Harmonization of Patient Assessment Instruments in the USA: a Compelling Case for Realism-Based Ontology

Werner Ceusters[1]

[1] Ontology Research Group, Center of Excellence in Bioinformatics & Life Sciences
SUNY at Buffalo, 701 Ellicott Street, Buffalo NY 14203, USA
ceusters@buffalo.edu
http://www.or.buffalo.edu/RTU/

ABSTRACT. The Centers for Medicare & Medicaid Services (CMS) maintain datasets covering millions of patients based on assessment data collected in terms of a number of mandated assessment instruments. The datasets are currently aligned in a data warehouse, but they have not yet been semantically integrated, therefore making comparisons impossible. The resultant problems have been recognized by CMS and have led to the development of the Medicare Continuity Assessment Record and Evaluation (CARE) instrument, which however does not solve the problem of semantic integration either with the existing datasets or with other leading assessment tools. Potentially, therefore, CARE may lead to yet another isolated information silo being added to the existing set. Furthermore, the CARE system does not make the existing resources useful for future research and it does not contribute to a global care assessment tool suitable for enabling both national and international comparisons. We argue that a realism-based ontology, when developed in the right way, can overcome these problems.

1 Cost and quality of post-acute care

In 2005, the United States spent 16% (up from 14% in 2000) of its Gross Domestic Product (GDP) on health care: $2 trillion, a greater share than any other developed country for which data are collected by the Organization of Economic Co-operation and Development. This is roughly an average of $6,700 per person of which 84% for personal health care, a component of national health expenditures that includes spending for hospital care, physician services, prescription drugs, nursing home care, dental care, and other types of medical care [U.S. Department of Health and Human Services 2007]. Medicare and Medicaid expenditures account for more than 25% of total personal healthcare expenditures. The dominance of the Medicare and Medicaid programs as payers of health services is even more pronounced in long-term care (LTC): in 2003, these two programs paid for 65% of formal LTC services delivered in the U.S [O'Brien 2005].

Patients can seek long-time care after a hospitalization in four different post-acute settings: skilled nursing facilities (SNFs), home health agencies (HHAs), long-term care hospitals (LTCHs), and inpatient rehabilitation facilities (IRFs). Medicare has prospective payment systems in place for each, based on patient assessment data collected in terms of a number of mandated assessment instruments: the *Inpatient Rehabilitation Facility Patient Assessment Instrument* (IRF-PAI) in IRFs, the *Minimum Data Set* (MDS) in SNFs; the *Outcome and Assessment Information Set* (OASIS) for HHAs, and the *Swing Bed-Minimum Data Set* (SB-MDS) for acute care hospitals allowed to provide long-term post-acute care. The Centers for Medicare & Medicaid Services (CMS) maintain data sets which are collected using these instruments and which cover millions of patients. Although CMS intended to use the data to control Medicare spending for post-acute care, spending has increased by an aver-

age of 7 percent per year since 1999: for 2005, CMS estimated that total spending for post-acute care was about $42 billion, making up about 13% of Medicare's total spending [Medicare Payment Advisory Commission 2007].

Another intended use of the data sets is to monitor the quality of the care given in these facilities. But also this goal is not satisfactorily reached: an outcome analysis involving stroke patients at two internationally recognized rehabilitation hospitals – one in Switzerland and one in the United States – showed that patients in Switzerland had significantly higher levels of functioning at discharge when compared to their U.S. counterparts even though the patient mix, structure, and process of rehabilitation were in many respects similar [Stuart et al. 2005].

2 Incompatibility of measurement instruments

It has been suggested that at least one reason why these instruments fail to have sufficient impact on cost containment and quality control is the non-comparability of the data sets that result from them. This is because of differences in (1) individual items used to measure phenomena of interest, (2) measurement scales employed, and (3) look-back or assessment periods, as well as because of the unidimensionality of individual items [Tobin & Gage 2007]. Their mutual incompatibility, in combination with the absence of an assessment instrument for acute care, hampers also the construction of a longitudinal view of patients when they move from one level of care to the next.

Although the tools measure the same broad aspects of patient care including functional and cognitive status, diagnoses and co-morbidities, there is considerable variation in the timeframes covered, the scales used to differentiate patients, and the definitions of the care included in the measures.

The tools vary substantially in how frequently clinicians must administer them and what time period the assessment covers. For example, the MDS is conducted close to (but not necessarily at) admission and periodically throughout the patient's stay (but not at discharge) and generally measures the patient's condition over the past 7 days. The IRF-PAI is typically administered on day 3 of the admission and at discharge, and captures the patient's status on that day.

There are considerable differences amongst the instruments concerning the way the same sort of phenomena ought to be measured, and how the results are to be conveyed. For functional status, the MDS requires information whether and how frequently the patient needed weight bearing or verbal encouragement to walk. The OASIS records a patient's ability to walk safely, once in a standing position; and the IRF-PAI includes the distances walked. Measures assessing cognitive status differ the most, for instance whether short versus long-term memory is assessed, how depression and delirium are to be evaluated; and what types of decisions patients are able to make. The registration of diagnoses and co-morbidities is quite inconsistent: the MDS does not use ICD-9 codes and the OASIS, in contrast to the IRF-PAI, does not require the use of all 5 digits of the ICD-9 code, thus limiting the comparisons of the severity of patients treated in different settings. Finally, even for measures where the definitions are the same, the instruments use varying scales: the MDS uses a four-point scale and measures the number of times a patient needs assistance with dressing and the type of help involved (weight bearing or verbal encouragement), whereas the IRF-PAI uses a seven-point scale to distinguish what share of the dressing a patient performs.

3 A move towards harmony … or not?

A first attempt to make the data sets more useful for comparing different types of facilities as well as for constructing a longitudinal view of the post-acute care administered to individual patients, consisted of pooling the data in the *Chronic Condition Data Warehouse* (CCW) developed by the Iowa Foundation for Medical Care [Iowa Foundation for Medical Care 2007]. The datasets are in this data warehouse *aligned* by means of an internally unique but unidentifiable beneficiary key which allows researchers to analyze information across the continuum of care. However, the data are currently not *semantically integrated*, precisely because of the differences in the assessment instruments mentioned earlier.

The resultant problems have been recognized by CMS [Kramer & Holthaus 2006], and this led to the development of the Medicare *Continuity Assessment Record and Evaluation* (CARE) instrument [Federal Register 2007]. Although the CARE data collection tool is based on the latest web technology, it does not solve the problem of semantic integration with the existing datasets either. Indeed, as witnessed by the CARE assessment forms, no attempt seems to have been made to achieve comparability of CARE with any other existing instrument, one striking example – amongst many others – being the choice of a '*2-day assessment period to refer to the first 2 days of admission and the last 2 days prior-to-discharge for look-back periods*' [U.S. Department Of Health And Human Services 2007a] where OASIS, IRF-PAI and MDS 3.0 respectively use a 1, 3 and 5-day assessment period.

Neither contributes CARE to semantic interoperability with other leading assessment tools such as the NIH-funded *Patient-Reported Outcomes Measurement Information System* (PROMIS) [Ader 2007] or the CMS-funded *Core Outcome and Comprehensive Assessment – Basic* (COCOA-B) *Data Set* [U.S. Department Of Health And Human Services 2006]. Whereas the latter is intended to measure post-acute care independent of facility type in ways similar to the facility-specific instruments, i.e. by relying in observers other than the patient, the former adds another dimension by its focus on the collection of *self-reported* data from a diverse population of chronic disease patients. Measuring patient-reported outcomes is particularly important in research studies where changes in clinical measurements or imaging results may not translate into recognizable benefits to patients and in clinical trials, where two treatments may have similar effects in controlling or curing disease but different effects on symptoms, function, or other quality of life issues.

Potentially, therefore, the outcome of CARE may be that yet another isolated information silo is added to the scene. In addition, there are concerns that the use of CARE '*would impose a huge resource burden on hospital nurses and other clinical and support staffs*' [Pollack 2007] precisely because (among other reasons) of its lack of integration with the existing workflow, practice management and Electronic Health Record systems.

4 Can ontology come to aid?

We believe that the assessment systems and associated data sets mentioned thus far – although designed to conform to the state of the art in measurement science – are currently mutually incompatible because they have been built without the aid of any ontological analysis of the domain(s) that they describe. Our experience and theoretical work thus far supports the hypothesis that to serve integration an ontology in the health domain should be built around a core of representational units which describe phenomena as they exist on the side of the patient or in his or her environment

[Smith & Ceusters 2007]. This is in contrast to standard approaches which have been tried in the context of these assessment tools, and which rely on direct mappings between vocabularies [U.S. Department of Health and Human Services 2006a] or terminologies [U.S. Department of Health and Human Services 2006b]. We believe that an approach to ontology which is based on philosophical realism allows semantic integration to be achieved with respect to both historical and future data collected by the mentioned systems as well as with other systems covering the same domain(s).

To test this hypothesis, the following objectives should be reached:

1. building a patient-centric ontology covering the entities in reality that must exist as referents for those terms (included constituent parts of compound terms) that are shared by at least two of the assessment systems and related datasets. To be meaningful; the ontology should conform to all OBO Foundry principles [Smith at al. 2007] and published in standard (OWL and OBO) formats;
2. defining in the terms of this ontology the dictionaries and data-elements of the assessment systems, as well as relevant portions of the World Health Organization's (WHO) International Classification of Functioning, Disability and Health (ICF) and of SNOMED-CT. This would allow the use of a standard terminology and easier linkage to international systems.
3. validating the ontology through several independent methods, including the degree to which it serves linkage of the available datasets.

4.1 Realism-based ontology

Key in this development is the innovative approach on ontology combining insights from philosophy and information science [Smith & Ceusters 2003]. An ontology, in this reading, is any structured representation of the types of entities that exist in reality in a domain of interest and the relations that exist between them. Ontologies in this sense are increasingly becoming an important tool for information integration and sharing, and for automated reasoning on diverse sets of data, as is illustrated by the successes of the approach in a variety of areas from computational genomics [Gene Ontology Consortium 2006] to anatomy [Haendel et al. 2008]. They are not to be confused with prevailing approaches to 'ontology' which are based on 'concepts' and which are not more than terminologies expressed in some computer-readable format or knowledge representation language with a model-theoretic semantics, Description Logics and OWL being the best known examples. Members of the Ontology Research Group, SUNY at Buffalo, as well as researchers at the Institute of Formal Ontology and Medical Information Science (IFOMIS) in Saarbrücken, Germany, have examined numerous terminologies of this sort in the past, and, by applying the realism-based approach, discovered several systematic mistakes in them [Ceusters et al. 2004], the most prominent examples being the earlier versions of the Gene Ontology, SNOMED [Ceusters et al. 2004a] and the NCI Thesaurus [Ceusters et al. 2005]. They did not stop by demonstrating the fundamental flaws in the underlying concept theory [Smith et al. 2005], but developed an alternative and more principled approach for the various stages of ontology authoring including the basic theoretical framework known as Basic Formal Ontology (BFO) [Fielding et al. 2004], the choice of appropriate relationships [Smith et al. 2005a], quality assurance and versioning [Ceusters & Smith 2006], mapping to other systems [Ceusters 2006], and how to use them in Electronic Health Records [Smith & Ceusters 2005]. All this has led to the creation of the Open Biomedical Ontologies Foundry whose task it is to watch over the application of these principles in ontologies intended to be useful for translational

medicine [Smith at al. 2007], and thus certainly for making disparate patient assessment systems compatible and comparable.

4.2 Methodology

A first step in the development is to study and compare the terminology used in the various assessments instruments as well as the data dictionaries and data models of the associated data sets. The purpose here is to identify areas of overlap at a (primarily) linguistic and terminological level.

Next comes ontology development itself, what starts by building the ontologies representing the portions of reality that are described by the terms in each assessment system. This must be done by using the principles of BFO to identify the types to which the entities in reality described by these terms belong to and to express the relationships that obtain between them. Within BFO, the main subdivision among entities is based upon whether or not at any moment of time an entity is fully present or is instead only partially present. The former type of entity is a continuant, and the latter an occurrent. Continuants (but not occurrents) are distinguishable on the basis of whether or not they are independent or dependent entities. An independent entity is an object, such as a molecule or a cell; whereas a dependent entity is, for example, the shape of a molecule or cell. Crucial to the distinction is that the latter require the former in order to exist (in an ontological sense of 'require' that is different from what is involved for example when we say that organisms require food or oxygen). These distinctions yield 3 categories of entities: dependent and independent particulars on the one hand, and occurrents on the other.

It is not only important to identify the entities that are common to the portions of reality described by the various systems, but also to identify key entities that are only implicitly, or not at all, addressed in the source systems. A suitable method is to employ the expansion paradigm developed in [Rudnicki et al. 2007] and that is based upon the three categories just sketched: (a) if an entity is a dependent continuant, identify the independent continuant on which it depends, (b) if an entity is an occurrent, identify the continuants which participate in it, and (3) if an entity is an independent continuant, do nothing. Repeat this expansion method for (a) and (b) until only independent continuants remain.

The third step is writing bridging axioms that make formally explicit how data expressed in terms of a specific assessment instrument are to be interpreted in function of the ontology.

In order to make the ontology useful for browsing by humans, a reference terminology has to be created. Criteria for high quality reference terminologies have been proposed for over more than fifteen years. A recent proposal is [Rosenbloom et al. 2008]. Relating this reference terminology to the International Classification of Functioning, Disability and Health (ICF) and to SNOMED-CT will allow for easier use in an international context.

To further enhance reusability, the ontology must be published in standard formats, candidates being OWL and the Open Biomedical Ontology formats. With respect to the former, more particularly OWL-DL, it should not be forgotten that the limited expressivity of this language does not allow all axioms to be published, nor that expression in OWL by itself would be a guarantee for quality [Ceusters & Smith 2003]. Therefore, we argue, it is better to use standard ontology languages such as OWL and the OBO formats only for *publication*, but not for *development*. Also the reference terminology should be published in a suitable standard language, those proposed by the LexGrid project being acceptable possibilities [Mayo Clinic 2007].

The sixth step is validation through, ideally, several independent methods. One is case report annotation, another one statistical validation. The latter consists of carrying out statistical analyses on a subset of the linked data, using ontology categories

that are not present in all or any of the individual data sets, and compare the results with similar analyses carried out on the raw data sets.

Conclusion

Outcomes assessment is a process by which a standardized methodology is applied to quantify changes that have occurred when passing from a situation at time t to a situation at time t+1. Essential to this process is the determination (a) of what it is in which (or for which) a change needs to be measured, and (b) of what measurement instrument should be used. When the measurements have been performed and analyses carried out, the next question is: what actions, if any, should be taken? In the US, many patient assessment instruments are in use. However, it is not clear whether they have thus far contributed to better outcomes. There is, for instance, still a need for quality initiatives to ensure that patients are served in the most medically appropriate and efficient setting for high-quality post-acute care [Executive Office of the President of the United States 2007]. Implementing such initiatives is difficult if the instruments used to measure change are incomparable. Realism-based ontology, we argue, might be the missing link.

References

[Ader 2007] Ader, D. Developing the Patient-Reported Outcomes Measurement Information System (PROMIS). Medical Care 2007;45(5):S1-S2.

[Ceusters 2006] Ceusters W. Towards A Realism-Based Metric for Quality Assurance in Ontology Matching. In: Bennett B, Fellbaum C. (eds.) Formal Ontology in Information Systems, IOS Press, Amsterdam, 2006;:321-332. Proceedings of FOIS-2006, Baltimore, Maryland, November 9-11, 2006.

[Ceusters & Smith 2003] Ceusters W, Smith B. Ontology and Medical Terminology: why Descriptions Logics are not enough. Proceedings of the conference Towards an Electronic Patient Record (TEPR 2003), San Antonio, 10-14 May 2003 (electronic publication 5pp)

[Ceusters & Smith 2006] Ceusters W, Smith B. A Realism-Based Approach to the Evolution of Biomedical Ontologies. Proceedings of AMIA 2006, Washington DC, 2006;:121-125.

[Ceusters et al. 2004] Ceusters W, Smith B, Kumar A, Dhaen C. Mistakes in medical ontologies: where do they come from and how can they be detected? in Pisanelli DM (ed) Ontologies in Medicine. Proceedings of the Workshop on Medical Ontologies, Rome October 2003, IOS Press, Studies in Health Technology and Informatics, 2004;102: 145-63.

[Ceusters et al. 2004a] Ceusters W, Smith B, Kumar A, Dhaen C. Ontology-based error detection in SNOMED-CT. Proceedings of MEDINFO 2004;:482-6.

[Ceusters et al. 2005] Ceusters W, Smith B, Goldberg L. A Terminological and Ontological Analysis of the NCI Thesaurus. Methods of Information in Medicine 2005; 44: 498-507.

[Executive Office of the President of the United States 2007] Executive Office of the President of the United States, Office of Management and Budget. Health and Human Services. http://www.whitehouse.gov/omb/budget/fy2007/hhs.html. Last accessed: December 26, 2007.

[Federal Register 2007] Federal Register: July 27, 2007 (Volume 72, Number 144)

[Fielding et al. 2004] Fielding JM, Simon J, Ceusters W, Smith B. Ontological theory for ontology engineering. Proceedings of the Ninth International Conference on the Principles of Knowledge Representation and Reasoning (KR2004), Whistler, BC, 2004;:114-120.

[Gene Ontology Consortium 2006] Gene Ontology Consortium, The Gene Ontology (GO) project in 2006. Nucleic Acids Res., 2006. 34: p. D322–D326.

[Haendel et al. 2008] Melissa A. Haendel, Fabian Neuhaus, David Osumi-Sutherland, Paula M. Mabee, José L.V. Mejino Jr., Chris J. Mungall, and Barry Smith. CARO — The Common Anatomy Reference Ontology, in Anatomy Ontologies for Bioinformatics: Principles and Practice, A. Burger, D. Davidson, and R. Baldock, Editors. 2008 (In press), Springer: New York.

[Iowa Foundation for Medical Care 2007] Iowa Foundation for Medical Care. Chronic Condition Data Warehouse. http://65.117.255.59/about.php. Last accessed: Dec 18, 2007.

[Kramer & Holthaus 2006] Kramer A and Holthaus D (eds.), Uniform Patient Assessment for Post-Acute Care; Final Report. Jan 25, 2006. http://www.bu.edu/hdr/documents/QualityPACFullReport.pdf. Last accessed: Dec 18, 2007.

[Mayo Clinic 2007] Mayo Clinic – College of Medicine. The Lexical Grid. http://informatics.mayo.edu/LexGrid/index.php?page=. Last updated: Jan 26, 2007. Last accessed: Jan 10, 2008.

[Medicare Payment Advisory Commission 2007] Medicare Payment Advisory Commission. A Data Book: Healthcare Spending and the Medicare Program. June 2007. http://www.medpac.gov/documents/Jun07DataBook_Entire_report.pdf. Last accessed: Dec 21, 2007.

[O'Brien 2005] E. O'Brien. Long-Term Care: Understanding Medicaid's Role for the Elderly and Disabled. The Kaiser Commission on Medicaid and the Uninsured, 2005.

[Pollack 2007] Pollack R. Letter to CMS - RE: CMS – 10243 (OMB#: 0938 – NEW), Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 72, No. 144). Sept 25, 2007.

[Rosenbloom et al. 2008] S. Trent Rosenbloom, Randolph A. Miller, Kevin B. Johnson, Peter L. Elkin, and Steven H. Brown. A Model for Evaluating Interface Terminologies. J Am Med Inform Assoc 2008; 15: 65-76.

[Rudnicki et al. 2007] Rudnicki R, Ceusters W, Manzoor S, Smith B. What Particulars are Referred to in EHR Data? A Case Study in Integrating Referent Tracking into an Electronic Health Record Application. In Teich JM, Suermondt J, Hripcsak C. (eds.), American Medical Informatics Association 2007 Annual Symposium Proceedings, Biomedical and Health Informatics: From Foundations to Applications to Policy, Chicago IL, 2007;:630-634.

[Smith & Ceusters 2003] Smith, B. and W. Ceusters, Towards Industrial-Strength Philosophy; How Analytical Ontology Can Help Medical Informatics. Interdisciplinary Science Reviews, 2003. 28(2): p. 106-111.

[Smith & Ceusters 2005] Smith B, Ceusters W. An Ontology-Based Methodology for the Migration of Biomedical Terminologies to Electronic Health Records. AMIA 2005, October 22-26, Washington DC;:669-673.

[Smith & Ceusters 2007] Smith B, Ceusters W. Ontology as the Core Discipline of Biomedical Informatics: Legacies of the Past and Recommendations for the Future Direction of Research. In: Gordana Dodig

Crnkovic and Susan Stuart (eds.) Computing, Philosophy, And Cognitive Science - The Nexus and the Liminal, Cambridge: Cambridge Scholars Press, 2007;:104-122.

[Smith et al. 2005] Smith B., Ceusters W, Temmerman R. Wüsteria. In: Engelbrecht R. et al. (eds.) Medical Informatics Europe, IOS Press, Amsterdam, 2005;:647-652

[Smith et al. 2005a] Smith B, Ceusters W, Klagges B, Koehler J, Kumar A, Lomax J, Mungall C, Neuhaus F, Rector A, Rosse C. Relations in biomedical ontologies, Genome Biology 2005, 6:R46.

[Smith et al. 2007] Smith B, Ashburner M, Rosse C, Bard J, Bug W, Ceusters W, Goldberg LJ, Eilbeck K, Ireland A, Mungall CJ, the OBI Consortium, Leontis N, Rocca-Serra P, Ruttenberg A, Sansone SA, Shah N, Whetzel PL, Lewis S. The OBO Foundry: Coordinated Evolution of Ontologies to Support Biomedical Data Integration. Nature Biotechnology 2007;25:1251-1255.

[Stuart et al. 2005] Stuart M, Ryser C, Levitt A, Beer S, Kesselring J, Chard S, Weinrich M. Stroke Rehabilitation in Switzerland versus the United States: A Preliminary Comparison. Neurorehabil Neural Repair 2005;19:139-147.

[Tobin & Gage 2007] Tobin J and Gage B. Post-Acute Care: Patient Assessment Instrument and Payment Reform Demonstration. Presentation to National Academy for State Health Policy, October 16, 2007. http://www.slideshare.net/nashp/post-acute-care-patient-assessment-instrument-and-payment-reform-demonstration. Last accessed: December 20, 2007.

[U.S. Department Of Health And Human Services 2006] U.S. Department Of Health And Human Services - Centers For Medicare & Medicaid Services. Program of All-Inclusive Care for the Elderly (PACE). http://www.cms.hhs.gov/QualityInitiativesGenInfo/10_PACE.asp. Last modified: Feb 23, 2006. Last accessed: Dec 18, 2007.

[U.S. Department of Health and Human Services 2006a] U.S. Department of Health and Human Services - Assistant Secretary for Planning and Evaluation - Office of Disability, Aging and Long-Term Care Policy. A Study Of Stroke Post-Acute Care Costs And Outcomes: Final Report. December 2006.

[U.S. Department of Health and Human Services 2006b] U.S. Department of Health and Human Services - Assistant Secretary for Planning and Evaluation - Office of Disability, Aging and Long-Term Care Policy. Making the “Minimum Data Set” Compliant With Health Information Technology Standards. July 2006.

[U.S. Department of Health and Human Services 2007] U.S. Department of Health and Human Services - Centers for Disease Control and Prevention - National Center for Health Statistics. Health, United States, 2007.

[U.S. Department Of Health And Human Services 2007a] U.S. Department Of Health And Human Services - Centers For Medicare & Medicaid Services. CMS-10243: CARE Tool Master Document (Core and Supplemental Items). Post OMB-version, October 29, 2007.