



HL7—Supporting Profiling & Enforcing Organizations Other Standards Development Organizations

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**Note: Portions of this presentation
were created and are provided by
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Agenda

- Health Level Seven (HL7)
- Profiling & Enforcing Organizations (P-E-Os)
- HL7 & other US Standards Development Organizations (SDOs)



Health Level Seven (HL7)

- ANSI accredited SDO
- Widely used between HIT systems in the > 33 countries
- US started in March 1987 but now has 33 international affiliates
- Involvement by governments has increased substantially in the last six years



33 HL7 Affiliates / Countries

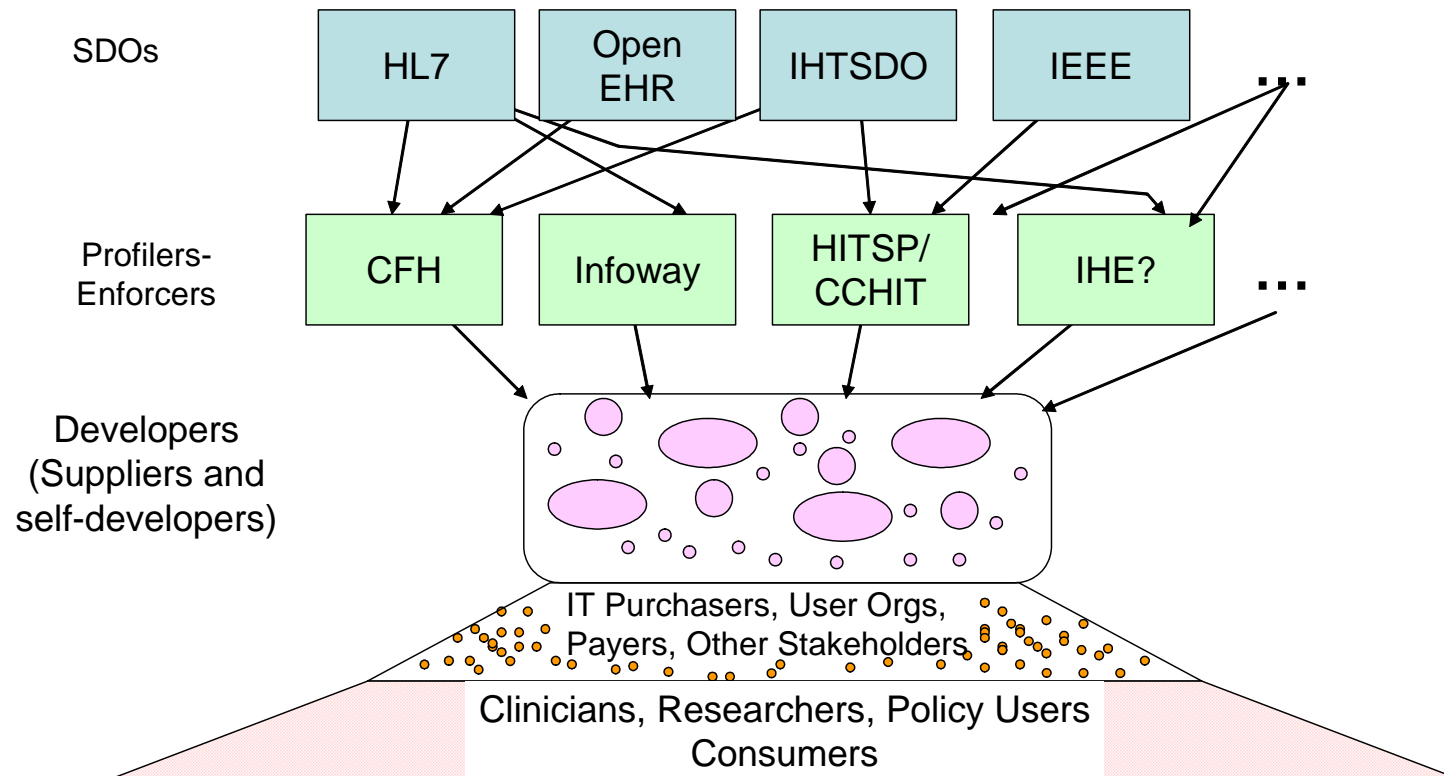


SDOs

- Take responsibility for producing standards in the form of documents or other mechanically usable intellectual property
- Are generally characterized by processes that include openness to all stakeholder groups
- Create standards that are in many governmental and some industrial situations much easier to enforce
- Usually require an unpredictable amount of time to achieve consensus.
- Almost no work products can be implemented with anything approaching plug and play interoperability without profiles to deal with issues defined under “Profilers”



Example of Entities in the business of Healthcare Standards



Gartner





P-E-Os

Profiler – Enforcer Organization (P)

- Generally takes responsibility for seeing that interoperable implementations happen in specific time frames
- Responds to time frames that are driven by external considerations such as governmental terms and budget cycles
- Are frequently tied directly or indirectly to broader expenditures on health IT
- Get clout by directly impacting:
 - The ability of developers to sell products or
 - User organizations to get funding to buy products



Profiler – Enforcer Organization (P)

- In order to meet goals a P-E always needs to produce profiles that constrain the generality of SDOs to specific combinations of use case, privacy policy, security, transport specifications and, in the case of healthcare, multiple external terminologies.
- A P-E usually needs to combine the work products of multiple SDOs in each profile and to provide “mortar specifications” to show how multiple standards work together.
- A P-E frequently needs to provide ad-hoc or “non-standards solutions” to fill holes where no workable standard is available in a timeframe that meets the needs of the P-E.



Profiler – Enforcer Organizations (E)

➤ While developing the profiles is a critical step, they do not magically bring about interoperability. A substantial investment is required in working with software developers to assist them in achieving compliance and then verifying compliance. The final step, verification, is often described as “certification.”

➤ **P-E-Os have become HL7’s largest and most influential stakeholders.**



Example P-E-Os

- caBIG (Cancer Biomedical Information Grid)
 - National Cancer Institute initiative that uses grant specifications and coordination with open source software initiatives to have substantial influence of the adoption of standards for interchange among cancer researches. Success would probably beget similar initiatives in other areas of clinical research.
- CCHIT (Commission for the Certification of HIT)
 - Creates profiles for functionality and interoperability, leveraging HITSP profiles where possible. Impact on interoperability is just beginning. Certifies products against those profiles. Clout comes from Stark relaxation reliance on CCHIT to qualify EMR products (and could also come from ARRA regulations).



Example P-E-Os

- Connecting for Health

- Part of the English National Health Service (NHS). Contractually enforces compliance on Systems Integrators with its profiles.

- HITSP (ANSI Panel in the United States)

- ONC has split the requirements for profiling and enforcing. HITSP has the profiling requirement. The means of enforcement are not clear, depending in part on the results of the NHIN Trial Implementations Project and decisions from the new administration on whether to maintain and how to enforce a Bush Executive Order mandating the use of HITSP profiles.

- Canada Health Infoway (Quasi-governmental Canadian agency)

- Establishes an architecture and standard profiles for Canada. Influences provinces through funding of projects.





HL7 & Other US SDOs

Major US HC SDOs

- ASC X12N (ANSI Approve SDO)

- Mandated by HIPAA regulations for the transactions related to authorizing care, paying claims and member enrollment for health plans.

- ASTM E31 (ANSI Approve SDO)

- Many standards documents are produced by a consensus group of only a few people and end up having little impact on the industry. Their Continuity of Care Record (CCR) standard has generated thought leadership in an important area of interoperability. The HL7 CCD which is and HL7 CDA implementation of the CCR has been specified as the National Standard.



Major US HC SDOs

- CDISC (Trade Association)
 - Standards for managing data during clinical trials. Some impact through the FDA.
- DICOM (Through ACR NEMA)
 - Dominant SDO for diagnostic imaging standards. Used by any P-E working in this domain.
- IEEE (ANSI Approved)
 - Primary impact now is a family of standards for medical devices known as IEEE 1073. These standards are the basis for ISO 11073 medical device standards.



Major US HC SDOs

- NCPDP (ANSI approved).
 - NCPDP standards dominate for transactions between electronic medical record systems, drugstores and mail-based prescription vendors.



SCO

- **SDO Charter Organization**

- Formed in January 2009
- Members include:

- ASTM
- CDISC
- DICOM
- HL7
- NCPDP
- WEDI (as a related-entity)
- X12



Other SCO Formal Observers

- American National Standards Institute (ANSI)
- Federal Health Architecture (FHA)
- HIT Standards Panel (HITSP)
- Social Security Administration (SSA)
- Integrating the Healthcare Enterprise (IHE)



SCO Leadership

- Chair: John Klimek (NCPDP Board Chair)
- Chair-elect: John Quinn (HL7 CTO)



SCO Initial Priority Projects

- Standards Landscape/Catalogue
- Medication History
 - HL7 in patient standard named in Medicare Modernization Act; NCPDP SCRIPT for ambulatory exchange.

These are two standards. This overlap may be chosen to be ignored. What could be worked on is the ability to make the raw medication history information of use to stakeholders (physicians, consumers, pharmacies, etc)?



SCO Initial Priority Projects

- Common data set of medication information
 - (UK may have some input to this). There are more clinical situations coming into the pharmacy. NCPDP and HL7 are working on electronic prescribing functional models. There are national and international efforts; efforts within USA government agencies. The exchange of medication information is important for now.
- Allergy –
 - Allergy information in C32. These concepts have been put into NCPDP SCRIPT for electronic prescribing. This was a request to formalize the XML tags when sharing this information. It was suggested that the tags should be what is common from HITSP.



Questions?

