcommittee will initiate the artifact approval process, which involves notifying the SDOs of the new artifact, and giving them a chance to comment on it.

  NOTE: The guiding presumption is that the Harmonization Working Group is the authoritative source of technical harmonization. Therefore all SDOs with interest in the subject matter should participate in the working group phase. HITSP Foundations Harmonization Subcommittee may, based on input from its members and formal comments from SDOs, determine that the artifact needs further work and refer it back to the Harmonization Working Group. HITSP Foundations Harmonization Subcommittee will not make technical changes to artifacts.

- HITSP Foundations Harmonization Subcommittee will formally notify all HITSP member SDOs of its intent to publish a harmonized artifact within 60 days. These notifications will occur at a regularly specified frequency, initially quarterly. Any SDO through its primary representative may submit a negative comment during this period. Such negative comments will be dispositioned by HITSP Foundations Harmonization Subcommittee and/or the Harmonization Working Group, until they are resolved.

  NOTE: Disposition will seek to resolve the negative to the submitter's satisfaction. However, decisions will be made by consensus and failing that by two thirds approval of voting members of

HITSP Foundations Harmonization Subcommittee (HITSP-member SDO representatives, HITSP Foundations co-chairs).

4.4 Publish harmonized artifact

The final publication process has not yet been determined. For now we are publishing in:

- United States Health Information Knowledgebase (USHIK) [http://ushik.org/registry/x/model_SSHP.html] [Contact: "Noah Stromer" <noah.stromer@gmail.com>]
- National Cancer Institute's Cancer Data Standards Repository (caDSR) [http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/cadsr [Contact: "George Komatsoulis" <komatsog@mail.nih.gov>]
- National Cancer Institute's Enterprise Vocabulary Services (NCI EVS) [http://evs.nci.nih.gov/] [Contact: Frank Cartel]
- SNOMED CT Reference Set [URL:] [Contact:]

Per principles, there is a uniform policy for versioning harmonized artifacts of a particular type, based on a predictable frequency.

A "**release"** is a compilation of approved additions, deletions, or criteria changes to the harmonized artifact, since the prior release. The date of every change (e.g. every addition or deletion from a value set) is captured. These changes are gathered together, at a frequency to be determined, and published. Such publication constitutes a new release of the harmonized artifact. Releases are identified by (at least) date/time.

NOTE: Value set releases will reference the current version of the source code system. This should not imply however that the value set version needs to be communicated. In fact, source code systems should adhere to good vocabulary practices (e.g. don't reuse codes, don't mutate the meaning of a code, clearly indicate retired vs. active codes) so that users can trust received codes without worrying about the value set release.

4.5 Evaluate harmonization process

Per principles, HITSP needs to minimize the overhead of cross-SDO collaboration. In order to do this, HITSP should iteratively review, refine, and streamline the process. Changes to the process can be approved similarly to how artifacts themselves are approved.

- Was there a need to deviate from the defined principles or processes?
- Is there a need to modify the defined principles or process?

5 Appendix

5.1 Small Scale Harmonization Project

The HITSP Foundations Harmonization Subcommittee is defining a process for harmonizing artifacts across SDOs. To iteratively test and refine the process, the subcommittee is undertaking a small scale harmonization project, that has a limited scope, but that will test the end to end process.

The objectives of the project are to:

- Develop and prototype a process for harmonizing standards (both fields and vocabulary) across SDOs.
- Based on the prototype, enable a determination of level of effort and timelines for addressing other domains (building and maintaining).
- Develop a process that is scalable (e.g. that can be extended to all domains of interest).
- Develop a process that is maintainable.
- Make recommendations for organization to implement terminology standards for the United States.
- Complete the prototype and prototype analysis in 3-6 months.

Because the objectives of the small scale harmonization project are as much about process as about product, the initial domain will be very limited. The intent is to iteratively develop a sustainable process that results in a harmonized product that SDOs will use in the construction of their own standards. By keeping the initial domain very limited, we should be able to explore a number of process options without getting bogged down in detailed mapping exercises.

- Model
  - Name
  - Date of birth
  - Marital status
  - Gender
- Terminology
  - Marital status
  - Gender
  - Procedure body site

- Methodology / process

- Organizational requirements to implement method and process.

5.2 Facilitating SDO adoption of harmonized artifacts

It is recognized that while HITSP Foundations Harmonization Subcommittee will develop harmonized artifacts, it is outside the scope of HITSP to enforce SDO adoption of such artifacts. There are however many ways in which HITSP can facilitate SDO adoption, such as:

- Clear forward / backward compatibility statement should accompany each change request.
- Provide adequate time to vet proposed changes within an SDO before approving.
- Support multiple value sets where necessary to support divergence of use cases.
- Allow SDOs to reserve the right to use a constrained view of harmonized artifacts.
- Allow SDOs to reserve the right to use mappings and translations as interim / transition strategy.
- SDOs have discretion over static vs dynamic binding, such that value set changes don't necessarily require a vote of the SDO.
- SDOs have discretion over extensibility, such that value set changes don't necessarily require a vote of the SDO. Extensibility allows for the exchange of codes that were introduced into a value set after the finalization of an SDO standard.
- Engage ONC in enlisting participation of federal agencies and support their early adopter role.
- HITSP Foundations Harmonization Subcommittee will request periodic reports from the SDOs regarding progress towards adoption (and adoption hurdles) for each harmonized artifact.
- Make sure reference terminology knows that we are using some of their concepts in a HITSP recognized value set

5.3 References

- CHI Demographics recommendations
  [http://www.whitehouse.gov/omb/egov/documents/demo_full_public.doc]
- CDC/NIH/Federal collaborations [Tim Morris Director of Shared Services at the CDC.
  tom1@CDC.GOV].
- NCI CaBIG: [http://cdebrowser.nci.nih.gov/CDEBrowser/]
- OASIS Code List Representation [http://www.oasis-open.org/committees/codelist]
- USHIK : [http://ushik.org/registry/x/]

5.4 Definitions

- **Coding system:** A coding system is a scheme for representing concepts using (usually) short concept identifiers to denote the concepts that are members of the system; defines a set of unique concept codes. Examples of coding systems are ICD-9, LOINC and SNOMED.

- **Harmonization Working Group:** A group of people working on a HITSP Foundations Harmonization Subcommittee harmonization project. (See section *4.1 Initiate project (i.e. create Harmonization Working Group)* for details).

- **Harmonized artifact:** A harmonized artifact is any unit of consensus that is the focus of a Harmonization Working Group project. Artifacts include value sets, information model fragments, etc.

- **Information model fragment:** An information model fragment is a portion of a larger reference information model that is the subject of Harmonization Working Group activities. Typically, Harmonization Working Groups will harmonize on small models, but each of these small models retain the ability to be coalesced into a larger unified reference information model.

- **Integrated vs. Federated terminology:** These terms refer to the spectrum of harmonized terminology solutions used to fulfill interoperability requirements, where on the one side (the "integrated" side) there is a single code system, managed by a single organizational entity, from which all subsets are drawn, and on the other side (the "federated" side) there are multiple code systems that in total fulfill the requirements. The federated code systems are independently maintained, but ideally work closely together in an effort to manage redundancy and consistency. **Semantic coherence** across the code systems in a federated network factors heavily in to the ability to integrate, where the more divergent the code system models, the more complex and costly the integration.

- **Release:** A release is a compilation of approved additions, deletions, and/or criteria changes to a harmonized artifact, since the prior release. These changes are gathered together, at a frequency to be determined, and published. Such publication constitutes a new release of the harmonized artifact. Releases are identified by (at least) date. (See section *4.4 Publish harmonized artifact* for details on release management).

- **Standards Development Organization (SDO):** One of four categories of HITSP membership, as defined in the HITSP Charter, Jan 5, 2006. HITSP membership categories include (a) "Standards development organizations" (SDOs); (b) "Non-SDO stakeholder organizations"; (c) "Governmental bodies"; (d) "Consumers".

- **Value set:** A vocabulary domain that has been constrained to a particular realm and coding system.

- o An **ENUMERATED** value set (aka an **EXTENSIONAL** value set) is one that is comprised of an explicit listing of the set of codes. Versioning occurs if values are added or deleted. SDOs typically have STATIC bindings to ENUMERATED value sets.
- o A **CRITERIA-BASED** value set (aka an **INTENSIONAL** value set) is one that is defined by a computable expression that can be resolved to an exact list of codes (e.g. "all SNOMED CT concepts that are descendants of the SNOMED CT concept Diabetes Mellitus"). Versioning occurs if the criteria changes. SDOs typically have DYNAMIC bindings to CRITERIA-BASED value sets.

- **Value set binding:** Specifies the relationship between a field in an SDO's specification and a referenced HITSP-recognized US Realm value set.
  - o A **STATIC** value set binding relates a field in an SDO's specification to a particular version of a value set.
  - o A **DYNAMIC** value set binding relates a field in an SDO's specification to a particular value set, without mention of a particular version.

- **Vocabulary domain**: The set of all concepts that can be taken as valid values in an instance of a coded attribute or field; a constraint applicable to coded values.

5.5 *Open Issues*

- How to support multiple concurrent processes? May help to discuss overall Foundations scope and timelines – to give advanced notice to SDOs so that we can assemble the various harmonization working groups who can then work in parallel. For instance, when do we anticipate working on harmonization of medication model? Financial models? Etc. A list of potential harmonization projects over the next 2 years includes:
  - All CHI-recommended value sets
  - Cross-HITSP Interoperability Specifications
  - Demographics
    - o Race / Ethnicity
    - o Living arrangements
  - Functional disability assessment
  - Financial
  - Lab
    - o Lab orders (SNOMED vs. LOINC)
  - Medications
    - o Structured SIG (NCPDP vs. HL7)
    - o Allergens (SNOMED vs. RxNorm)