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American Dental Association
Standard No. 1039

Standard Clinical Conceptual Data Model

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 1039 FOR STANDARD CLINICAL CONCEPTUAL DATA MODEL

The Council on Dental Practice of the American Dental Association has approved American Dental Association Specification No. 1039 for Standard Clinical Conceptual Data Model. Working Groups of the ADA Standards Committee on Dental Informatics (SCDI) formulate this and other specifications and technical reports for the application of information technology and other electronic technologies to dentistry's clinical and administrative operations. The ADA SCDI has representation from appropriate interests in the United States in the standardization of information technology and other electronic technologies used in dental practice. The specification was forwarded to the American National Standards Institute with a recommendation that the specification be approved as an American National Standard. Approval of ADA Specification No. 1039 as an American National Standard was granted by the American National Standards Institute on April 25, 2006.

The ADA SCDI thanks Mark Diehl, Mark Diehl Consulting, Frederick, MD, as chairman of Working Group 11.1, Standard Clinical Architecture for the Structure and Content of an Electronic Health Record, for leading the development effort.

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FOREWORD

(This foreword does not form a part of the ANSI/ADA Specification No. 1039 for Standard Clinical Conceptual Data Model).

In 1992, there was interest in the standardization of clinical information systems related to electronic technology in the dental environment. After evaluating current informatics activities, a Task Group of the ANSI Accredited Standards Committee MD156 (ASC MD156) was created by the ADA to initiate the development of technical reports, guidelines, and standards on electronic technologies used in dental practice. In 1999, the ADA established the ADA Standards Committee on Dental Informatics (SCDI). The ADA SCDI is currently the group that reviews and approves proposed American National Standards (ANSI approved) and technical reports developed by the standards committee's working groups. The ADA became an ANSI accredited standards organization in 2000.

The scope of the ADA SCDI is:

"To promote patient care and oral health through the application of information technology to dentistry's clinical and administrative operations; to develop standards, specifications, technical reports, and guidelines for: components of a computerized dental clinical workstation; electronic technologies used in dental practice; and interoperability standards for different software and hardware products which provide a seamless information exchange throughout all facets of healthcare."

This specification was prepared by SCDI Subcommittee 11 on Electronic Dental Records (Mark Diehl, chairman).

Addendum to the Foreword for this Reaffirmation:

In 2012, the ADA Standards Committee on Dental Products approved a change in the terminology used for standards. ADA standards will no longer utilize the term Specification; standards will now be named as ADA Standards.

With this notice, this ADA Specification is now termed an ADA Standard. Where the term "specification" is used, it should be considered as "standard." It will be re-named as an ADA Standard in its next revision.

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1 Introduction (Informative)

This section presents a background to this normative conceptual model, its scope and purpose, the contents of this standard, and its anticipated use and conformance criteria.

1.1 Background

Access to quality and economical healthcare remains a high priority among Americans. For decades, the healthcare industry held a belief that appropriate use of information technology would provide the key to solving problems of healthcare cost, quality and access. This belief has been championed by the federal government, leading to a number of public and private sector initiatives.

In 2004 President Bush stated: “There . . . needs to be innovation in the health care field, as well as the rest of our society. One of the interesting things about health care, it's kind of like a cottage industry that has yet to adapt to the new technologies of the 21st century. And, therefore, there are missed opportunities when it comes to helping control costs and to provide quality care.”¹ From a healthcare industry perspective, Gartner reported IT spending in the healthcare industry is currently outpacing inflation by a factor of 2:1, and while increasing about 7% annually it still lags significantly behind that of other industries.² Gartner finds current healthcare IT spending is 2.5% of operations cost while the national industrial average is 3.9%, and to achieve parity with the national industry average, healthcare would have to increase spending by over 55%. The president further notes, “The proper role of the federal government, in my judgment on this, is to help set a national standard so that the myriad of producers have something around which to make proper decision-making when it comes to the use of IT technology.”³

Many in the healthcare industry believe that the key to improving quality, economy, and access in healthcare is found within the clinician's workflow patterns especially at the point of clinical decision making. At the core of clinical decision making is the data obtained from a patient and from biologic, chemical, or physical process. The clinician integrates, interprets, and acts on this data based on the common body of professional knowledge and the clinician's experience with many similar patients or processes.⁴ The resulting clinical information has broad use, from being employed to care for the patient to being processed and returned into the common body of professional knowledge.⁵

In 1919, the American College of Surgeons specified the nature of the information comprising the patient's medical record as:

- Patient identification data,
- The chief complaint,
- Personal and family history,
- History of the present illness,

¹ Whitehouse.gov: “Bush Outlines Path for Lasting Prosperity” Remarks by the President at the Newspaper Association of America Annual Convention, March 21, 2004.

² Gartner Dataquest, August 2003.

³ Whitehouse.gov: “Bush Outlines Path for Lasting Prosperity” Remarks by the President at the Newspaper Association of America Annual Convention, March 21, 2004.

⁴ Van Bommel, J., and M. A. Musen (Eds.). Handbook of Medical Informatics. 1st edition. Springer. 1997.

⁵ Mervat, A., Grostick, S., Hanken, M. A., and E. Jacobs (Eds.) Health Information: Management of a Strategic Resource. Saunders. 2001.

- Results of the physical examination,
- Results of consultations, radiologic examination and clinical laboratory,
- A provisional or working diagnosis,
- Medical and surgical treatments provided,
- Progress notes,
- Histopathology – gross and microscopic findings,
- The final diagnosis,
- Patient condition on completion of care,
- Follow-up notes, and
- Autopsy findings in the event of death.⁶

For most of the Twentieth Century, patient health and other clinical data was typically recorded and maintained as a paper record. In the last two decades, this media failed to keep pace with operational, regulatory and technologic advances. The advantages of automation over physical media in integrating and presenting patient health information and the common body of professional knowledge for clinical care are further presented as a rationale for applying information technology to clinical care.⁷

Automating clinical information has become a focal issue on the national agenda. A decade ago, Congress reviewed information technology and healthcare issues and considered government options to promoting improved care through technology.⁸ Automating the information contained in patient health records remains an essential piece of government policy. In the 2004 State of the Union Address, President Bush noted: "By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care." The President also has stated a vision that: "Within the next 10 years, electronic health records will ensure that complete health care information is available for most Americans at the time and place of care, no matter where it originates."⁹

At the 2004 NHII Secretarial Summit¹⁰, Department of Health and Human Services Secretary Thompson noted: "Health information technology can improve quality of care and reduce medical errors, even as it lowers administrative costs." He estimated that information technology has the potential to save 10 percent of the annual spending on health care while improving patient care. Thompson also said that the privacy and security of electronic medical records could be improved compared to those of paper-based records while offering substantially greater access to and control of health records by consumers.

At that Secretarial Summit, Dr. David Brailer presented a report describing a strategy for a National Health Information Infrastructure (NHII) with an electronic health record (EHR) at its core.¹¹ This report identified four goals for the NHII:

⁶ Minimum Standards, 1919, Bulletin of the American College of Surgeons. 8/4. 1924.

⁷ Shortliffe, E. H. and M. S. Blois. The computer meets Medicine and Biology: The Emergence of a Discipline, in Shortliffe, E. , Perreault, L. E., Fagan, L. M. and G. Wiederhold (Eds.). Medical Informatics: Computer Applications in Health Care and Biomedicine. Springer. 2000

⁸ U.S. Congress, Office of Technology Assessment, *Bringing Health Care Online: The Role of Information Technologies*, OTA-ITC-624 (Washington, DC: U.S. Government Printing Office, September 1995).

⁹ Whitehouse.gov: "Transforming Health Care: The President's Health Information Technology Plan." March 29, 2004.

¹⁰ Secretarial Summit on Health Information Technology in the NHII 2004: Cornerstones for Electronic Healthcare.

¹¹ Brailer, David. The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care. Available online via the DHHS website at www.hhs.gov .

- *To inform clinical practice* by bringing health information directly into clinical practice through electronic health records.
- *To interconnect clinicians* by making health information portable among users and along with the movement with consumers from one point of care to another.
- *To personalize care* by providing access to “consumer-centric” information that would enable individuals to manage their own health and assist with their personal healthcare decisions.
- *To improve the health of the population* by facilitating the “collection of timely, accurate, and detailed clinical information to allow for the evaluation of healthcare delivery and the reporting of critical findings to public health officials, clinical trials and other research, and feedback to clinicians.”

The expected result from implementing the NHI includes improving patient safety through the reduction of medical errors and duplicative services, reducing clinician time performing administrative tasks away from care delivery, and enabling clinicians to increasingly concentrate on improving patient care services and care outcomes. These improvements can only be achieved through effective information management and technology to assist clinician access to critical healthcare information when making clinical decisions.

The American Dental Association maintains a vision comparable to that of the NHI, where a continuum of patient health data, unencumbered by boundaries dictated by profession, specialty or discipline contributes toward improved quality of health outcomes, patient safety, and economy of care delivery.¹² As part of this vision, the Association considers the electronic health record to be a collection of patient data in automated form, rather than an automated version of the conventional physical paper document. This standard conceptual model document considers the electronic health record as equivalent to the computer-based patient record, being a repository of electronically maintained information about an individual's lifetime health status and health care from conception through postmortem.

1.1.1 Information is Essential to Health Care Decision Making

The essential role of information in the health care decision making process has been widely documented over the past several decades. In its 1919 Minimum Standards, the American College of Surgeons established that the information in the patient's health record be complete, accurate, and accessible.¹³ As noted in the 1996 concept model document¹⁴, the clinician or patient decision maker needs information to make decisions that to achieve the best health care outcomes this information must be:

- Complete and accurate, and relevant to the case at hand,
- Available at the time and place of the decision, and
- Presented in a form best employed by the individual decision maker.

These are fundamentally the same criteria cited by the American College of Surgeons in 1919. Automation contributes substantially to patient safety through access to clinical information through:

- Providing access to that information at the time and place needed by those making decisions affecting the

¹² The American Dental Association's vision of seamless accessibility of health information throughout all facets of health care, independent of profession, discipline or specialty, or care delivery environment, is stated in the ADA's Policy, “Seamless Electronic Patient Record (1996:694)”.

¹³ Minimum Standards, 1919, Bulletin of the American College of Surgeons. 8/4. 1924.

¹⁴ ADA Council on Dental Practice. COHR Concept Model, Benchmark Version 1.0. American Dental Association Feb. 1996.

patient's care.

- Delivering that information in a form best employed enables the human decision-maker to efficiently apply that information to clinical decisions.

Access to complete and accurate information prevents *errors of omission* where information essential to the clinical decision is absent.

This information only reaches its peak value if it is available when and where needed and in an optimally useable form – this information must be readily understood and be *actionable* by the decision maker. The presentation of this information must also be tailored to fit the decision maker's often unique workflow pattern. The absolute availability of complete and accurate information, while often unattainable, remains the gold standard to which care delivery and supporting information systems aspire.

By the 1960s, health care knowledge and clinical practice was rapidly growing and becoming increasingly complex. In 1968 Dr. Lawrence Weed broke with tradition to offer a new and rational way to organize and present clinical information. He recognized the difficulties of using the traditional narrative health record given the increasing body of information available from clinical sources and the common body of professional knowledge.¹⁵ Weed proposed the Problem-Oriented Medical Record (POMR) as a solution to the problem of organizing and presenting patient clinical information and documenting the clinician's thought process from data collection through diagnosis and treatment. Takeda notes that Dr. Weed's proposal was a turning point in managing health information, and that over the past 35 years clinicians have structured clinical data to ensure availability of complete and readable data in a useable and relevant format.¹⁶ Today, we find increasing patient involvement in making health decisions, leading to a need to deliver a patient's own health information in a manner that they can best understand to participate in their own healthcare processes.^{17,18}

1.1.2 Departing the Paper Legacy

For the greater part of the Twentieth Century, paper records were customary throughout business and industry. Healthcare practitioners used a paper healthcare record to collect, organize, store and present patient health information for both clinical decision making and to provide a historical record of their decision processes and services provided. While the use of paper records increasingly provided a solution to the problem of how to manage patient health information through the early 1900s, the content, format, and presentation were far from uniform throughout the United States. Leading practitioners and institutions promoted their own individual methods for documenting patient care. Documentation standards were absent as was a consensus on best practices for creating and managing patient records. Paper-based records and information management methods eventually matured to follow generally accepted guidelines and best practices regarding content and structure, the transcription of patient information, privacy and disclosure of information, authentication of entries, and record storage and retention. In the latter half of the century, state legislatures, and regulatory and accreditation bodies increasingly exercised control over patient records and record management practices. Clinical and management practices matured, optimizing the structure, content, and management of these records, largely directed toward a paper-based technology.

¹⁵ Weed LL. Medical Records That Guide and Teach. N Engl J Med. 278:593-600 and 652–7. 1968.

¹⁶ Takeda, H. Commentary: What has Changed after Dr. Lawrence Weed's Paper in 1968. in van Bommel, J. H. and A. T. McCray, et.al. Yearbook of Medical Informatics: The Promise of Medical Informatics. 1999.

¹⁷ Ross SE, Lin CT. The effects of promoting patient access to medical records: a review. J Am Med Inform Assoc. 10:129–38. 2003.

¹⁸ Winkelman, W.J. and K. J. Leonard, Overcoming Structural Constraints to Patient Utilization of Electronic Medical Records: A Critical Review and Proposal for an Evaluation Framework. JAMIA 11/ 2:151-161. Mar/Apr 2004.

As electronic computers proliferated during the 1960s, pioneers in medical information began seeking ways to apply automation technology to remedy the inherent deficiencies of paper-based records.^{19, 20} Weed noted that manually data entry into a POMR would not achieve the desired benefits, and that a computer-based solution was required: “I set forth my hopes that development of the computerized problem-oriented medical system (PROMIS) would help coordinate the many providers of care.”²¹ Since then, the difficulties of using paper records in an increasingly information-intensive environment have been widely discussed in the healthcare professional and trade press. For example, Webb and Powell note that paper-based record technology becomes progressively inadequate in an increasingly information intensive health care environment, having problems with data availability at the point of care, variance in format and coding, legibility problems, and issues of duplicate, inconsistent, conflicting, and redundant information.²² The 1997 revision of the Institute of Medicine report on the computer-based patient record effectively summarizes the failings of the paper document among the reasons for automating patient records,²³ and Murphy discusses the impact of technology on this collective body of patient and related clinical data to clinical care, and summarizes the rationale for transforming the paper-based health record to an electronic health record.²⁴

Initially, the automated health record was only an electronic equivalent of the traditional paper or problem-oriented record. Computer-based patient record vendors limited their products to a change of media, with the computer screen and printout replacing the previous hand- or type-written text pages. While many electronic health record products continue to be automated versions of paper-based documents, experience has revealed that merely exchanging paper for electronic technology carries along many of the shortcomings of paper documents. In addition, when working with larger patient loads and increasing volumes of clinical data, many of the failings of paper documents are magnified by the efficiency which automation provides. Retaining the look and feel of paper-based health records directs attention to the form of the record rather than the substance of its data content and how this data is best used by the individual clinician. It leads to a focus on the interaction with the user rather than how the information content can be best employed to enhance personal health, care delivery, documentation, and other critical uses.

While intrinsic limitations of the PBR systems have been widely discussed in the health informatics community as a justification for migration to the EHR, the technology solutions of the 1990s have been largely constrained by information processing and clinical workflow constructs optimized for that paper-based technology. Advances in information and communication technologies have enabled a transition from records management concepts based on paper records. Regardless of whether PBR or EHR technology, fundamental problems remain independent of technology. The data contained in health records remains inconsistent across and within organizational boundaries. Business drivers often result in health data being compartmentalized by health profession, discipline, and specialty, thus impeding access to health information by all legitimate users, and compromising the continuity of patient care.

A fundamental conceptual analysis is required to develop a single uniform perspective of whole-patient care, and the data needed to support that care. This data must be universally applicable to any health care profession, discipline or specialty, and accessible by and able to be employed by any legitimate user in any care delivery environment. The benefits of data interoperability on healthcare cost, quality and access will not be achieved until the healthcare industry achieves a shared understanding of this data from the perspective of the processes it supports.

¹⁹ Collen, M. F. A History of Medical Informatics in the United States 1950-1990. Bethesda, MD:AMIA. 1995.

²⁰ A brief overview of early development of chartless and electronic health records is available on the EHR Web: <http://www.ehrweb.org/ehrweb/ehroverview/pages/history.htm>

²¹ Weed, L.L. Medical Records, Medical Education, and Patient Care. Cleveland: Case Western Reserve University Press. 1969.

²² Webb B and K. Powell. From a paper to an electronic medical record. Inform Healthc Aust. 5(3):97–100. 1996.

²³ Dick, R. S., Steen, E. B. and D. E. Detmer. The Computer-Based Patient Record: An Essential Technology for Health Care, revised edition. The Institute of Medicine. 1997.

1.1.3 Electronic Health Record Views Vary

Two views of the fundamental nature of the electronic health record continue to be held in the health informatics community. These views often are derived from the individual's perspective of what health information is and how it is employed – a medical records professional, for example, may view the electronic health record as a document, while a database-oriented medical informaticist may view the electronic health record as a collection of data elements. Each viewpoint has merit within the context of its respective envisioned use.

This divergence of views is also found in the health informatics standards community, for example, work efforts within ASTM and HL7 EHR activities address both the EHR document standards and the content and structure of EHR data. One view addresses clinical information and the EHR as a standardized document while the other view addresses clinical information and the EHR as standardized data. Standards activities viewing the EHR as a standard document focus on the content and format of health information as presented to the user. The intent is to provide a guideline for efficient exchange of health information, as information interoperability. It operates on a premise that this information interoperability will improve the economy of care delivery and improve quality by providing practitioners all information they require for the case at hand. Standards activities viewing the EHR as standard data focus on the content and structure of data that clinicians need to best deliver care. The intent is to provide a standard data content and structure that is independent of the presentation and therefore accommodates differences among the types and format of health records by profession, specialty, organization, or user preference. It is based on the premise that understanding the information needs of the clinician's decision processes and how information interacts in care delivery workflow will improve healthcare economy, quality and access.

This normative conceptual data model supports both views of the EHR – it can provide the data infrastructure for standardized documents and it can provide a standard data structure capable of delivering data tailored to clinicians' workflow and work patterns for the EHR and other uses such as clinical decision support.

1.2 Purpose and Scope

This document views clinical information from the perspective of how standardized data structure and content can best support healthcare delivery independent of technology, healthcare profession or specialty, or care delivery environment. It develops this understanding through a high level structured analysis of the fundamental activities shared throughout the delivery of healthcare services and the principal types of data needed to support these activities.

1.2.1 Purpose

The purpose of this document is to develop and present a shared understanding of the structure and content of data needed to support healthcare processes. This conceptual model forms the foundation for more detailed data representations in clinical information and the structure and content of data presented in the various types of electronic health and patient records.

1.2.2 Scope

This document provides descriptions and graphic depictions of those activities and data structures specific to clinical healthcare and population health services. It addresses mainstream views of individual and population health and care delivery processes within the United States. In drawing generalities shared among practitioners and providers, this model does not reach the depth of detail where the differences in clinical and business practices require differences in supporting data content and structure.

²⁴ Murphy, G. F. Electronic Health Records: A Unifying Principle Chapter 17. in Mervat, et. al., Eds., Health Information: Management of a Strategic Resource. Saunders. 2001.

This document addresses non-clinical data structures (e.g. administrative, financial, supply chain, etc.) only to the extent that these are directly related to personal and population health and directly support healthcare delivery processes.

This document does not address or establish standards for clinical care. It does not establish standards for the quality, efficacy or effectiveness of clinical practice, or the conduct of clinical research. This document does not address alternative healthcare practices, and may not appropriately describe care delivery processes found outside the United States. Likewise, it does not establish informatics standards for manufacturing processes in the healthcare supporting industries.

1.3 Modeling Healthcare

A model is a representation of real or envisioned things or events. Models are often used to gain an understanding of structures and processes where size and complexity renders human perception or comprehension difficult or impossible. Models help explain, analyze or predict processes and structures which currently exist, have existed in the past, or may exist in the future. Modeling assists human intellectual processes to obtain an understanding where size and complexity confound or defeat comprehension by inspection or conventional analysis.

The size and scope of the care delivery environment, along with the complexity of health knowledge and health care processes, makes comprehension impossible for an individual relying on mental capability alone. Modeling is, therefore, an appropriate technique to gain a comprehensive understanding of healthcare processes and the data supporting these processes.

The key to success in creating a standard conceptual healthcare data model is to build the model to effectively describe or represent the data needed by healthcare processes shared across professions, specialties and care delivery environments. Such a large and complex process must to be described by a high level or conceptual process model. The shared understanding presented in this conceptual process model then provides the foundation for a conceptual data. This model directly links the structure and content of the conceptual data model to healthcare processes shared among all health professions, specialties and care delivery environments.

1.3.1 What are Conceptual Models?

Conceptual models address only the significant elements of a process or structure. They ignore irrelevant or confounding information and detail beyond that necessary to understand the process or structure. Conceptual models accurately presenting the result in a simple, easily understood fashion. The outcome, an understanding of the object being modeled, is the critical measure of success of the model.²⁵ The best healthcare conceptual models lead to an understanding of existing and future structure and process that ultimately improves health, and enables the construction of efficient and effective information systems to support these processes.

Conceptual process and data models may be used for many purposes. Process models analyze and document existing processes as sets of component activities. These models identify opportunities for the improvement, simplification and streamlining of those processes that add value to the organization, its products or services, and ultimately to the improved health of individuals and populations. When the conceptual data model is derived from a process model, the data structures enable and support the target functionality through transformation into databases supporting the envisioned future processes. Without this linkage to a process model, a data model cannot be shown to accurately support the intended clinical or business processes.

²⁵ ASTM 2145 Standard Practice for Modeling in Health Informatics. American Society for Testing and Materials. 2001.

This publication presents both a conceptual clinical activity model and a conceptual clinical data model in an integrated modeling approach. In this approach, the activities which are intended to be supported in *the future* are modeled, and then the future data requirements are identified through a subsequent data modeling effort. The Integrated Definition language (IDEF)²⁶ has been successfully applied in healthcare for activity and data modeling in both the public and private sectors.^{27,28} Both the 1996 COHR Concept Model, and ANSI/ADA Specification 1000 logical data model and implementation physical data model were prepared using the IDEF. Appendix C. presents an overview of the IDEF notation used in this document.

1.4 Description of this Document

This document is composed of four parts:

1. An introduction that provides the healthcare context, model rationale, scope and purpose, etc.
2. The informatics foundation of the conceptual model from the context of healthcare policy, clinical process and regulations.
3. The conceptual process model, as a top-down, hierarchical description of the care delivery and supporting activities.
4. The conceptual data model as an identification and description of the essential data structure needed to support the conceptual processes.

The appendices present the terminology used in this document, a description of the modeling methodology employed to create the conceptual models, and references.

1.4.1 Changes from the 1996 Concept Model

Appendix A. presents a brief history of the preceding 1996 ADA COHR Concept Model document. While the conceptual models in this document resemble those in the 1996 Conceptual Model document, these have been enhanced and revised to reflect changes in care delivery processes, the medico-legal and regulatory environment (e.g. HIPAA requirements), and advances in the healing arts and sciences. The conceptual activity model presented in this document is an extract of an standard healthcare process model in development in ASTM.²⁹ The conceptual activity and data models in this document retain a clinical care focus and it has been enhanced particularly in the population health area. The conceptual data model is as a consequence more robust than the 1996 model. Also, with publication of the ANSI/ADA Specification 1000, there is no longer a need to include an abbreviated logical data model and metadata to validate the conceptual model.

1.4.2 Terms Used in This Document

The terms, definitions, and acronyms used in this conceptual model document are consistent with the emerging ASTM

²⁶ IDEF methodology described by the National Institute of Standards and Technology, Federal Information Processing Standards Publications 183 Integrated Definition for Function Modeling (IDEFO) and 184 Integrated Definition for Information Modeling (IDEFIX), 23 December 1993.

²⁷ Bourke, M. K. Strategy and Architecture of Health care Information Systems. New York:Springer. 1994.

²⁸ DoD Health Affairs: IDEF Process and Data Models used in the Military Health System Functional Area Model – Activity (FAM-A) and Functional Area Model – Data (FAM-D), various dates.

²⁹ ASTM E31.23 Work Item 5068 - Standard Healthcare Conceptual Process Model. Draft in preparation.

E31.19 specification on a Standard Terminology for Health Information Systems.³⁰ The need for this Standard Terminology is that a proliferation of terms, acronyms, and descriptions for the electronic health record and related clinical system concepts over the past decade has created substantial confusion throughout the healthcare industry. A decade ago, the accepted term was the computer-based patient record (CPR or CBPR)³¹, while today many hospitals, medical centers and provider organizations are striving to deploy enterprise electronic medical records (EMRs) and other subtypes of electronic health records. Such variants of the electronic health record continue to be known by many terms, often indicating a specific vision specific to a particular organization, care delivery modality, geographic region, or practitioner specialty.

While there remains no universally accepted definition, nature or composition of the EHR, the definition proposed by Huffman, "a compilation of pertinent facts of a patient's life and health history, including past and present illness(es) and treatment(s), written by the health professionals contributing to the patient's care" is appropriate for this normative conceptual model.³² Waegemann noted that the electronic health record is a collection of patient data in automated form, rather than an automated version of the conventional physical patient record.³³ This view of the EHR best fits this conceptual model and contemporary medico-legal views of electronic health records. This normative conceptual model views the EHR to be a comprehensive body of patient data from which specific information can be extracted and assembled as needed to meet the unique needs of the case at hand.

Appendix B. presents an overview of relevant terminology issues. Among all the varied contexts and preferences, the common denominator as used in this document describes the electronic health record as:

1. a body of clinical and supporting information
2. specific to an individual health service recipient
3. covering a specific period of time.

Attention to the concept of 'information' is essential. Where data may exist independent of human use, information is actionable data placed in a context so that it can be used. In the architecture of a healthcare information system, the data layer stores and manages this health data, the application layer converts that data into information and the presentation layer delivers this information to the human user. Ideally this is complete and accurate information delivered precisely when and where needed, and in a form best used.

1.5 Anticipated Uses of this Conceptual Model

This concept model is suitable for a variety of uses in the analysis, design, development, and evaluation of healthcare processes and supporting information systems. In addition this model can provide the basis for the ongoing development and evolution of health informatics standards. For example, among the uses of the clinical conceptual activity model are:

- To develop a shared understanding of clinical functions;
- To identify and describe the functional requirements of clinical information systems;

³⁰ ASTM E31.19 Work Item 6553 Standard Terminology for Health Information Systems establishes a baseline consensus standard terminology for health information systems.

³¹ Dick, R. S. and E. B. Steen. The Computer-based Patient Record: An Essential Technology for Health Care. Washington, D. C.:National Academy Press. 1991.

³² Huffman, E., Medical Record Management, 9th ed., Berwyn, IL:Physician's Record Co. 1990.

³³ Waegemann, C. P., The Five Levels of the Ultimate Electronic Health Record. Healthcare Informatics. 12/11:26-35. Nov, 1995.

- To provide a shared foundation for the development of the electronic health record and other clinical data systems;
- To provide a shared platform for analysis, planning and evaluation of healthcare processes;
- To provide a foundation for future investigation into the nature of the clinical process, and research in health services management and administration.

Likewise, the conceptual data model can be used:

- To provide a basis for and to guide evolution of the ANSI/ADA Specification 1000;
- To better understand the association of healthcare data to the processes it supports;
- To assist clinical and health services managers, administrators, and researchers in the collection, management, analysis, and interpretation of clinical data;
- To support creation of additional systems design elements, such as use cases, swim lanes, etc.

Together, the activity and data models can provide the conceptual foundation for data interoperability throughout healthcare.

This conceptual model is not directly applicable to clinical practice, and particularly, it does not establish any standards for clinical care. As with all health informatics standards, the user of this document has the responsibility to establish appropriate health and safety practices and to determine any regulatory limitations inherent with its use.

1.6 Compliance Criteria

The normative portions of this document, the models and descriptions, and the informative components are individually identified. Users may state compliance with the normative provisions of this document by using the process and data models, their concepts and representations, along with the basic names and relationships for both activities and data.

This standard concept model may be extended by adding additional detail, such as for deriving detailed analytical, planning, or systems development models. Extensions to the standard model and any recommendations for revision to this document should be forwarded to Paul Bralower at bralowerp@ada.org for consideration in the future evolution of this standard.

2 The Foundation of the Clinical Concept Model (Informative)

This section presents the theoretical basis for the normative conceptual clinical process and data models from the clinical care, public health and healthcare administration, medico-legal/regulatory, and accreditation perspectives.

2.1 Why Standardize Electronic Health Information

The Electronic Health Record along with seamless exchange of health information is the fundamental premises of interchange and interoperability envisioned in the NHII. Providing health information via an EHR and unfettered data exchange are not new concepts: Collen traced these tracks through the efforts of many health informaticians from the mid-1980s onward.³⁴ A significant portion of their activities were directed toward identifying the need for and then developing standards for the clinical information and health data exchange.

³⁴ Collen, M. F. A History of Medical Informatics in the United States 1950-1990. Bethesda, MD:AMIA. 1995.