



American National Standard/
American Dental Association
Standard No. 1067

Electronic Dental Record System Standard Functional Requirements

ADA American
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Association®

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 1067 FOR ELECTRONIC DENTAL RECORD SYSTEM STANDARD FUNCTIONAL REQUIREMENTS

The Council on Dental Practice of the American Dental Association has approved American Dental Association Standard No. 1067 for Electronic Dental Record System Standard Functional Requirements. Working Groups of the ADA Standards Committee on Dental Informatics (SCDI) formulate this and other standards 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 standard was forwarded to the American National Standards Institute with a recommendation that the standard be approved as an American National Standard. Approval of ADA Standard No. 1067 as an American National Standard was granted by the American National Standards Institute on May 6, 2013.

This standard was prepared by a task group of ADA SCDI Working Group 11.1 on Standard Clinical Data Architecture. The ADA SCDI thanks the members of the task group and the organizations with which they were affiliated at the time the specification was developed.

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FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 1067 for Electronic Dental Record System Standard Functional Requirements.)

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:

"The ADA SCDI shall develop informatics standards, technical reports and guidelines and interact with other entities involved in the development of health informatics standards aimed at implementation across the dental profession."

The taskgroup conveys special thanks to the ADA's Patrick Cannady and Janeen Walls for their valued support in defining these requirements.

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1.0 Introduction (Informative)

Dentistry shares a common heritage with Medicine including the documentation of our patients' health conditions, diagnoses, and treatments. A century ago our practitioners created handwritten notes about individual cases in laboratory-style notebooks using various notations, shorthand script and ciphers. The structure and content of these notes were defined by each practitioner to fit their personal style and practice.

Early in the 20th Century both professions began to formalize the nature of the clinical records we maintained. In 1919, the American College of Surgeons¹ specified the information to be contained in the patient's medical record as:

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

Likewise, G. V. Black², among others, similarly formalized the notation used in documenting dental care around a blended text-graphic format. Black linked the record structure and notation directly to the examination, diagnosis, treatment planning, and treatment processes. Vendors subsequently published a variety of paper dental record charts, forms, and folders, presenting variations on a text-graphic representation of oral structures, examination findings, and treatments proposed and performed. This variety presented the practicing dentist with a range of document styles and formats from which they could select whatever best fit their professional preferences.

The first computer applications in dentistry were public health studies of populations in the late 1940's. In 1948, Klein and Kramer reported using Hollerith-type punch card technology to record the results of dental examinations.³ These cards could record ten data items for deciduous and permanent teeth. As computer technology evolved and more capable main-frame systems became available, greater amounts of epidemiology data could be recorded and maintained, and increasingly sophisticated statistical analyses could be performed. By 1968, data entry evolved from punch card to mark-sense to optical character recognition technology.⁴ Such epidemiology applications were well suited to the large, mainframe systems then available.⁵ At that time the potential for computer use in dental business and clinical applications began to be explored.^{6,7,8,9,10,11} With the advent of microcomputers in the late 1970s, computing capability became

¹ Minimum Standards, 1919, Bulletin of the American College of Surgeons. 8/4. 1924.

² Black, Arthur D., G.V. Black's Work on Operative Dentistry, Vol. 1. Pathology of the Hard Tissues of the Teeth, Oral Diagnosis. 8th edition, and previous editions. Medico-Dental Publishing Company, 1948. Pages 59-76 and following.

³ Klein, H. and M. Kramer. A Dental Examination Record Form for Statistical Machine Tabulation. J. Dent. Res. 27:170, 1948.

⁴ Pennell, E. H. and S. S. Herman. A Mark Sense Card for Recording Dental Examination Findings. J. Dent. Res. 31:113, 1952.

⁵ Marthaler, T. M., Bandi, A. And M. Steiner. Computers in Preventive Dentistry. Int. Dent. J. 30:201, 1980.]

⁶ Mauch, R. S. Automation Comes to the Dental Office, JADA 68:70, 1964.

⁷ Cobin, A. S. An Uncomplicated Method for Automating Endodontic Treatment Records. Oral Surg. 22:519, 1966.

affordable to the typical practicing dentist, many of whom experimented with automating their paper-based business and clinical records.¹² Through the 1980's and 90's practitioners experimented with microcomputer systems, leading to hundreds of systems and applications that covered a broad range of functions in both general and specialty practices. While many of these systems and application did not survive, their contribution to the body of knowledge about the functions and operation of dental computer systems has brought us to our current level of dental computing capability.

As computer technology evolved, the ADA took several important steps in the automated records domain:

- designating the American Dental Association as the steward of data content and policy in Dentistry¹³
- the 1992 House of Delegates Resolution¹⁴ to facilitate development of the computer-based dental patient record, and
- the 1996 House of Delegates Resolution advocating seamless availability of patient health data across the healthcare professions, specialties, and care delivery environments.¹⁵

This latter resolution stated: "The American Dental Association believes that, for optimal patient benefit, with assurance of confidentiality safeguards, appropriate health information should be available at the time and place of care to practitioners authorized by the patient through the development of a computer-based patient health record." This resolution addressed the need for interoperability of health data across provider professions and specialties to benefit the patient. It took the view of the whole-patient, noting that patient well-being and optimum outcomes often need provider access to patient health information sources beyond the traditional boundaries of care delivery. This resolution establishes a vision of a whole-patient health record that is not limited to a dental health record.

The ANSI/ADA Standard 1067 is one of a sequence of standards that implement the ADA House of Delegates Resolution 92H-1996. This standard addresses the functions performed by dental computer systems to document the dental health services in a whole-patient care environment. This document is structured through the merger of the clinical process model in the ANSI/ADA Specification 1039 and the detail presented in the HL7 EHR System Functional Model. Appendix A of this document lists the activities currently identified for a proposed Standard Clinical Process Model.

1.1 Identifying and Organizing the Functional Requirements

This proposed standard reflects the collective viewpoint of healthcare providers, vendors, and other stakeholders and interested parties. These functional requirements were drafted by the SCDI Dental System Functional Requirements task group using the Health Level Seven Electronic Health Record System Functional Model Release 1.1 as an initial overall organizing framework. The draft requirements were initially edited by the SCDI project team, and then reviewed by SCDI Work Group 11.1. The draft specification was then prepared with the requirement statements organized consistent with the enhanced Clinical Process Model. The draft specification was reviewed according to ANSI approved SCDI procedures, including 'All Interested Parties' review.

⁸ Kilpatrick, H. C. Automated Bookkeeping Controls for the Dental Profession. N.Y. State Dent J. 34:76, 1968.

⁹ Christopher, A. The Role of Computers in Dentistry. JADA 74:720, 1967.

¹⁰ Council on Dental Practice. Computer Technology in Dental Practice. JADA 101:938, 1980.

¹¹ Transactions of the 67th World Annual Dental Conference. Computers in Dentistry. Int. Dent. J. 30:189, 1980.

¹² Diehl, M C. and E. J. Nieburger. A History of Computer Applications in Dental Private Practice. Proceedings, AAMSI Congress 1987. Pages 362-66.

¹³ ADA Board Resolutions B-118-1995 to B-121-1995.

¹⁴ ADA House of Delegates Resolution 18H-1992 (Trans 1992:597)

¹⁵ ADA House of Delegates Resolution 92H-1996, supplement to ADA annual reports and resolutions. Chicago 1996:282–3.

Functional requirements were included by the SCDI task group if considered essential in at least one dental care setting. These functional requirements were developed with technology neutrality, imparting no particular preference for specific technologies, devices, or architectures. Additional narrative information intended to describe or clarify a concept presented in the requirement statement have been included where the requirements team and reviewers felt necessary

1.1.1 HL7 EHR-S Functional Model Framework

The functional requirements were described in a conceptual hierarchy, employing the concept of Functional Granularity as presented in the HL7 Functional Model. In the HL7 EHR-S FM, “Functional Granularity is a term used to describe the level of abstraction at which a requirement is represented. Requirements typically grouped together in practice or by system function have been consolidated where appropriate. Thus in this specification, functional requirements that are related through the clinical process have been clustered together for a cohesive presentation.

The HL7 EHR-S Functional Model is an international standard and an American National Standard that presents an organized list of the functions associated with an electronic health record system.

This list of functions is described from a user perspective to provide what HL7 states as “a consistent expression of system functionality”.¹⁶ From the HL7 perspective, the term “system” covers a continuum of options for the implementation of the stated functions. This continuum includes those core healthcare functions that are typically provided by those applications that manage electronic healthcare information at the system data tier. This continuum also includes capabilities at the application tier, such as clinical decision support. Finally this continuum includes presentation tier capabilities such as involve data acquisition, interoperability, and integration.

While stated as an EHR-S Functional Model, the capabilities described in the function continuum are very much applicable to clinical information systems in general.

Like this Specification, the HL7 EHR System Functional Model is technology agnostic: the standard functions make no statement or inference about which technology is used. How the stated functions are implemented are outside the scope of the Functional Model. The HL7 Functional Model also makes no statement about the data content of the electronic health record.

The HL7 EHR-S Functional Model is composed of a functional outline or hierarchy of three sections:

- Direct Care,
- Supportive, and
- Information Infrastructure.

This hierarchy is successively decomposed into functions of increasing granularity, providing appropriate levels of detail for functions within a specific section. There are thirteen subsections according to the diagram below.¹⁷

¹⁶ HL7 EHR System Functional Model, Release 1. Chapter 1: Overview. February 12, 2007

¹⁷ *ibid.* Page 10.

Direct Care	DC.1	Care Management
	DC.2	Clinical Decision Support
	DC.3	Operations Management and Communication
Supportive	S.1	Clinical Support
	S.2	Measurement, Analysis, Research and Reports
	S.3	Administrative and Financial
Information Infrastructure	IN.1	Security
	IN.2	Health Record Information and Management
	IN.3	Registry and Directory Services
	IN.4	Standard Terminologies & Terminology Services
	IN.5	Standards-based Interoperability
	IN.6	Business Rules Management
	IN.7	Workflow Management

(figure 2)

HL7 EHR System Functional Model Sections and Subsections

This hierarchy contains an organized list of functions associated with the HL7 view of a generic EHR System rather than a statement of all functions associated with a specific EHR System product or class of products. The statements in this list are identified in outline form, indicating the parent-child relationship among functions and sub-functions. Within these subsections are over 140 individual function statements that include:

- a Function Name,
- a Function Statement, and
- Conformance Criteria.

The Conformance Clause stated the normative language for the function and defines the minimum requirements for claiming conformance. The Conformance Clause describes the essential concepts necessary to understand and implement the function. The Conformance Criteria are normative.¹⁸ In many cases there is also associated information, e.g. a function description that is informative.

The HL7 EHR-S Functional Model serves as the starting point to identify those functional requirements appropriate for dental information systems.

1.1.2 Health Care Process Model

The health care process model described in this document is an enhancement of the model previously presented in Specifications 1000 and 1039. Where the HL7 Functional Model has a context of information management and communication, the process model in this document approaches healthcare from a patient-centered and healthcare outcomes context. As presented in Section 3 and detailed in the appendices, the structure of the enhanced Process Model from the ANSI/ADA Specification 1039 includes elements of the HL7 EHR-S Functional Model and can be cross-mapped to the Functional Model.

¹⁸ Refer to the HL7 EHR-S FM R1.1 standard for specific details and requirements for conformance.

1.1.3 Developing the Dental System Functional Requirements

The dental system functional requirements were developed using the following process:

- Identify potential functional requirements from the HL7 EHR-S Functional Model conformance statements.
- Prepare additional requirements statement not covered in the HL7 Functional Model including those specific to information management in dentistry and dental information systems.
- Edit the candidate functional requirements as:
 - o Break down any compound requirements into single requirement statements.
 - o Simplify any complex requirement statements into simple, direct statements.
 - o Eliminate redundancy and circular relationships.
- Review the candidate list of functional requirements:
 - o Add requirements as needed.
 - o Rephrase requirement statements where indicated.
 - o Remove technical requirements and those that are un-necessary or redundant.
- Organize the list of dental system functional requirements according to the hierarchy presented in the enhanced process model – see activity listing in Appendix A.
- Incorporate the requirements list and structure into this document.
- Review according to established SCDI processes.

These functional requirements state what processes, tasks, or actions the electronic dental system performs. These requirements do not specify how the system is to perform these tasks. For example, a requirement statement transcribed directly from the HL7 EHR-S Functional Model a statement may read: “The electronic dental system MAY provide the ability to route results to patients by methods such as phone, fax, electronically or by mail.” The portion that reads “by methods such as phone, fax, electronically or by mail.” specifies how these results are to be routed. The dental system functional requirement statement, however, reads “The electronic dental system MAY provide the ability to route results to patients.” specifying only what task (i.e. routing results) is required.

1.1.4 The Dental Requirements Functional Hierarchy

The Dental System Functional Hierarchy is a product of the process model node tree diagram described in Section 3.3 of this document. The system functional requirements are organized according to this functional hierarchy.

1.1.5 Requirements Section Format

Each section presents requirements in a table form as illustrated below:

Req't No.	Requirement Statement	HL7 EHR-S FM 1.1 Reference
X.X	Xxxxxxx statement xxxxxxxxxxxxxxx.	XX X.X
X.X	Xxxxxxx statement xxxxxxxxxxxxxxx.	XX X.X
X.X	Xxxxxxx statement xxxxxxxxxxxxxxx.	XX X.X

In this chart the Req't No is the line item number or requirement identifier. The Requirement Statement is a text statement of the requirement. The Requirement statement is equivalent to the HL7 Functional Model Conformance Statement. The HL7 EHR-S FM 1.1 Reference is the functional model section and conformance criteria number to which the dental functional requirement relates or applies; this reference is not necessarily a direct equivalence to the HL7 statement.

In addition, some of the dental functional requirement statements have descriptive narrative presented in a subsequent table as illustrated below:

Req't No.	Requirement Statement Descriptive Narrative
X.X	Xxxxxxx statement narrative xxxxxxxxxxxxxxxx.
X.X	Xxxxxxx statement narrative xxxxxxxxxxxxxxxx.
X.X	Xxxxxxx statement narrative xxxxxxxxxxxxxxxx.

1.2 Purpose and Scope

Functional requirements identify the tasks or behaviors to be performed by an information system or a component of the system. This requirements specified in this document apply from the basic system component supporting a solo practitioner to the most rigorous environment, providing system interoperability coordinated across multiple care delivery settings.

1.2.1 Purpose

The purpose of this document is to identify the minimum functionality required of an electronic dental system to perform effectively in an interoperable and coordinated care environment.

1.2.2 Scope

The scope of this document is the functional requirements for the dental health care domain, consisting of information system support for direct and indirect dental services, supporting functions, and functions of the electronic dental system infrastructure.

An important point is that in providing a capability to perform a system task or support clinical activity does not require that the clinician perform specific professional activities: specifying standards of professional practice, standards of care, and medico-legal requirements are outside the scope of system functional requirements.

1.2.3 Importance of This Standard

A belief that information technology will improve the quality and efficiency of delivery of healthcare services is one of the core tenets of current healthcare reform initiatives. In one of the foundation studies in health informatics, Jydstrup and Gross analyzed the workflow in three hospitals, finding that information processing by clinicians varied by individual, type

of service, and profession, but overall averaged about one quarter of their workday.¹⁹ The capability to improve provider workflow has long been known. Blum noted that modifying workflow is a potential benefit of clinical information systems.²⁰ After conducting studies on provider acceptance of clinical information systems, Metzger and Teich noted that a successful patient care information system must fit patient care processes and provider work patterns.²¹

Determining these work patterns is difficult, owing to great variance from among the healthcare professions and specialties, among the specifics of individual cases, regional and organizational variances, and variance in provider technique - "what works best in my hands". Fickenscher noted that standards improve healthcare quality and patient safety by reducing variance.²² Given the great extent of variance, an attempt to develop reasonably uniform and standardized workflow descriptions cannot be accomplished without excessive definition and harmonization efforts. A top-down standardized process model has the potential to most economically establish a baseline description that can be incrementally extended and refined, and provide a basis to improve clinical system utility and acceptance.

1.2.4 Typical Uses of These Requirements

As noted in the HL7 Functional Model, these functional requirements can be used to:

- "Facilitate describing end user defined benefits such as patient safety, quality outcomes and cost efficiencies in terms of standard EHR-S functions.
- "Promote a common understanding of EHR functions upon which developers, vendors, users and other interested parties can plan and evaluate EHR-S functions.
- "Provide the necessary framework to drive the requirements and applications of next level standards, such as EHR content, coding, information models, constructs and interoperability for information portability between sub-systems of an EHR-S and across EHR-S'.
- "Establish a standards-based method by which each realm (country) can apply these EHR functions to care settings, uses, and priorities.
- "Inform those concerned with secondary use of EHR data and national infrastructure what functions can be expected in an EHR System."

An important point to recognize is that these requirements apply only to the capabilities of the dental information system. These statements place no requirements on the practicing dentist or human user to perform these functions. All decisions about how the practicing dentist uses the functions provided by the computer system are at the professional discretion of the dentist.

1.3 Terms, Acronyms, and Definitions

This specification employs the terms, acronyms, and definitions as noted subsequently.

¹⁹ Jydstrup, R. A. and M. J. Gross. Cost of Information Handling in Hospitals. Health Services Research. Winter 1966: 235-271.

²⁰ Blum, B. Information Systems for Patient Care. Springer. 1984. ISBN0387909125.

²¹ Metzger, J. and J. Teich in Drazen, E., Metzger, J., Ritter, J. and M. Schneider. Patient Care Information Systems: Successful Design and Implementation. Springer. 1995. ISBN0387942556.

²² Kevin Fickenscher, M.D. as noted in Goldstein, D., et. al. Medical Informatics 20/20: Quality and Electronic Health Records Through Collaboration, Open Solutions, and Innovation. Jones and Bartlett. 2007. ISBN 0763739251.

1.3.1 Terms and Definitions

The following technical terms are used in this document:

Term	Definition
Record	A compilation of facts or body of data.
Record System	A computerized or automated system, or sub-system component of a system, that receives data, operates on, stores, retrieves, and delivers that data to the user, another system, or system component.
Electronic Health Record	The collected body of an individual's health information stored in electronic form.
Electronic Health Record System	A computerized or automated system or sub-system component that interfaces with the electronic health record data.
Electronic Medical Record	A combination of processes and data structures, used by the medical practitioner and patient, for purposes of documenting, conveying, etc., clinical facts, diagnoses, treatment plans, and services provided.
Electronic Medical Record System	The automated processes and technology that operate on data in the electronic medical record and interact with the user.
Electronic Dental Record	A combination of processes and data structures, used by the dental practitioner and patient, for purposes of documenting, conveying, etc., clinical facts, diagnoses, treatment plans, and services provided. Also referred to as Computer-based Oral Health Record (COHR).
Electronic Dental Record System	The automated processes and technology that operate on the electronic dental record.
Advance Directive	A healthcare proxy made by the care recipient.
Structured Data	Data that can be accurately and consistently identified in a record through features such as a uniform pattern or an indexing mechanism.
Unstructured Data	Data having no internal organization, form or structure and is therefore not accurately and consistently identifiable. Free text narratives found in business and clinical documents are a type of unstructured data.

1.3.2 Acronyms and Descriptions

The following acronyms are used in this document:

Acronym	Term
COHR	Computer-based Oral Health Record
EMR	Electronic Medical Record
EDR	Electronic Dental Record, also referred to as the COHR
EHR	Electronic Health Record
EMRS	Electronic Medical Record System
EDRS	Electronic Dental Record System

EHR-S or EHR-S	Electronic Health Record System
CDS	Clinical Decision Support
eRx	Electronic Prescribing or Electronic Pharmacy
HR	Human Resource
I/O	Input/Output, typically the data input and output functions of a process or system component
IDEF0	The ANSI standard Integrated Definition process modeling methodology.
RIS	Radiology Information System
PACS	Picture Archiving and Communication System

1.4 Foundation Concepts

Functional requirements are statements that define those functions that a system is supposed to perform. Functional requirements state what the system will do but not how the system will accomplish these functions. For example a typical functional requirement might be “The system shall calculate a total charge for the encounter.” but not “The system shall display the listing of fees on the superbill in order of increasing value to the right of the billed procedure, add these fees, and display the total fee in the lower right of the superbill form.” A software developer decides how a functional requirement can be best achieved in the system - this provides the software engineering flexibility to create the most efficient solution for the system and to differentiate the software from competitors.

Functional requirements are subject to strict control by organizations serving as *stewards* of specific data content and data policy. In the case of all functional requirements for dental information systems, electronic dental systems, or electronic dental record systems, the designated data steward is the American Dental Association through Board Resolutions B-118-1995 through B-121-1995.²³ Other organizations have stewardship over functional requirements in their domain of electronic health record systems serving medicine and health care specialties and generally.

1.4.1 Health Care Basis

The basis for all health care derives from the human contract whereby:

- Individuals have needs for health care services as a condition of being.
- Some of these services are performed by the individual themselves.
- Those services that cannot be performed by the individual are performed by others for which they are entitled to appropriate compensation.

This is the core process for all health care. Other processes, such as reimbursement, supporting industry, health education and research, etc., derive the reason for their existence from this core process and would not exist absent this process.

All aspects of this core process employ decision making – the clinician’s choice of the appropriate examination techniques, the care recipient’s decision on when to apply a medicinal agent, the tactical choices made by during a

²³ American Dental Association Board of Trustees Resolutions B-118-1995 through B-121-1995.

surgical procedure, etc. The availability of information used to make the decisions in this core process is a limiting factor and gives rise to the fundamental functional requirement: “The electronic system must provide complete and accurate information to the health care decision maker, at the time and place of decision, and in a form best used.” All functional requirements ultimately trace back to this single requirement.

The functional requirements stated in this document apply only to the electronic system supporting dental care services. This document and the standard functional requirements contained within it do not establish or recommend clinical standards or mandate specific aspects of patient care by any healthcare provider.

1.4.2 The EHRS vs. Clinical Information System

The Electronic Health Record System is more correctly termed a subsystem in that it is a technical component of the larger clinical information system. An Electronic Dental System is a special class of Clinical Information System, consisting of an EHRS foundation (the Computer-based Oral Health Record System or Dental EHRS), with Decision Support, Imaging, and similar systems in any combination.

1.4.2.1 The EHR System Defined

The efficacious and efficient use of information and information technology has become an essential factor in the delivery of safe, quality, and economic health services. Reports from the Institute of Medicine (IOM) underlined numerous reasons for the increasing failure of the care delivery system and have called for a transformation of this system through effective and efficient application of information technology.

This transformation involves a change in care delivery processes and the availability of essential information enabled by this technology. This transformation has a foundation in the use of validated data in the form of both care recipient electronic health records and reference data in the common body of health knowledge. The automated clinical system or clinical information system is the information technology that assists in the creation and validation of this data, operates on, persists, and delivers this data to the user.

In contrast, systems engineering and architecture classifies major system components as subsystems. For example, in a generic system there is a data subsystem, an application subsystem, a user-interface subsystem, etc.

In defining functional requirements it is essential to have a practical descriptive definition of the EHR and the EHR System. A consensus from published works describes the EHR and EHR System as in the table below:

Source	Definition/Description
Published works:	
Abdelhak, M., Grostick, S., and M. A. Hanken. Health Information: Management of a Strategic Resource. 4 th edition. Elsevier. 2011. ISBN 9781437708875.	- The EHR system can be one or many technical components assembled to operate on the EHR data to provide specific functionality. - The EHR system performs healthcare information management processes and conforms to specific requirements.
Coiera, E. Guide to Health Informatics. 2 nd edition. Hodder Education. 2003. ISBN9780340764251.	The EHR system is not a simple replacement of the paper health record system – electronic processes have different capabilities and limitations than do paper record systems.
Dick, R.S, Steen, E.B., & Detmer, D.E. (Ed.s). The Computer-Based Patient Record: An Essential Technology.	The EHR system is a set of components that form the mechanism by which patient records are created,

Washington, DC:National Academy Press. 1991 and updated 1997.	- used, stored, and retrieved. - A patient record system is usually located within a health care provider setting. It includes people, data, rules and procedures, processing and storage devices (e.g., paper and pen, hardware and software), and communication and support facilities.
Englehardt, S. P. and R. Nelson. Healthcare Informatics: An Interdisciplinary Approach. Mosby. 2002. ISBN 0323014232.	"A generally accepted view of the EHR is as an electronic database of healthcare data about an individual."
Murphy, G., Waters, K., Hanken, M. A., and M. Pfeiffer (eds.). Electronic Health Records: Changing the Vision. W. B. Saunders. 1999. ISBN 0721673864.	- The EHR is "... any information relating to the past, present, or future physical/mental health or condition of an individual which resides in electronic system(s) ..." - The EHR system consists of people, process, and technology elements combined to meet specific functional requirements.
Pryor, A. in Ball, M. and M. Collen (eds.). Aspects of the Computer-based Patient Record. Springer. 1992. ISBN 0387977236.	A CPR system (the EHR-S) by design manages the entire patient care record.
Roach, W. H., Hoban, R. G., Broccolo, B. M., Roth, A. B., and T. P. Blanchard. Medical Records and the Law, 4 th edition. Sudbury: Jones and Bartlett. 2006. ISBN 0763734454.	Medico-legally, the EHR is a body of data about an individual's health status, health condition, or health services, and is in an electronic form.
Shortliffe, E. H. and J. J. Cimino (eds.). Biomedical Informatics: Computer Applications in Health Care and Biomedicine. 3 rd edition. Springer. 2006. ISBN 0387289860.	- The EHR is a repository of electronically maintained information about an individual's lifetime health status and health care. - The EHR System adds information management tools to the EHR.
Whetton, S. Health Informatics: A Socio-Technical Perspective. Oxford. 2005. ISBN 0195550781.	The EHR is "... a comprehensive, longitudinal collection of an individual's health information, including both medical and non-traditional health- and lifestyle-related information ..."
Winter, A., Haux, R., Ammenwerth, E., Brigl, B., Hellrung, N. And F. Jahn. Health Information Systems: Architecture & Strategies, 2 nd edition. Springer. 2011. ISBN 9781849964401.	"The electronic health record (EHR) is the collection of medical data relating to one subject of care, i.e. the patient, that is stored in the computer-based part of a health information system."

Likewise the EHR and EHR-System are defined in standards as:

Source	Definition/Description
Standards:	
ISO/TS 18308, 2003; CEN 13606, 2000.	A system for recording, retrieving and manipulating information in electronic health records.
ASTM E1384-07	- An electronic health record is any information related to the past, present or future physical/mental health, or condition of an individual. - EHR data resides in one or more electronic systems or applications that capture, transmit, receive, store, retrieve, link and manipulate the EHR data.
ANSI/ADA Specification 1000:2001	EHR data is produced by healthcare processes and is operated upon by the EHR system to enable, regulate, and support these processes.

ANSI/ADA Specification 1000:2001	• Presents a standard clinical process model to support the EHR data model.²⁴
ANSI/ADA Specification 1039	• Provides foundation for the clinical process and medico-legal requirements. • Establishes the baseline conceptual process model.²⁵
HL7 EHR-S Functional Model version 1	• Provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S).
ANSI/ADA Specification 1058	• Presents the Forensic Dental Data Set to be used in conjunction with ANSI/NIST-ITL for transmission of data useful in identifying unknown deceased individuals.
ANSI/NIST-ITL	• Used to transmit data to law enforcement, military, intelligence and homeland security organizations around the world.

All of these definitions distill the EHR-System down to a set of processes that perform data acquisition, manipulation, storage, recovery, and presentation of EHR data. Over the years various professional and trade media references have included other functionality to the EHR-System, the systems architecture view remains that the EHR-S is actually a subsystem. Those additional functions, such as clinical decision support, are components of the larger clinical information system.

1.4.2.2 The Clinical Information System Defined

The clinical information system is a collection of system components arranged to perform functions that support the delivery of healthcare services. The system is logically composed of discrete layers connected through discrete interfaces:

System Component	Description
User	The system user is a human that interacts with the system through the presentation layer, or another system that communicates with it.
User Interface	
Presentation Layer	The component of a system that performs functions that process data for interaction with the user and with the application layer.
Application-Presentation Interface	
Application Layer	The subsystem component that operates on and manipulates data to perform the functions designed for the system. The application layer interacts with the presentation and data layers.
Application-Data Interface	
Data Layer	The subsystem component that persists or stores data. The data layer only interacts with the application layer.

A system user, regardless of whether a care provider, care recipient, or other authorized party, is a logical component of the system.

²⁴ Based on the clinical conceptual process model published in the ADA Computer-based Oral Health Record Concept Model version 1.0, February 1996.

²⁵ Enhancement of the process model published in the ANSI/ADA Specification 1000:2001.

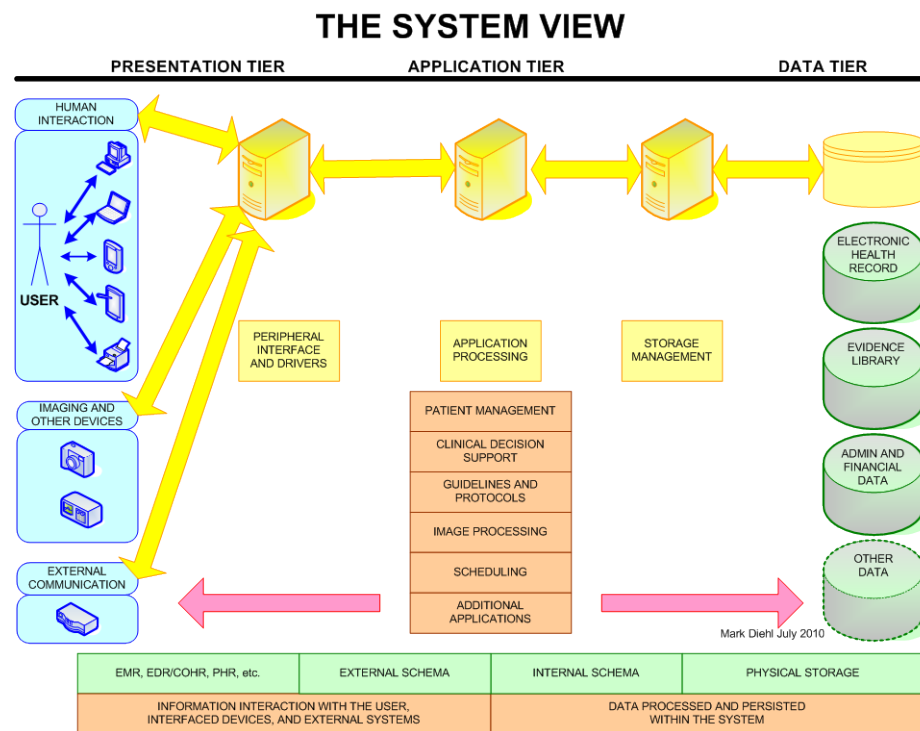
The views presented by Winter, et. al.²⁶, is typical of the architectural description of the clinical system:

- o The system is designed to accomplish functions,
- o A function is performed in an organization (in this case a clinical service) to contribute to its mission and goals, and
- o A business process describes how a function is performed.

In this document, functional requirements are defined for the clinical system as a whole rather than limited to just the EHR Subsystem.

1.4.3 Clinical Information System Components

When the logical design is translated into a physical system, the components labeled “layer” become labeled “tier”. The data tier, for example, consists of physical storage devices and the structure of stored data optimized for these storage devices. The diagram below illustrates the physical components (tiers) that correspond to the logical layers of the system design.

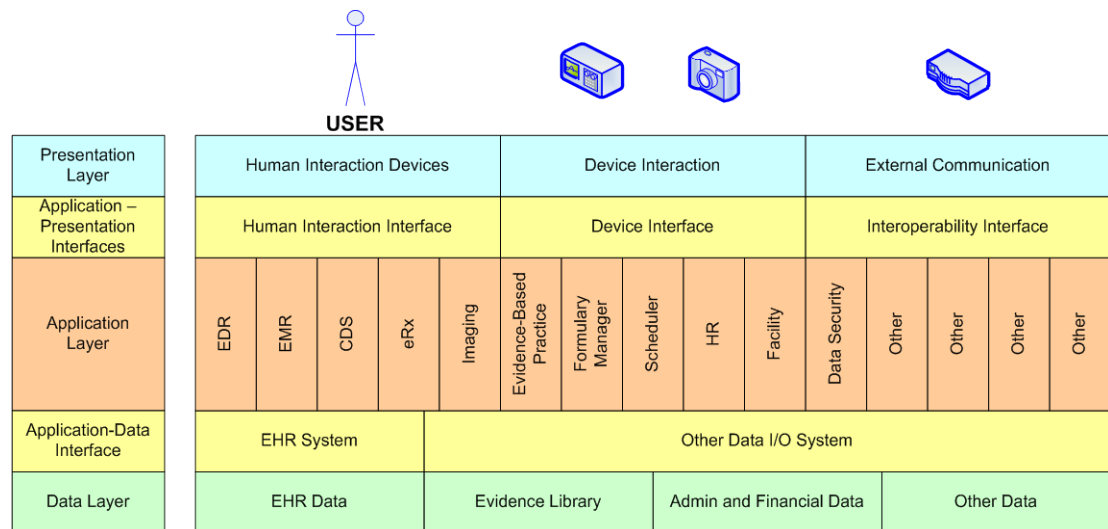


How System Components Fit Together

²⁶ Winter, A., Haux, R., Ammenwerth, E., Brigl, B., Hellrung, N. And F. Jahn. Health Information Systems: Architecture & Strategies, 2nd edition. Springer. 2011. ISBN 9781849964401.

1.4.4 System Architecture

The diagram below illustrates how the system view translates in various dental system components.



System Architecture Logical View

1.5 Referenced Documents

Document references for this specification include national and international standards, and reports, monographs, and texts from various sources.

1.5.1 National and International Standards

Standard Identifier	Standard Title
ANSI/ADA Specification 1000:2001	Standard Clinical Data Architecture for the Structure and Content of an Electronic Health Record.
ANSI/ADA Specification 1039:2007	Standard Clinical Conceptual Data Model
ASTM E1384-07	Standard Practice for the Structure and Content of the Electronic Health Record (EHR).
CEN 13606, 2000.	Health informatics - Electronic Health Record Communication.
HL7 EHR-S FM v. 1.	HL7 EHR System Functional Model
ISO/TS 18308, 2003	Health informatics -- Requirements for an electronic health record architecture.
ANSI/ADA Specification 1058:2012	Forensic Dental Data Set
ANSI/NIST-ITL 1-2011	Data format for the interchange of fingerprint, facial, and other biometric information
DICOM	Digital Imaging and Communications in Medicine

1.5.2 Published Works

The following published works were used in the preparation of this document.

Title
Abdelhak, M., Grostick, S., and M. A. Hanken. Health Information: Management of a Strategic Resource. 4 th edition. Elsevier. 2011. ISBN 9781437708875.
Amatayakul, M. K. Electronic Health Records: A practical Guide for Professionals and Organizations. Chicago: AHIMA. 2009. ISBN 9781584262190.
Ball, M. and M. Collen (eds.). Aspects of the Computer-based Patient Record. Springer. 1992. ISBN 0387977236.
Blum, B. Information Systems for Patient Care. Springer. 1984. ISBN 0387909125.
Bourke, M. K. Strategy and Architecture of Health Care Information Systems. Springer. 1994. ISBN 0387979824.
Coiera, E. Guide to Health Informatics. 2 nd edition. Hodder Education. 2003. ISBN 9780340764251.
Dick, R.S, Steen, E.B., & Detmer, D.E. (Ed.s). The Computer-Based Patient Record: An Essential Technology. Washington, DC:National Academy Press. 1991 and updated 1997.
Englehardt, S. P. and R. Nelson. Healthcare Informatics: An Interdisciplinary Approach. Mosby. 2002. ISBN 0323014232.
Goldstein, D., Groen, P. Ponkshe, S. and M. Wine. Medical Informatics 20/20: Quality and Electronic Health Records Through Collaboration, Open Solutions, and Innovation. Jones and Bartlett. 2007. ISBN 0763739251.
Higgs, J. and M. Jones. Clinical Reasoning in the Health Professions. 2 nd Edition. Butterworth-Heinemann. 2000. ISBN 0750639075.
Murphy, G., Waters, K., Hanken, M. A., and M. Pfeiffer (eds.). Electronic Health Records: Changing the Vision. W. B. Saunders. 1999. ISBN 0721673864.
Roach, W. H., Hoban, R. G., Broccolo, B. M., Roth, A. B., and T. P. Blanchard. Medical Records and the Law, 4 th edition. Sudbury: Jones and Bartlett. 2006. ISBN 0763734454.
Shortliffe, E. H. and J. J. Cimino (eds.). Biomedical Informatics: Computer Applications in Health Care and Biomedicine. 3 rd edition. Springer. 2006. ISBN 0387289860.
Strauss, S. E., Richardson, W. S., Glasziou, P., and R. B. Haynes. Evidence-Based Medicine: How to Practice and Teach EBM, 3 rd Edition. Elsevier. 2005. ISBN 0443074445.
Whetton, S. Health Informatics: A Socio-Technical Perspective. Oxford. 2005. ISBN 0195550781.
Winter, A., Haux, R., Ammenwerth, E., Brigl, B., Hellrung, N. And F. Jahn. Health Information Systems: Architecture & Strategies, 2 nd edition. Springer. 2011. ISBN 9781849964401.

Numerous additional publications from the trade and professional press, including various publications and symposia proceedings of the American Medical Informatics Association and the American Health Information Management Association, were used as background sources in the preparation of this document.

2.0 Compliance with this Specification (Normative)

The requirement statements in this document extend beyond the Electronic Health Record Subsystem and apply to electronic dental systems such as:

- o The electronic health record system,
- o The electronic dental system and applications,
- o Clinical decision support system and applications.,
- o Electronic pharmacy system and applications,
- o Dental imaging system and applications,
- o Dental patient management system and applications,
- o Managed care and similar systems and applications.

2.1 Meaning of Conditional Statements

In the requirement statements presented in this document, the words SHALL, SHOULD, and MAY convey the same meaning as in the HL7 EHR-S Functional Model document:

- SHALL means that the function is mandatory.
- SHOULD means that the function is optional but recommended.
- MAY means that the function is optional at the discretion of the developer.

In future iterations of this document, statements may be re-classified either being promoted (e.g. changing a SHOULD to a SHALL) or demoted (e.g. changing a SHALL to a SHOULD). Considering the investment needed to create a system the project team recommends that developers consider implementing SHOULD statement requirements.

2.2 Specification Compliance

Where a feature is included in a dental system, the feature must fully comply with all functional requirements stated in the appropriate section of this Specification. For example, if a dental system provides decision support to the clinician, then it must have the functionality stated in all SHALL statements of the Decision Support functional area. All SHOULD and MAY statements are optional.²⁷

²⁷ Optional requirements may become mandatory in future versions of this specification.

3.0 A Standard Health Care Information Process Model (Informative)

The functional requirements in this document are grouped and organized by healthcare process as shown in the hierarchical diagram as expanded from the process model presented in Specification 1039. In this model, providing health care services is composed of four fundamental processes:

- Managing health services
- Creating the capability to deliver health services
- Providing health services
- Supporting health service delivery.

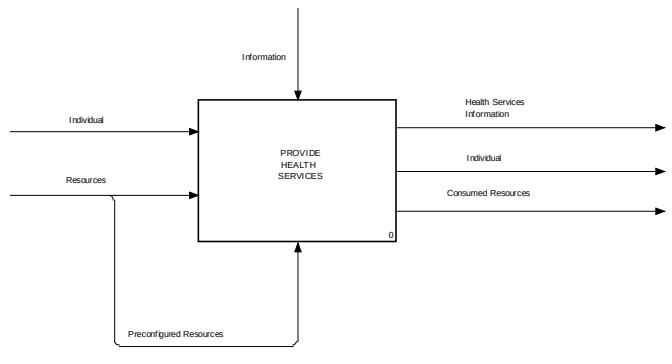
The functional requirements in this specification relate to the Provide Health Care Services process as described in this Section. As in the Specification 1039 this model employs the IDEF0 notation.²⁸

3.1 Enhanced Process Model

The functional basis of the requirements stated in this document is the health care process model from the ANSI/ADA Specification 1039 enhanced with detail from the HL7 FM function and conformance criteria, and with consensus input of workgroup members and reviewers. The Electronic Health Record component addresses data used in and produced by the Provide Population Health Services, the Provide Individual Health Services, and the Provide Health Care Support Services activities.

3.1.1 Context Diagram

The model context diagram is illustrated below:

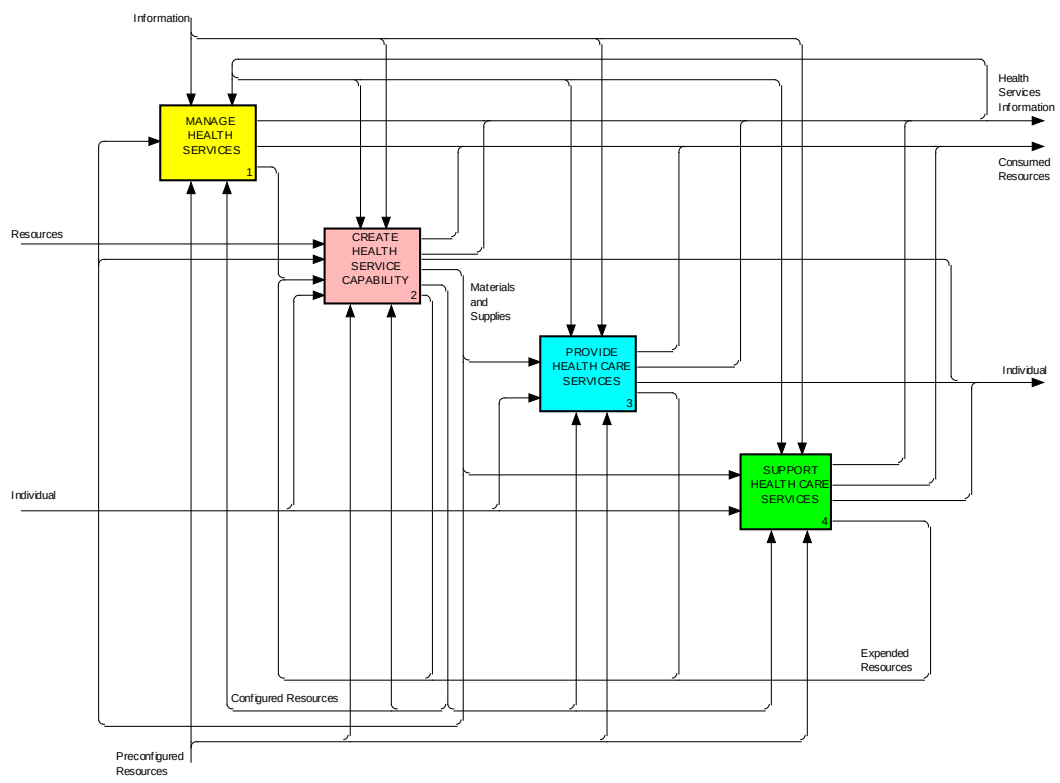


IDEF0 Context Diagram

This level of the model demonstrates health service data are recursive. Data produced by subordinate activities eventually are used to exert control over other activities at this or lower levels of the model. In the reality of the clinical setting, data can only be an output from and control health service activities – it is created and used to guide decision making. This data is always a control, it cannot be an input because it cannot be altered or destroyed.

²⁸ IDEF0 diagrams will be supplemented by UML process flow diagrams in a future publication.

3.1.2 First Level Decomposition



Core Processes of the Health Care Process Model.

As expanded from the ANSI/ADA Specification 1039:

The MANAGE HEALTH SERVICES activity involves the planning, organizing, directing and controlling sub-activities for the delivery of healthcare services. The principal product of this activity is information which various individuals use to control the health care enterprise, regulate and control personal and population health services, and present facts about the nature of, access to, the cost of, and the quality of services needed, planned or provided. Likewise, information such as government regulation, accreditation standards, and the common body of professional knowledge is used by those performing these activities. This information represents the guidance, direction and regulation required to control the other health service activities and to enable sound clinical decisions. This information is not stored in an electronic clinical record system, but may be produced by the system and is often used by the health care provider or manager through the system.

The CREATE HEALTH SERVICE CAPABILITY activity includes all activities necessary to acquire, configure for use, and maintain all resources employed in delivering health care services. Resource management is a principal function of Create Capability where these resources are changed into an output consisting of configured resources ready for use by individuals performing tasks in health care delivery, management, planning, etc., functions. The Create Capability activity is performed under the control of information, including information developed by the Manage Health Services activity. Health service information, including items such as equipment maintenance cost and supply consumption rates, is an output of the Create Capability activity. There are no entries for this activity in the electronic health record, but information created by this activity is used in the management and delivery of health care services to individuals and populations.

The PROVIDE HEALTH CARE SERVICES activity involves all aspects of health service delivery to individuals and groups of individuals, to communities, or to populations as a whole. In this activity, health services to groups of individuals are determined, planned, and resourced, and previously delivered population health services are evaluated. For the Individual, this activity produces health service data that is persisted in the electronic health record and/or other records maintained by the clinical system. The data includes identification a/o description of health services needed and delivered. This activity performs under the control of Population Health Service Direction, an output of the Manage Health Services activity. This activity also operates under control of data that becomes information used by the health care professional in the decision processes employed in the course of examination, diagnosis, treatment planning and treatment. One output from this activity is the Population Health Intervention, essentially doctor's orders for direct care to those individuals that compose the subject population. Other outputs include information that describes the population, its health status, its health care needs, and the services provided to it. Much of this information is developed through processing the data in the electronic health records of those individuals who are members of the population, and/or may be provided in electronic health record information for the population as a single entity.

The SUPPORT HEALTH CARE SERVICES activity comprises all aspects of non-patient-care activities needed to provide health care services. This activity includes components such as patient management and personal services, environmental services, and the provision of administrative and financial services. This activity produces health service data needed for patient care support and for the operation of the health care facility, and the organization as a business entity. Health care support information created by this activity becomes one element in the Health Service Information output stream with various portions used as controls in other core processes.

3.2 Relationship to EHR Data

This data can also be made available outside the course of care to an individual. An example is through a clinician's contribution to the common body of clinical knowledge – this data is then available for use by another clinician through evidence-based practice, and clinical guidelines and protocols, and professional best practices. This data also includes the basis for decisions made, courses of care offered to the care recipient or their authorized representative, services elected and services provided. Operationally, once created and attested-to by a responsible party, its data can only be read: medico-legal requirements preclude it being changed or deleted.

As previously noted, data produced by the first two activities, MANAGE HEALTH SERVICES and CREATE HEALTH SERVICE CAPABILITY are not maintained in the electronic health record, much of the data produced in the PROVIDE HEALTH SERVICES TO POPULATIONS and PROVIDE INDIVIDUAL HEALTH SERVICES activities is developed from and/or persisted in the electronic health record, while only a portion of the SUPPORT HEALTH CARE SERVICES data is persisted in the electronic health record. This specification concentrated, therefore, on these two activities as illustrated in the shaded oval of the diagram.

The diagrams along with activity designation, names and definitions are current as of the drafting of this document.

3.3 IDEF0 Note Tree Diagrams

The Node Tree is a graphic device employed in the IDEF0 notation to focus attention on the hierarchy of activities. For this Specification, the Node Tree diagram serves to organize the functional requirements according to the roles these have in patient care and the provision, management and support of health services. The Node Tree diagram for the PROVIDE HEALTH SERVICES diagram is illustrated below: