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What is done, what is needed and what is realistic to expect from medical informatics standards

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Abstract

Medical informatic experts have made considerable progress in the development of standards for orders and clinical results (CEN, HL7, ASTM), EKG tracings (CEN), diagnostic images (DICOM), claims processing (X12 and EDIFAC) and in vocabulary and codes (SNOMED, Read Codes, the MED, LOINC). Considerable work still remains to be carried out. Abstract models of health care information have to be created, to cover the necessary domain, and yet be simple enough to assimilate, implement, and manage. This requires a high degree of abstraction. Enormous amounts to develop standardized vocabulary are still required to complement such a model, and to define the subsets that apply to given contexts. © 1998 Elsevier Science Ireland Ltd. All rights reserved.

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1. What is 'done'

The word 'done' is used loosely. We are never really done with anything, especially as it relates to information systems. The clinical systems world is like a fractal, and when we look very closely at the layer that we understand, we see another layer of complexity just below the current one to digest and standardize.

I recall a document called 'Current Medical Terminology', published by the American Medical Association in the early 1980s. It bragged about having completely catalogued all of the terms in medicine. It contained a mere 5000 entries. Today's medical dictionaries such as Stedman's [1] contains 80 000 or more entries. The current releases of SNOMED [2] (systemized nomenclature of human and veterinary medicine) and Read Codes [3] contain many hundreds of thousands of concepts and are still growing.

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ICD10-PCS is a set of tables [4] being developed for health care financing administration (HCFA) by 3M Corporation, and contains more than a million procedural codes. Nathan Myhrvold's assertion that there will "always be a software crisis because ambition absorbs all advances" [5] applies equally to standards. As soon as we sniff success in one domain of standards, we find other targets of opportunity and extend our expectations. Yet, medical informatics and the industry at large has or is well on the way to solving many standardization problems.

1.1. Message standards

I think we have 'solved' the standardization problem of transmitting patient clinical information (reports) from one system to another. Laboratory results can be sent via Health Level Seven (HL7) ORU [6], American Society for Testing and Materials (ASTM) 1238 [7] and Comité Européen de Normalisation (CEN) ENV 1613 [8] messages, radiology and many kinds of clinical observations, and x-ray reports via HL7 and ENV 12539 [9] messages, diagnostic images themselves via Digital Imaging and Communications in Medicine (DICOM) [10] messages, and EKG tracings via a CEN standard [11] that I like to call the Jos Willems' standard due to him being the main force behind it. It is of interest to note that our last Burdick EKG cart came with the Jos Willems' standard installed. Most of the above standards have been in active use for many years. For example, in the US, the vendors of just about every type of clinical system from GI endoscopy, OB ultrasound, cardiac echo systems, laboratory systems, radiology information systems, pharmacy systems, to nurse triage systems, advertise support for HL7 standards although the fidelity to the standard varies.

Similarly, the distribution of ADT registration information has been mastered via HL7 and CEN ENV 12538 [12], the transmission of community pharmacy information messages via HL7 and National Council for Prescription Drug Programs (NCPDP) [13] messages, as well as the transmission of simple claims via Accredited Standards Committee (ASC) X12 [14] messages, to name a few. The health care industry understands these problems, has substantial experience with the standards, and can show hosts of successful implementations.

Orders messages have also been standardized, and many successful implementations exist. However, it is not certain as to whether we have mastered the communication of clinical orders to the same degree as clinical observations. In part, this may be due to orders being more complicated beasts than clinical observations. Orders mutate—in some institutions radiologists change as many as 30% of ordered procedures to different and more appropriate procedures. They explode—a request for routines becomes a request for urinalysis, complete blood count and electrolytes. They repeat—an order for 9 am glucose is repeated each day. They cascade—an abnormally low hemoglobin may trigger tests for iron if the median cell volume is low and other tests if it is high.

However, the real challenge of orders may arise from a more fundamental difference between orders and observations. Observation messages interact mostly with the receiving computer and can consider themselves successful if they load properly into the receiving clinical application. An order message interacts with the receiving system, but it must also interact with the people who fulfill the orders. This implies a much larger set of assumptions about behaviors and processes in the receiving system and may require the standardization of these processes. The fact that people are in the loop adds to the challenges. 'Wicked Problems, Righteous Solutions' [15] is an informative book about software development strategies. It is easy reading, well-referenced and provides many good insights. One of its axioms is that the computerization of any system that depends upon human behavior for its success is automatically a wicked (very difficult) problem. Due to the fact that we cannot be sure as to how the human will behave within the system, the development must include some trial and error cycles.

1.2. Terminology

Successful has also been achieved with the development of standard codes/vocabularies for base clinical concepts, mostly nouns and simple noun phrases that might be stored in the fields of the standard messages. The venerable ICD9 codes are the most familiar examples.

Every country has a solid code system for drugs. In the US, the national drug code (NDC) [16] is the ubiquitous drug code. It happens to be a very 'ugly' code requiring a new code for each new drug, manufacturer of the drug, dose, package size, and package printing. However, in the world of standards, ubiquity wins over beauty. The ubiquity of the NDC code most likely explains the extraordinary 90% penetration of message standards (NCPDP) in community pharmacies in the US. Furthermore, ugly codes, if granular enough, can be converted to pretty codes by simple table lookups. Indeed, three major companies (MediSpan, First Data, and Multum) now provide data bases in the US that convert NDC codes to pretty codes and provide additional information regarding each NDC code.

We have been involved with the development of codes for laboratory tests and clinical measurements via the Logical Observations Identifiers Names and Codes (LOINC) committee for the last four years. The LOINC committee is an ad hoc committee with representatives from academic medical informatics, commercial laboratories, and system vendors. More than 30 individuals have contributed to LOINC [17], including academicians such as Georges DeMoor, Diane Leland, John Baenziger, Tom Fiers, Stan Huff, Dean Bidgood, Bruce Bray, Alan Golichowski, Jim Case, Blaine Takesue, Doug Martin, Karl Hammermeister, Dennis Leavell, Jim Cimino, Angelo Rossi Mori, Ray Aller, Arden Forrey, Jeff Suico, and Anders Thurin. LOINC's goal is to do for the laboratory and other clinical measurement what the NDC did for pharmacy messaging, i.e. to provide a universal code for pooling observations from many sources for the purpose of clinical display and outcomes management.

The LOINC data base now contains over 13 000 laboratory and clinical observations, including entries for tests such as serum glucose, heliobacter pylori IgM antibodies and measurements such as diastolic blood pressure, ultrasound measured fetal head circumference, abdominal girth, and body weight. It is specifically designed to provide universal codes for HL7's OBX-3 field, and the corresponding fields in the related ASTM, CEN, and DICOM standards. The first version of LOINC (6000 terms) was distributed through the Duke HL7 web site in April of 1995. In September of 1997, the tenth version (vs J) was placed on the same server. A Visual Basic program—the Regenstrief LOINC mapping assistant (RELMA)—is also distributed. With RELMA, a user can quickly find the terms in LOINC that correspond to terms in their local test or observation dictionaries. The LOINC data base and RELMA mapping program are both available for perpetual free use at the Duke HL7