
From Clinical Records to Regulatory Reporting: Formal Terminologies as Foundation

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Achieving goals of healthy people and populations is dependent on available and relevant data for health care decisions. New technologies enable reuse of data for decisions, however it is clear that uniform data standards and in particular standards around terminological data will be required to achieve reuse. Terminological data related to functioning and disability presents unique challenges because of the conceptual ambiguity within the field. The International Classification of Functioning, Disability, and Health (ICF) provides a clarifying conceptual foundation for functioning and disability data, but is not structured as a formal terminology. The need for a concerted and coordinated effort is emphasized.

INTRODUCTION

An historical disconnect exists between what health care providers record in clinical documentation systems and reporting requirements such as those put forward by public health, accrediting, and regulatory agencies. An often-repeated mantra among information engineers and endusers alike is “record once, reuse often.” Health care settings typically provide the counterexample to this philosophy, where recording the same patient data for many different reasons in many different places is the norm. In this article, we limit our discus-

sion of this situation to descriptions of patient functioning and disability although the principles and conclusions may apply to diagnostic and procedural domains equivalently. The emphasis is on interoperability, comparability, and data quality across disparate information systems and the need for an interface between clinical documentation systems and other reporting requirements.

The rapid development and deployment of information technologies enables data to be captured at the point of acquisition and then stored, indexed, and retrieved in electronic formats for use across multiple settings and software applications. This means that, if data about patients are carefully structured and encoded, those data can be electronically transferred, shared, exchanged, and meaningfully used to support a variety of uses such as automated alerts, decision support, quality assessments, individual patient or population surveillance, and outcomes analyses, or regulatory reporting. That is, the data are said to be interoperable across computer systems. While the benefits attributed to information technology are evident in many fields, considerable development efforts are required in health care and particularly in the area of patient medical record information (PMRI) in order to realize the potential of these newer technologies (National Committee on Vital and Health Statistics, 2002; Institute of Medicine, 1997).

In particular, uniform data standards related to terminology are critical if clinical data are to be transmitted among providers,

The authors are with the Mayo Clinic. The research for this article was supported in part by the National Institutes of Health under Award Number 1 R01 LM07453-01. The views expressed in this article are those of the authors and do not necessarily reflect the views of the Mayo Clinic or the Centers for Medicare & Medicaid Services (CMS).

payers, and regulatory agencies. Standards that concern computer hardware and networking protocols have long been in place in order to physically transfer data across networked computer-based systems. Uniform data standards are also needed that enable the machine processing of terminological data, exploiting new hardware, software, and network technologies. Longitudinal patient descriptions drawn from patient records could provide profoundly accurate and complete data about patients and be highly resistant to fraud or abuse. The trick is to achieve such utopian functioning without imposing greater cost or provider burden. The concepts and terms associated with functioning and disability are the focus of this article.

Summary groupings of patient characteristics and outcomes, aggregated into high-level classification categories, provide more manageable data for payers, policy developers, and regulatory and surveillance organizations. However, those who require aggregated data for oversight functions are presently neither equipped nor inclined to process large volumes of detailed data for each patient; similarly, providers and patients alike may be loath to disclose such intimate detail. Using reporting forms that are developed to reflect specific needs for data and information, the burden of providing and classifying data has historically fallen to providers with an expectation that an auditable trail supporting such data is available in clinical records or administrative databases. Such reporting has required human form-fillers to populate the required data fields. It is difficult for providers to sustain such administrative overhead.

The vision we proffer for the future is that relevant clinical data could be abstracted from clinical records to meet reporting requirements. Computer-based records, already demonstrably saving money and

improving patient care in many settings, could evolve to accommodate emergent standards in data structures and terminologies. Premised upon such comparable data, classification “groupers” analogous to those that assign diagnosis-related groups to collections of *International Classification of Diseases Ninth Revision, Clinical Modification* (Centers for Disease Control and Prevention, 2003) data could operate on more detailed patient record data to define reporting codes and values for regulatory oversight as well as more direct patient benefits such as decision support.

In this article, we first overview the broad conceptual domain of functioning and disability, and the methods typically used to record and classify these data. More pertinently, we review current approaches to the way we standardize expressions of concepts in the domain of functioning and disability: data sets, clinical assessment instruments, and classification systems. We then describe formal terminologies as a future approach to achieving comparable data in computer-based systems and compare the ICF (World Health Organization, 2001) with emerging standards for such terminologies. Finally, we consider the evolutionary steps that could be taken to realize this vision.

Imposing provider burden and additional costs is not an acceptable option. Nor is an infrastructure capable of supporting algorithmic reporting from patient records in place. However, remarkable progress in the electronic patient record standards community has been made over the past 5 years that can make practical many elements of this vision. Clearly, an evolutionary path which can be adopted by providers because it is sensible should guide our thinking. This transforms the question into what might be done to encourage the development of patient medical record information systems that are

structured and coded in ways that enable the derivation of reports from those systems, and what needs to be changed from the regulatory and policy side to enable this transition.

CLASSIFYING AND NAMING DOMAIN CONCEPTS

Over five decades have passed since the World Health Organization (WHO) (2001) defined health as not only the absence of infirmity and disease but also a state of physical, mental, and social well-being. Among the terms used to describe concepts within this broad domain are functional status, quality of life, health-related quality of life, functioning and well being, and health status. In this article, we use the term functioning and disability to refer to the conceptual domain areas described by the WHO (2001); functioning encompasses concepts within the broad domain of body functions, activities, and participation while disability encompasses concepts within the broad domain of impairments, activity limitations, or participation restrictions.

The consistent and comparable characterization of concepts associated with functioning and disability is essential to achieving the goals of healthy people and healthy populations. Although the literature indicates that an enormous amount of effort has focused on standard terms by which to express and communicate such concepts, most of that work has been completed absent a widely agreed upon conceptual framework that characterizes the domain content. Subsequently, the domain has long been described as containing a “bedlam vocabulary” and advancement in the field as a “forward merry-go-round of progress” (Verbrugge and Jette, 1994; Leidy, 1994). The lack of consistent and comparable data with which to describe transitions in health states is further rec-

ognized as a critical gap in Federal health policy development (Medicare Payment Advisory Commission, 2001).

Classifications reflect the conceptual structure of a domain and represent the way we organize our knowledge; they are important in developing computer-based systems because the rules with which we classify concepts underlie the ways we construct the algorithms that enable the storage and retrieval of data in computer-based systems. Terms are the linguistic or lexical labels we use to designate and communicate about concepts within domains and classes. Codes comprised of numerals, letters, or combinations thereof are commonly used to designate concepts within computer-based systems. When terms and their associated codes are organized into the conceptual structure of the domain, the result is a classification system that provides a foundation for many software developments.

The coordination of classifications with the encoding of concepts is essential to the development of software that enables systems to intelligently navigate across the domain. This is because the placement of concepts within a class, and classes within a classification system, suggests there are shared semantics or meanings among things that are grouped together. While people can readily understand this shared meaning, semantics must be made explicit to computer-based systems in order for computer programs to meaningfully exchange and manipulate data. Making the meaning of concepts and classes associated with functioning and disability explicit is especially difficult because of the conceptual ambiguity that has long existed within the field.

Scientists and clinicians alike have recognized that ambiguity in naming and classification results in ambiguous communication. This has resulted in three approaches

to classifying and naming the concepts within the domain of functioning and disability: data sets, clinical assessment instruments, and classification systems.

Data Sets

Data sets meet predefined needs for data and information. Typically, forms with specific questions and phrases that reflect the end-users need for data provide the structure by which persons record values that populate specific fields within the data set. In this approach to data entry, standardized terms, phrases, and sentences are presented in a highly structured format in order to encode concepts related to functioning and disability, thereby enabling consistent and comparable data. The recording of data is accomplished by people who complete the forms on paper and then enter the data into an electronic format, or by completing an electronic version of the form. Often the form provides a structure for organizing clinical data elements into categories that are later aggregated even further in order to meet the goals of various statistical classification and reporting requirements. The important point is that the person completing the form is presented with a controlled and limited set of terms and values and must understand the underlying purposes for which the data set was constructed in order to correctly complete the form. The amount and nature of information available for sharing and reuse for purposes such as automated alerts, decision support, quality monitoring, outcomes research, and policy development is constrained by the limited scope of the data set.

CMS provides oversight of three data sets that focus on concepts related to functioning and disability: (1) the minimum data set (MDS) (Morris et al., 1990), a component of the resident assessment instru-

ment for skilled nursing facilities, (2) the Outcome and Assessment Information Set for Home Health Care agencies (OASIS), and (3) the inpatient rehabilitation facility patient assessment instrument (IRF PAI) (Centers for Medicare and Medicaid Services) for rehabilitation units. Identified limitations are that across these data sets, different aspects of functioning and disability are assessed, different rating scales are used, and the time periods in which assessments are completed differs. Even when similar aspects of functioning and disability are assessed, the ways in which those data are recorded diminishes the comparability of the data. For example, the MDS long-term care data set requires that a value of 0-3 be entered into each of five data fields indicating over the course of 7 days the frequency with which a resident exhibits a variety of behaviors classified as behavioral symptoms. One item concerns each of the following: wandering, verbally abusive behavior symptoms, physically abusive behavioral symptoms, and resists care. Behavioral symptoms are further classified as mood and behavior patterns. The OASIS data set requires that a single item be checked indicating, over the course of 1 month, the frequency of behavioral symptoms (e.g., wandering episodes, self abuse, verbal disruption, physical aggression, etc.). These behavioral problems are further classified as neuro/emotional/behavioral status. The developers of both data sets were likely interested in the same clinical data. If specific and detailed clinical descriptions were recorded and indexed within the patient's medical record using standardized and uniform data standards, clinically relevant data could be retrieved and aggregated for reporting requirements using automated processes.

The present situation lacks information allowing an analysis of the variation in patients and patient outcomes across post-

acute care (PAC) settings, and subsequently insufficient information on which to base policy decisions (Medicare Payment Advisory Commission, 2001). The Benefits Improvement and Protection Act of 2000 requires that a report be made to Congress on the development of clinical assessment instruments that could be used to assess functioning and disability in all PAC settings. A discussion of clinical assessment instruments as a way to provide consistent terminology for concepts within the domain of functioning and disability is presented here.

This situation is not specific to PAC. The data sets on which most public health statistical reporting systems are based were similarly developed independent of each other, and are described as “a patchwork of data collection systems” (National Committee on Vital and Health Statistics, 2000). In response, the National Committee on Vital and Health Statistics (NCVHS) has led an initiative involving several Federal agencies and national groups to define a National Health Information Infrastructure and recommend a set of technologies, standards, applications, systems, values, and laws that support all facets of individual health, health care, and public health (National Committee on Vital and Health Statistics, 2002). Among the goals of the National Health Information Infrastructure is that reporting requirements could be derived from patient medical record information. The terminology data standards required to enable this goal are discussed later.

Clinical Assessment Instruments

Clinical assessment instruments are a specialized type of data set that are developed based on a measurement approach to standardizing the definition and expression of concepts associated with function-

ing and disability. This approach has foundations in both psychometric theory and econometric theory (McDowell and Newell, 1996). Psychometric theory provides a set of rules by which to provide standardized representations of concepts using numeric scaling of attributes which, when aggregated, provide reliable and valid representations of the concept and its factorial structure. Econometric theory similarly lends guidance to defining whether objects fall into the same or different categories with respect to given attributes, however the emphasis is on comparing perceived health benefits per unit of resource use. In contrast to the general data sets discussed, the methods with which clinical assessment instruments are developed emphasize the control of factors that may affect obtaining a true score. Estimates of the reliability and validity of instruments indicate, for example, whether the items within the instrument are consistent and correlated with the total score, or with other criterion based references.

Challenges related to the development and use of clinical assessment instruments to characterize functioning and disability are well described. One issue concerns the perspective of functioning represented in the assessment instrument: objective (i.e., directly measurable) or subjective (i.e., self-reports concerning perception and evaluation). Objective assessments assume that functioning is an observable characteristic and that professional estimates are more valid than the information provided by patients while subjective assessments allow for personal views, preferences, and expectations to be included. Another issue concerns the level of detail provided by a given instrument. Generic assessment instruments that emphasize general questions about functioning allow comparisons across groups, while disease specific assessment instruments provide more

detailed information about the impact of specific diseases or health conditions on functioning. One of the most challenging conceptual issues concerns whether functioning and disability can be characterized in a unidimensional format, or whether a profile of domain specific measures is required.

Noting the bewildering array of characterizations of health-related quality of life, Ferrans (Forthcoming) described three groupings of clinical assessment instruments that reflect the scope of concepts and terms used to provide standard expressions and therefore comparable data related to functioning and disability. The first category includes clinical assessment instruments that are concerned with the correction of problems, or problems for which improvements are desired (e.g., physical dysfunction, symptoms, mental health problems, work-related disability, and self-care). The Katz and Akpom (1976) activities of daily living index is an example of this type of instrument, emphasizing basic physical functions such as bathing, dressing, toileting, transferring, and eating. A second category of clinical assessment instruments focuses not only on the impact of disease on physical functioning, but also the impact of disease on other aspects of life (e.g., financial status, ability to work, etc.). The impact of disease on aspects of functioning beyond physical and mental functioning is emphasized, however the negative impacts of disease remain the focus of these efforts. The Older Americans Resources and Services (OARS) Multidimensional Functional Assessment Questionnaire is an example of this second category of functioning and disability instruments, including questions related to physician visits, days in hospital, and economic resources as well as more basic physical functions (George and Fillenbaum, 1985). Clinical assessment instruments that

focus on the impact of health and health-related states on positive aspects of life are the third category described, and the most comprehensive in that the concerns of the previous two categories are extended to positive aspects of life such as improvements in relationships associated with changes in health or illness. The SF-36 and its derivatives are examples (Ware, Kosinski, and Keller, 1994).

The important points are that there are great variations in the way experts classify concepts within the domain of functioning and disability, and that persons developing data sets do not go through the same development process as persons developing clinical assessment instruments. This has implications for software development as well as the intelligent navigation of concepts within electronic patient medical record information systems.

Two approaches to using the semantic model of the Clinical Logical Observation Identities, Names, and Codes (LOINC[®]), a standard for data exchange of observation identifiers have been described (White and Huan, 2002; Bakken et al., 2000). In the earlier publication, the LOINC[®] (Regenstreif Institute, 2003) schema was extended to assessment instruments by “dissecting” the instruments into components (name of the scale and item), property (scale type or impressions), timing, system (object of the measurement), scale (type of scaling used) and method (observed or reported). In the later publication, additional extensions were proposed that specified the conceptual and operational definitions of the assessment instruments and the variable definition. The goal of both initiatives was to support sharing and reuse of data associated with clinical assessment instruments while at the same time attending to considerations that affect the reliability and validity of the concept measured. Further investigations of these sorts of approaches, and their

utility for a range of data reporting formats, are essential to unambiguous expressions of functioning and disability concepts.

Classification Systems

Broadly defining functional status as the daily activities in which one engages as well as one's participation in life situations and society, the NCVHS subcommittee on populations recommended the use of a uniform code set and classification system for concepts within the domain of functional status. The argument put forward was that an internationally agreed upon classification and coding system was needed to support health care decisionmaking, and that the ICF was the only viable code set presently available (National Committee on Vital and Health Statistics, 2001).

First published in 1980 as the *International Classification of Impairments, Disabilities, and Handicaps* (ICIDH) (World Health Organization, 2001) the early emphasis of this classification system was on the notion of responses or consequences to disease. Soon after its publication, ICIDH was criticized for its perpetuation of medical-based notions of functioning, and for ignoring other factors that are important in understanding and describing the process of handicap, namely social and environmental factors. The next revision process of ICIDH sought to move from emphasizing consequences of disease to classifying components of health, and according to the current version of ICF, takes a neutral stand with regard to etiology. After 10 years of development effort involving input from over 800 international domain experts working through 10 collaborating centers worldwide, the WHO ratified the efforts in May 2001 as the ICF.

The specific aims of the developers of the ICF were to provide a scientific basis for understanding the distribution and

determinants of health and health-related states; establish a common language in order to improve communication among users of such data; permit comparisons on functioning, disability, and health across countries, providers, setting, and programs; and provide a coding scheme for health information systems (World Health Organization, 2001). Although to date the utility and merits of ICF's codes and classification remain largely untested, the NCVHS clearly recognized that the ICF might hold immediate value in efforts to standardize functional status expressions in PMRI systems.

The narrative overview of the ICF that is published in the introduction to the coding manual describes the ICF as conceptually organized around two broad classes of health and health-related states: the first is functioning and disability, and the second contextual factors. The content of the manual is then organized according to body functions (eight chapters), body structures (eight chapters), activities and participation (nine chapters), and environmental factors (five chapters) (Tables 1-3).

The published coding conventions of the ICF allow users of the system to select and combine codes from multiple classes in order to encode a profile of an individual. The coding system is alphanumeric and the codes carry meanings that help people interpret the placement of coded terms within the classification. For example, codes associated with the class of body function all begin with the letter "b," body structure codes begin with "s," activities and participation with "d," and environmental factors with "e." Three digit numbers are then attached to each letter, with the first numeral identifying subclasses under each of the "alpha" coded classes listed.

Extensions to codes are used to add qualifiers to specific terms. In this way, function and disability concepts can be

Table 1
ICF Domains Within the Components of Body Functions and Body Structures

Body Function	Body Structure
Mental functions	Structures of the nervous system
Sensory functions and pain	Eye, ear, and related structures
Voice and speech functions	Structures involved in voice and speech
Functions of the cardiovascular, hematologic, immunologic, and respiratory systems	Structures of the cardiovascular system, immunological, and respiratory system
Functions of the digestive, metabolic, and endocrine	Structures related to the digestive, metabolic, and endocrine system
Genitourinary and reproductive function	Structures related to the genitourinary and reproductive system
Neuromuscular and movement related functions	Structures related to movement
Functions of the skin and related structures	Skin and related structures

SOURCE: (World Health Organization, 2001.)

Table 2
ICF Domains Within the Component of Activities and Participation

Activity and Participation
Learning and applying knowledge
General tasks and demands
Communication
Mobility
Self care
Domestic life
Interpersonal interactions and relationships
Major life area
Community, social and civic life

SOURCE: (World Health Organization, 2001.)

expressed on a continuum. Seven qualifiers that indicate problems in body functions and/or structures can be attached to coded terms to indicate the extent of impairment (no impairment–complete impairment, not specified, or not applicable). Ten additional qualifiers can be added to body structure codes to indicate the nature of a change in structure (no change–qualitative changes, not specified, or not applicable). Seven qualifiers can be added to activity and performance codes to indicate performance and capacity problems (no difficulty–complete difficulty, not specified, or not applicable). For the environmental codes, two sets of seven qualifiers each indicate whether a given environmental factor is a barrier (no barrier–complete barrier, not specified, not applicable) or a facilitator (no facilitator–complete facilitator, not speci-

Table 3
ICF Domains Within the Component of Environmental Factors

Environmental Factor
Products and technology
Natural environment and human-made changes to environment
Support and relationships
Attitudes
Services, systems, and policies

SOURCE: (World Health Organization, 2001.)

fied, not applicable). As an example, the following profile might be applied to a person with a sprained ankle:

b770 Gait pattern functions
s75022 Structure of ankle and foot, unspecified
d450.2 MODERATE DIFFICULTY walking
e320+1 MILD FACILITATOR friends

Developers have identified several possible directions for the future development of the ICF including establishing an international data set and establishing links with measures of health-related quality of life (World Health Organization, 2001). While mapping across nomenclatures and classifications has intuitive appeal as a way to reconcile these different approaches to encoding concepts with a domain, such mappings have proven to be difficult to accomplish and maintain because of differences in data structures and the exponential explosion that occurs when each

nomenclature or classification against which one maps may contain hundreds and sometimes thousands of terms. Efforts to derive clinical assessment instruments with acceptable psychometric properties from data elements within existing data sets have also proven to be difficult, one of the motivations for the work previously described in relation to representing clinical assessments instruments using clinical LOINC®. A development we propose is the evolution of the ICF into a formal terminology system that will enable machine interpretation of the semantic properties that, at present, are only implicit in the ICF structure. This requires making explicit the concepts, attributes, and relationships among ICF concepts and classes. While this semantic information is understandable to people reading the manual and interpreting the existing coding scheme, it is implicit within the narrative text that accompanies the ICF. Computers require precise and explicit formal representations of semantic information in order to enable machine interpretation of data.

TERMINOLOGY AS FOUNDATION FOR COMPARABLE DATA

The ways in which we have historically handled textual data in computer-based systems are closely related to the development of the technologies that enable the processing of data; enumerated coding schemes represent the data processing limitations imposed by legacy technology. Rapid advances in data storage capacities, database designs, and internal and external networks have enabled new ways to record, store, index, and retrieve terminological data. We are now concerned with representing concepts and knowledge in ways that can be understood by machines while retaining fidelity to the underlying understanding that comes with human

effort related to concepts and knowledge classifications. Classifications such as the ICF strive to organize the content of an entire domain in a way that facilitates our understanding of the essential characteristics or attributes and the values associated with those attributes that define membership within specific classes. Assuming an adequate knowledge base, the nature of the “is_a” relationships within the classes of such systems are readily discernable by people who are using the classification system to index or retrieve data. Unfortunately, such relationships are not readily discernable by computers and must be made explicit.

Formal terminologies encode explicit information about concepts, the relationships between concepts, and the attributes and values of concepts within a domain. Foundational to this is a method for describing concepts by their related attributes, and the development of logical operations and their associated algorithms that enable machine understanding of a domain. The vision is that given a carefully designed PMRI system that incorporates formal terminologies, data recorded at the point of care can be made available for reuse in other applications by applying a variety of rule-based and statistical processes. A migration from enumerated classification schemes to the derivation of reports from clinical data is technically possible. However, this requires significant effort focused around the structure of data in order to enable machine understanding of concepts.

Characteristics of Formal Terminologies

Three seminal articles describe the necessary and sufficient characteristics of formal terminologies; these characteristics are summarized here (Chute, Cohn, and

Campbell, 1998; Cimino, 1998; Rector, 1999). More recently, the term ontology has been applied to terminologies that demonstrate all of these characteristics.

- *Concept Orientation*—The focus of formal terminologies is on the concepts within a particular domain, and the algorithmic identification of terms associated with those concepts. This requires that each concept must have a single meaning, that every term must correspond to one and only one concept, and that codes do not carry meaning; rather the meaning of a concept is made evident by specifying the attributes of the concept. As names and knowledge evolve, legacy names and codes must be retained. Additionally, formal terminologies must accommodate synonymy and lexical variants, and a thesaurus must be available for automated identification of terms associated with concepts. These factors highly influence the utility and appropriateness of terminologies in clinical applications.
- *Comprehensive and Complete*—The scalability of terminologies that accommodate multiple needs for data present several challenges. The developers of Systemized Nomenclature of Medicine Clinical Terms (SNOMED CT®) (2003), one of the largest health care terminologies, report that the most recent release includes 330,000 concepts associated with 850,000 terms and 50,000 semantic relationships. It is also possible that several well-coordinated, smaller terminologies may be required in order to provide comprehensive and complete coverage of different health care domains. Decisions about the comprehensiveness and completeness can only be made in relation to the intended use and scope of the terminology.
- *Atomic and Compositional*—Primitive or atomic levels of data are required at a

level of granularity that preserves their meaning when combined with others, while not so loaded with meaning that combinations of concepts are constrained. The idea is that concepts are represented at a level that enables their assembly and disassembly for different uses. In the previous ICF example, walking can be considered an atomic level data element, while moderate difficulty is a modifier of that concept. At the most basic level, by applying the operator and a compositional statement could be constructed indicating moderate difficulty walking.

- *Explicit Formalism*—A formal logic or inference engine to accomplish concept compositions is equivalent to the notion of an assembly language that enables the compositionality of primitive concepts into more complex concepts independent of application specific needs for information. A type of first order logic, description logics, appears to be particularly well-suited for this purpose, although various other formalisms remain under investigation.
- *Multiple Classifications*—Transforming data into information requires that multiple views of relationships among concepts are supported within the terminology so that all reasonable hierarchical paths can be navigated for retrieval purposes. This requires the expression of parent-child relationships, multiple inheritances, and the navigation of semantic neighborhoods and networks. Single hierarchies are more manageable for people who want to know how to classify and retrieve things, however multiple hierarchies are required for machine navigation and entry into semantic networks from various points.
- *Representation of Context*—Terminologies must be coordinated with structural models of the electronic record in order

to avoid context-sensitive ambiguity. Although a standardized patient record format has not yet emerged, increasing collaboration on this issue is evident. Additionally, codes should not be tied to the position of the concepts within a specific hierarchy because, in so doing, the code carries meaning that is not interpretable by machines.

- *Aggregation Logics*—Rules by which to intelligently support accurate and reproducible groupings of data must be developed and function as an intermediary between terminologies and classifications. The need is for a continuum of aggregation from small clusters of like conditions or events, to purpose-specific aggregations for reporting requirements such as the CMS PAC data sets and other statistical reporting systems. In contrast to the formalisms that enable meaningful compositions of atomic level concepts, these formalisms would essentially provide a bridge between the formal terminology and classification systems.

Comparison of ICF to Terminology Criteria

The development of a formal terminology around functioning and disability is particularly challenging because of the conceptual ambiguities that have characterized the domain. Although classifications such as the ICF were not developed in consideration of requirements for formal terminologies, they are rich sources of the relevant terms, concepts, and relationships required for formal terminologies and, thus, provide an important starting point for formal terminology development. Since the ICF represents a consensus on a conceptual structure of the domain and also defines terms within the domain, it is reasonable to consider the ICF as a starting

point for a formal terminology focused on functioning and disability. This does not preclude the inclusion of terms and concepts suggested within data sets and clinical assessment instruments, nor the often detailed descriptions of functioning and disability that may occur in clinical records as free text or as locally developed coding schemes. The important point is that if data are to be reused and shared across multiple systems and applications (i.e., interoperable) terminological data must be structured according to standards for formal terminologies. Following, we compare the ICF as it presently exists with the characteristics of formal terminologies described earlier.

- *Concept Orientation*—The specific intent of the developers of the ICF was to designate terms associated with defined concepts, and to provide conceptual definitions of those terms. It will be necessary to make explicit the definitional attributes of these concepts in order for the ICF to evolve to a formal terminology. As mentioned earlier, the coding system of the ICF contains semantics, that is, the code “b” communicates an understanding the coded term is about a concept within the body structure class. The meaning of the letter “b” as body structure is not evident to a computer-based system. Concepts must be made explicit in relation to attributes of the concept, not the code associated with the concept. It is also not clear how revisions to the coding of concepts will be managed by ICF. Many lessons can be learned from coding changes in similar classification systems (e.g., ICD changes from version 9 to 10).
- *Comprehensive and Complete*—The ICF data table includes 1,495 coded data elements. Because of the recent publication of this coding system, field studies to determine the completeness of the content

coverage provided by the ICF are just beginning. It is likely that more terms and concepts will be required as the use of ICF expands.

- *Atomic and Compositional*—The ICF seeks to be a high-level classification and methods are described that enable users to combine terms across component classes in order to form a profile of an individual. However, there are no constraints that protect against potential nonsensical combinations of terms. Human effort and judgment is required to determine which classes and which terms across classes make sense to combine.
- *Explicit Formalism*—There are no published explicit formalisms associated with the ICF at this time. This is an important area for development.
- *Multiple Classifications*—The ICF contains a single—not a multiple—inheritance structure. A multiple classification will be required as work proceeds to make explicit the attributes of concepts within the ICF because any single attribute may be shared by multiple concepts. Since attributes are also concepts, computer algorithms must be constructed to traverse from any single concept functioning as an attribute to all concepts whose definition shares that attribute.
- *Representation of Context*—The ICF coding scheme retains semantics that facilitate human effort to understand the placement of ICF codes within the classification structure, but that are not machine interpretable.
- *Aggregation Logics*—As with explicit formalisms, there are no aggregation logics associated with the ICF at this time.

For the ICF to function as a formal terminology, thereby serving as a foundation for the reuse of clinical data in meeting aggregated reporting requirements concerning functioning and disability, will require that efforts be directed toward

structuring the ICF as a formal terminology. This is the way the implicit semantics of the ICF can be made explicit for computer processing. The challenges associated with evolving from a classification system such as the ICF to a formal terminology are non-trivial, and can contribute to a sense of “analog beings trapped in a digital world” (Rector, 1999).

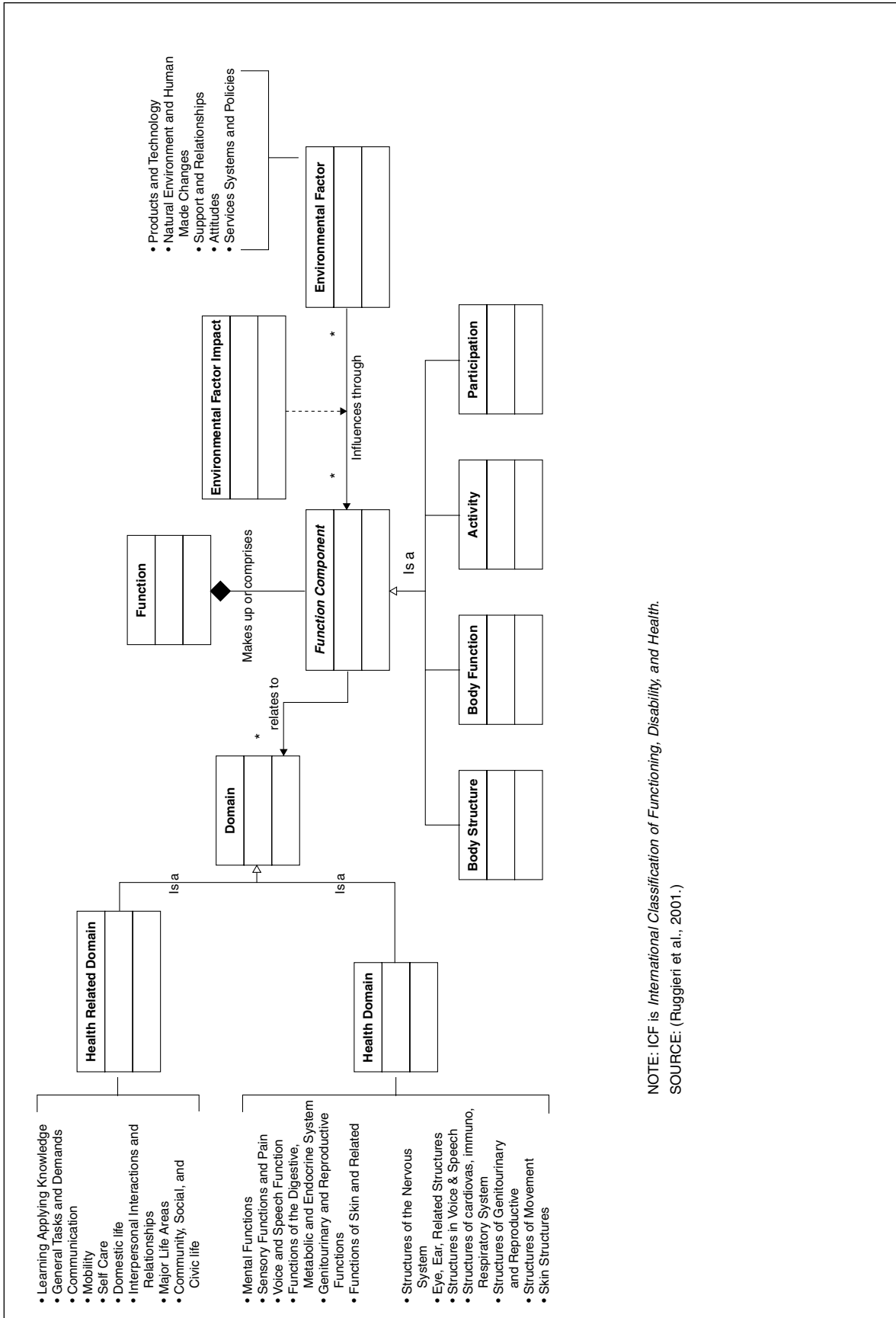
As a first step in this development, members of our group have been working to make explicit the semantic classes and relationships within the ICF (Ruggieri et al., 2001). Figure 1 illustrates initial work to explicate the ICF ontology, with the hope of formalizing the conceptual underpinnings of ICF. The figure was constructed using a Unified Modeling Language visual modeling application that imposes syntactic rules for the purpose of enforcing logical consistency in the modeling effort (Jacobson, Booch, and Rumbaugh, 1999).

Terminologies provide the content of messages within computer-based systems; further specifications are required to package and send messages that include that content. One of the major standards development organizations working to develop message formats for information exchange is Health Level 7 (HL7[®]) (www.hl7.org).

In contrast to terminologies that provide for the consistent interpretation of the meaning of data, HL7[®] messaging formats provide the syntax for formatting messaging. Both are required for interoperability of health data, and both require explicit models as a foundation for software engineering.

Information models express how information can or should be conveyed or messaged within a domain. We do not attempt to provide an extensive discussion of information models; our focus here is on formal terminologies. However, it is worth noting that ICF suggests not only an ontology or semantic model, but also an information

Figure 1
ICF Ontology, Derived from Conceptual Decomposition of the ICF Introduction, Expressed in Unified Modeling Language



NOTE: ICF is *International Classification of Functioning, Disability, and Health*.
 SOURCE: (Ruggieri et al., 2001.)

model. ICF specifies (although again implicitly) not only the conceptual classes in its ontology, but also the information classes and information structure or syntax by which meaning can be conveyed. Figure 2 illustrates the nature of the information exchange within ICF, again using a Unified Modeling Language based visual modeling application.

EVOLUTIONARY STEPS FORWARD

To achieve the vision we outline of formal terminologies as a foundation for the reuse of clinical data, many steps need to be taken. These need not be in parallel, though synchronization would facilitate adoption. For example, as regulatory reporting requirements evolve, health information standards should accommodate what is required. Similarly, regulatory reporting policymakers should examine what required information could reasonably appear in patient records; reporting requirements as well as computer-based clinical record developments might thereby be helpfully informed. Finally, a body of research remains to integrate these many facets of functioning and disability. A focused national agenda on infrastructure and standards development that can achieve practical data integration would be invaluable.

Data Standards

Uniform data standards are essential to achieving the goal of interoperable data across PMRI systems and other applications and uses of clinical data. In particular, formal terminologies are required for sharing information across disparate systems and the linkages and comparisons of data in secure environments. Congress demonstrated a commitment to this with the passage of the Health Insurance Portability

and Accountability Act of 1996, and the NCVHS is actively promoting data standards in conjunction with the broader goal of a national health information infrastructure. Of particular note, the NCVHS has established criteria for recommending to the Secretary of the Department of Health and Human Services standards that related to PMRIs. HL7[®] messaging standards are recognized as a core PMRI standard, and terminology standards are expected to follow soon.

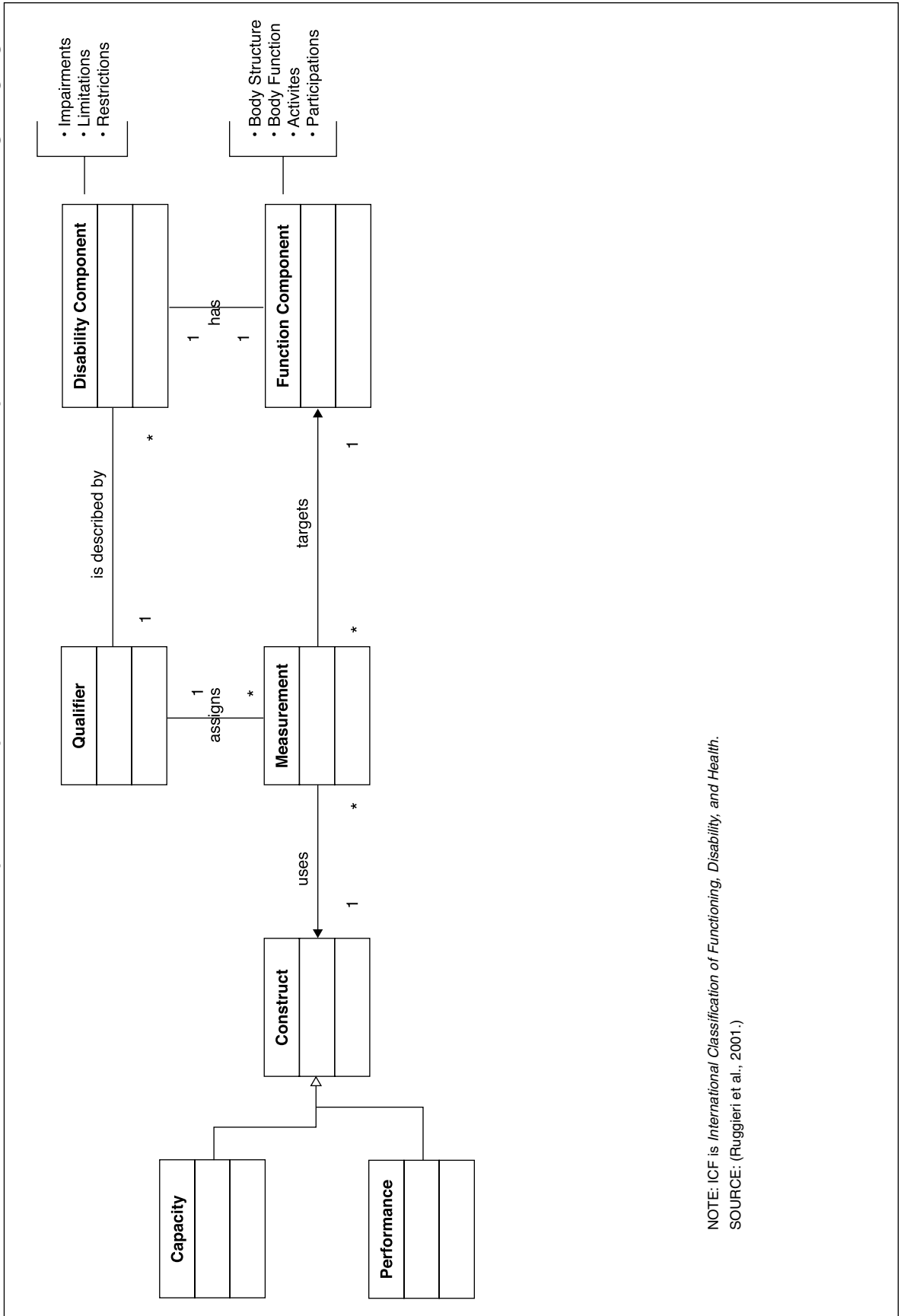
Reporting Requirements

Impartial observers consider that presently most regulatory reporting requirements do not fully consider what information is available. Indeed, some may argue that the questions reasonable persons might seek to ask about quality of care and patient outcomes are difficult to address from presently collected information. A detailed enumeration of data elements and values that should be changed is beyond the scope of this article and indeed beyond the wisdom of the authors. However, general principles might be considered.

An ultimate measure of patient quality of care is patient outcomes. While mortality is an unambiguous measure, finer gradation is hopefully sought. Measures of functioning and disability provide a framework for such finer measures, and could be adopted in reporting data sets. Fair measures of outcome could include repeated measurements of functioning, seeking trends of improving or worsening status. While adjustment for age, morbidity, and prognosis must be accommodated, the longitudinal profile of functioning would directly address many of the goals health services researchers and regulators ultimately seek to understand.

These expressions of functioning could

Figure 2
ICF Information Model, Derived from Conceptual Decomposition of the ICF Introduction, Expressed in Unified Modeling Language



NOTE: ICF is *International Classification of Functioning, Disability, and Health*.
 SOURCE: (Ruggieri et al., 2001.)

be derived from underlying patient record descriptions that are based on formal terminology, and then algorithmically aggregated into the higher-level categories required by various reporting systems. The principles for such aggregation comprise a body of work to itself, but modern terminology structures and information models for patient records can support the logical structures that enable accompanying aggregation logics (rules databases) to operate.

Clearly, data relevant to functioning and disability must be meaningfully characterized in PMRI systems for these sorts of aggregations to occur. Broadly speaking, one must concede that functioning and disability are presently incompletely represented in most clinical records. It is likely that forced fields will be required in patient records. The required focus is on how we can better balance characterizations of functioning and disability in patient medical records, with derivable data for quality and regulatory reporting.

Patient Record Structure

Electronic patient records today are highly idiosyncratic, vendor-specific realizations of patient record subsets. They adopt few, if any, health information standards, and very rarely accommodate controlled terminologies where they might be sensible. The reason for this epidemic of incompatible data has more to do with the limitations of available information standards and machineable vocabularies than with any fundamental unwillingness to adopt standards. A compelling business case, for system vendors or patient providers, simply has not emerged to foster standards adoption and systems integration.

However, the emergence in the past few years of highly sophisticated and useful data standards is beginning to change this

reality. The draft Version 3 information models and data types from HL7[®] promise a practical basis on which viable systems capable of interchanging comparable data could be built. Similarly, the terminology community has proffered the description-logic based SNOMED CT[®] as a paradigm for engineering and implementing controlled terminologies where they make sense.

Continued efforts to express the ICF as a formal terminology that either stands alone or is incorporated within larger formal terminology initiatives are essential because of the critically important conceptual work that underlies the ICF. Without assuring that the conceptual clarity the ICF lends to the domain is made explicit through a formal terminology, it is unlikely that the reuse of functioning and disability data in patient medical record systems will be successful.

Exploration of generalizable aggregation logics for converting terminology elements in well-defined HL7[®] contexts are being explored. A demonstration of the algorithmic creation of required aggregations of functioning and disability from patient record prototypes, for example a prototype demonstrating the retrieval of data for the MDS from a patient record, is an important next step.

The co-evolution of more modern and algorithmic reporting requirements could further create a plausible business case for system vendors and patient providers to embrace standards-based information systems. The tangible side benefit of facilitating internal quality improvement processes and scalable decision support services would synergize with regulatory reporting evolution. The desirable goal of having vendors and providers alike choose to migrate to well-formed patient records and terminology foundations is conceivably cost effective and value added.

Enabling Research Agenda

Sufficient progress has been achieved in our understanding of functioning characteristics, achievable reporting goals, information systems standards, and classification logics to permit the formation and defense of the vision we have proposed. However, many gaps exist in our underlying patient record model, standards specifications, terminology logics, and perceived regulatory objectives. Each of these gaps defines a body of crosscutting research to close them. Harmonization of this research, to ensure the comparability and interoperability of the patient data elements, would afford obvious efficiencies.

While the research agenda to achieve this vision is formidable, we should not ignore how far we have come in recent years to make this vision possible. The remaining gap is vastly smaller than our progress. Pursuing these final elements in a concerted way would offer health care profound efficiencies in reporting about quality and resources. More importantly, the dividend of enabling improved health care that is truly information-enabled would become practical.

In conclusion, efficient and effective health care is critically dependent on the availability of relevant data and information. The goal of comparable data related to functioning and disability has fueled the development of data sets, clinical assessment instruments, and coding systems. Unfortunately, those initiatives have developed in isolation from each other and are largely detached from the development of patient medical record information systems and associated initiatives concerning uniform data standards.

The requirements for computer-based systems that would enable the reuse of clinical data to meet reporting require-

ments include a structured terminology that provides information about attributes of the concepts that encode domain knowledge, an information model that emphasizes the structure by which different types of information are related to each other in electronic messages within or across applications and information systems, and explicit logics on which definitional and aggregation inference rules are based in order to build computer software that implement the reuse of data. The emphasis in this article is on the ICF as a base from which a formal terminology of functioning and disability could be developed. If such an effort is integrated with other formal terminology initiatives, the needs of various reporting requirements could be intelligently derived from the clinical record. The technologies required to achieve this vision are available, however achieving the vision awaits a concerted and coordinated national effort.

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