Work on standards for the EHR in the context of all such standards for the Health Information Domain (HID) began 25 years ago within ASTM's Standards Committee E-31, then named Computerized Systems which primarily focused on data capture in laboratory environments. However, in 1981 the Dept of Veteran’s Affairs (DVA) already had underway a project for Electronic Health Record (EHR) components for its facilities and one of those components that is a foundation stone for the information domain in healthcare enterprises was the Registration Module. This module had just been implemented within the DVA architecture. It thus became the subject for one of the first of E-31’s EHR standards since this module serves all functions, including those for the clinical laboratory. This present discussion document is directed at informing all of those interested in any aspect informatics standards for healthcare, as well as those individuals who may be participating in the activities of the E-31 Technical Committee, about the significance and implications of the standards documents that have been produced as a result of the work of this Technical Committee. It is critical for all individuals who may be working in the areas of informatics standards for healthcare to appreciate these implications in order for them to continue to participate in the full range of activities that lead to the use and benefits of Information and Communication Technology to healthcare. It is critical specifically because there is widespread recognized fragmentation of the activities and perspectives of both standards participants and other responsible individuals outside of standards development activities such that many activities clash and derogate the work of all of these otherwise complementary efforts that should be leading to common benefits.

The E-31 work that led to the definition of the EHR Registration module was directed at being an effort to define the conceptual content basis of what would be one part of a model for the HID and would be useful in implementing working systems (such as the VA’s beginning system). At that time, concurrent work also began by the IEEE Computer Society on the basic principles for Life Cycle Management of information systems; that effort eventually became an international effort under the Joint Technical Committee 1 (JTC1) of the ISO and IEC standards bodies. The E-31 efforts were, therefore, carefully conditioned to be complementary to the work of other SDOs but to draw on the synergy, for healthcare, of defining the meaning of the Conceptual Content. A number of leading healthcare professional discipline societies had E-31 members as participants at that time. Among them were: American Health Information
Management Association (AHIMA), American Nurses Association (ANA), American Association for Clinical Chemistry (AACC). Links were also established with other SDOs. HL7 was established in the late 1980s and NCCLS (now Clinical Lab Standards Institute – CLSI) was already active in general lab standards. Much early informatics standards work related to messaging standards for clinical laboratory data and clinical laboratory data.

Nevertheless, considerable work continued within E-31 on the core standards that underpin the structure and content of the EHR while associated E-31 work related to issues of Privacy and Confidentiality in the use of the data captured within the EHR. These standards complement the structure and content common conventions in helping to define the associated business processes that generate, and then use, both the Patient Care data that is captured in the EHR and the related Resource Management data that support the care processes. Patient Care is first priority but Resource Management is also essential. The E-31 Standards Catalog also reflects work on conventions that relate a structured approach to EHR data to textual approaches to patient care data. These perspectives must be viewed as complementary and synergistic rather than conflicting. The E-31 standards have been created to establish that relationship for the conceptual content as well as to document clear Requirements for the Implementing Technology. These standards efforts have also been directed at collaborative work with other Standards Developer Organizations (SDOs) and participation in the organizational structure of the US Voluntary Consensus Standards system as well as the International Standards system. The following discussion of the catalog of E-31 standards will seek to explain how each document contributes to this framework.

Discussion

The following list of standards documents will be briefly discussed in terms of the significance of each one within the full “Enterprise View, Life Cycle Principles” perspective. This perspective is essential for tying the conceptual content to the implementation processes for that content using the Technical Infrastructure within a given healthcare enterprise.

Standards Listing by E-31 Subcommittee

E31.15 Health Care Data Capture

OID:1.2.840.10065.1902

E1959 Standard Guide for Requests for Proposals Regarding Medical Transcription Services for Healthcare Institutions
OID:1.2.840.10065.1959
E2117 Standard Guide for Identification and Establishment of a Quality Assurance Program for Medical Transcription
OID:1.2.840.10065.2117

E2184 Standard Specification for Healthcare Document Formats
OID:1.2.840.10065.2184

OID:1.2.840.10065.2185

E2344 Guide for Data Capture through the Dictation Process
OID:1.2.840.10065.2344

E2364 Standard Guide to Speech Recognition Technology Products in Health Care
OID:1.2.840.10065.2364

E2502 Guide for Medical Transcription Workstations
OID:1.2.840.10065.2502

**E31.25 Healthcare Data Management, Confidentiality, Security and Privacy**

E1239 Standard Practice for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems
OID:1.2.840.10065.1239

E1340 Standard Guide for Rapid Prototyping of Information Systems
OID:1.2.840.10065.1340

E1384 Standard Practice for Content and Structure of the Electronic Health Record (EHR)
OID:1.2.840.10065.1384

E1633 Standard Specification for Coded Values Used in the Electronic Health Record
OID:1.2.840.10065.1633

E1714 Standard Guide for Properties of a Universal Healthcare Identifier (UHID)
OID:1.2.840.10065.1714

E1715 Standard Practice for An Object-Oriented Model for Registration, Admitting, Discharge, and Transfer (RADT) Functions in Computer-Based Patient Record Systems
OID:1.2.840.10065.1715

E1744 Standard Practice for View of Emergency Medical Care in the
Computerized-Based Patient Record
OID:1.2.840.10065.1744

E1762 Standard Guide for Electronic Authentication of Health Care Information
OID:1.2.840.10065.1762

E1869 Standard Guide for Confidentiality, Privacy, Access, and Data Security
Principles for Health Information Including Electronic Health Records
OID:1.2.840.10065.1869

OID:1.2.840.10065.1985

E1986 Standard Guide for Information Access Privileges to Health Information
OID:1.2.840.10065.1986

E1987 Standard Guide for Individual Rights Regarding Health Information
OID:1.2.840.10065.1987

Information
OID:1.2.840.10065.1988

E2017 Standard Guide for Amendments to Health Information
OID:1.2.840.10065.2017

Digital Signatures
OID:1.2.840.10065.2084

OID:1.2.840.10065.2085

E2086 Standard Guide for Internet and Intranet Healthcare Security
OID:1.2.840.10065.2086

E2145 Standard Practice for Modeling in Health Informatics
OID:1.2.840.10065.2145

E2147 Standard Specification for Audit and Disclosure Logs for Use in Health
Information Systems
OID:1.2.840.10065.2147
E2171 Standard Practice for Rating-Scale Measures Relevant to the Electronic Health Record
OID: 1.2.840.10065.2171

E2182 Standard Specification for Clinical XML DTDs in Healthcare
OID: 1.2.840.10065.2182

OID: 1.2.840.10065.2183

E2211 Standard Specification for Relationship Between a Person (Consumer) and a Supplier of an Electronic Personal (Consumer) Health Record
OID: 1.2.840.10065.2211

E2212 Standard Practice for Healthcare Certificate Policy
OID: 1.2.840.10065.2212

E2369 Standard Specification for the Continuity of Care Record (CCR)
OID: 1.2.840.10065.2369

E2436 Standard Specification for the Representation of Human Characteristics Data in Healthcare Information Systems
OID: 1.2.840.10065.2436

E2473 Standard Practice for the Occupational/Environmental Health View of the Electronic Health Record
OID: 1.2.840.10065.2473

E2538 Standard Practice for Defining and Implementing Pharmacotherapy Information Services within the Electronic Health Record Environment and Networked Architectures
OID: 1.2.840.10065.2538

**E31.35 Healthcare Data Analysis and Interoperability**

OID: 1.2.840.10065.1284

E2087 Standard Specification for Quality Indicators for Controlled Health Vocabularies
OID: 1.2.840.10065.2087

OID: 1.2.840.10065.2210
E2457 Standard Terminology for Health Informatics  
OID:1.2.840.10065.2457

Detail

**EHR Basic Structure**

These standards detail both the basic structure and its description as well as the implications of the key segments of the record.

**E1239 Standard Practice for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems**

This document describes the key initial function that supports both the EHR and the supporting ancillary services. This function establishes the root of the patient EHR data structure and all other data structures that refer to a unique patient. It enables these references to “point” to this record of demographic data rather than reproduce it. The data elements of this segment, which are further detailed in Practice E-1384 and Specification E-1633 as well as modeled in Practice E-1715, characterize the demographic attributes of an individual, any of which may be used for either management of an ancillary information subdomain or for the financial functions of Resource Management.


This Guide was originally created to give guidance to the usage of commonly assembled “terminologies” used in both paper and Electronic Health Records and to introduce systematic procedures for the usage and management of such collections. It was partially linked to the work of the ISO Technical Committee (TC-37) on terminology; these links still remain informal.

**E1715 Standard Practice for An Object-Oriented Model for Registration, Admitting, Discharge, and Transfer (RADT) Functions in Computer-Based Patient Record Systems**

This document was created in order more specifically define the data elements in the Demographic (1) and Encounter (14) segments of the EHR. Encounter segments define events and capture those attributes that have been defined by the NCVHS Core Data Set that also define a substantial fraction of reportable data for Population Health.

**E1384 Standard Practice for Content and Structure of the Electronic Health Record (EHR)**
This document, which followed immediately the completion of E-1239 that was key to all activities in the HID, was created to provide a comprehensive structure to all those data that were being collected in paper patient care records. It draws on the insights and knowledge of the AHIMA professional discipline but coupled with the contributions of the various specialty disciplines. In particular it was intended to help define the integration of clinical laboratory data with all other patient care data required in the care record. This document is referred to in various educational and informational publications about the EHR. In 1993 it was extensively referenced in detail within the book “The Computer-based Oral Health Record” prepared by an independent project of the American Dental Association.

**E1633 Standard Specification for Coded Values Used in the Electronic Health Record**

This standard specification details the value sets for explicit data attributes given in Standard Practice E-1384 and has undergone initial harmonization with the HL7 tables as well as with the X12N standards for those attributes used in the HIPAA and other resource management electronic transactions.

**E2087 Standard Specification for Quality Indicators for Controlled Health Vocabularies**

This Specification is directed at means to evaluate the various terminologies and vocabularies used within the EHR, both within defined structural elements and in textual attributes, in order that in implemented systems, various processing components can extract unambiguous data from the various segments of the EHR for both support of patient care cognitive processes and for abstraction of reportable data for analysis and characterization of patient populations. It complements Specification E-1633 in evaluating all defined vocabulary value sets used in the EHR. It has a role in the implementation of specific information architectures for healthcare enterprises.

**E2171 Standard Practice for Rating-Scale Measures Relevant to the Electronic Health Record**

This Standard Practice directly supports specific data elements within the Encounter Receipt and Disposition Phases that document Health Status. One data element in each of those phases records the overall value of an identified Health Status measure while another substructure records the array specific query responses that comprise that overall value so that, for “Quality Management” depending upon the nature of the measure, various implications of the overall status measure can be extracted for relationship to other attributes of the encounter. This Practice was created by expert health service statisticians in order to enable the ability to quantitatively analyze the quality of health services.
delivered, the nature of individual health conditions and the overall improvement in population health status. References are given to the various statistical schemes for measuring health status that might be used for any specific encounter but it does not indicate any required usage; this is the responsibility of the healthcare enterprise at which the encounter occurs.


This Specification explicitly complements that of E-1633 as well as that of the ADA standard 1039 Clinical Concept Data Model and its companion Standard Specification 1000. Each of these ADA documents and the E-31 EHR standards are consistent with each other and have major consistencies with the two major HL7 messaging standards. Since Patient-centered Care is primary in the HID, clear, explicit and unambiguous data values for these attributes are essential. The uses of these values in implemented systems in order to attain interoperability will need to be pursued and this Specification will be involved in the CCHIT certification of interoperable systems.

**EHR Views**

This group of standards describes how the basic EHR structure can be viewed for particular purposes during the range of activities in patient care either in various settings or by various specialty disciplines. They have been created, up to the present, for certain common and high priority perspectives but new standards could easily be created for any useful situation that needs to highlight those basic attributes already described for the basic EHR. In addition the CLSI standards that originated in E-31 that relate primarily to the Clinical Laboratory Information Subdomain and link the EHR to the clinical laboratory are: LIS-8A (prior ASTM E-1639), LIS-9A (prior ASTM E-2118) which most certainly utilize the Registration/ Demographic capabilities noted above for the basic EHR.

**E1744 Standard Practice for View of Emergency Medical Care in the Computerized-Based Patient Record**

This Practice was created to complement the Standard Practice E-1384 for use in Emergency Medical systems and it is compatible with 1988 CDC DEEDS report. The data in Segment 14 for Encounters contains attributes applicable to EMS responder units. The attributes are applicable to the NCVHS Core Data Sets applicable to such care settings. Recent emphasis on harmonization within the ANSI HITSP Process will require a new re-examination of all other standards that apply to EMS and emergency care that must become consistent and a part of the common conventions for an interoperable EHR.

**E2473 Standard Practice for the Occupational/Environmental Health View of the Electronic Health Record**
This recently completed Standard Practice is for viewing the common conceptual content of the EHR, as documented in Standard Practice E-1384, when it is used for occupational and environmental care that will need to be interoperable with the healthcare enterprise information architectures of the worker/individual’s private care system. It describes extensions that are common in either work settings or settings of care for managing particular environmental hazards. The common conventions needed for the communication (as guided by the ONCHIT NHII/NHIN programs) of patient data among the various provider organizations supporting a given individual will require the common conceptual content developed in this Practice in addition to those communication standards contributed by other SDOs of the ANSI HITSP. These common conventions will be used by all of the various health professional disciplines, and their professional education programs, in guiding the use of patient health data by multidisciplinary teams for patient-centered, quality managed and evidence-based care.

**E2538 Standard Practice for Defining and Implementing Pharmacotherapy Information Services within the Electronic Health Record Environment and Networked Architectures**

This most recently approved EHR “View” is directed at the primary healthcare intervention, that of administering pharmacotherapy agents. Among the key non-practitioner participants in this element of a “Treatment Plan” for an assessed and defined Health Condition are both pharmacists and clinical laboratorians (e.g. Therapeutic Drug Monitoring sub-specialists). Also a major factor is the concern for heredity effects in pharmacotherapy. This means that a view of all of the patient data that might affect decisions about a strategy about pharmacotherapy should rely on common conventions known by all participants, including both patient care and resource management aspects (e.g. e-prescribing). This Practice develops the common conceptual content basis for such conventions and calls attention to those established implementation processes for creating enterprise information architectures that deliver the desired cognitive support. It draws on the other E-31 standards on the EHR basic properties.

**Steps Involved in Implementing an EHR**

While E-31 from its early stages has recognized the IEEE-CS and ISO/IEC JTC1 general information systems engineering standards for management of system and software Life Cycles that are equally applicable to systems for healthcare, it has recognized that certain aspects of those principles were more highly relevant to healthcare enterprises and settings. Thus, Guide E-1340 and Practice E-2145 arose to expand the guidance for implemented system evolution in healthcare. These standards, however, actively point to the applicability of the general standards at particular points in the evolutionary trajectory of healthcare systems.
They emphasize how the practitioners should be involved in documenting the “Requirements” for conceptual content and system behavior that engineers will need during the design and testing processes of implementation and that both practitioners and implementers will need for Validation of Requirements and Verification of system behavior during the Life Cycle. In these processes they will be referring to both the Basic EHR and the EHR View groups of standards and the other informatics standards that these groups point to.


This Guide was created early in the evolution of health informatics standards and drew on the observed processes used in the Dept of Veterans Affairs in the development of its enterprise information architecture. These processes also influenced the first general Life Cycle Process standards of the IEEE-CS and illustrated the iterative nature of the feedback from the conceptual content specialists in healthcare to the implementer team participants.

**E2145 Standard Practice for Modeling in Health Informatics**

This Practice, which has been initially focused on Modeling in support of the healthcare community, is actually completely general but relevant to the uses of modeling within the general implementing enterprise organizational context. Nevertheless, it has immediate relevance and benefit to the healthcare community in pursuing the “Enterprise view, Life Cycle Principles” approach by supporting clear representation of Conceptual Content.

**E2457 Standard Terminology for Health Informatics**

This terminology was created explicitly to collect the full range of terms about the Conceptual Content as well as the implementing technology related to the application of ICT to healthcare. It draws on both national and international collections of terms used in describing all aspects if information architectures used in healthcare enterprises and the processes of the implementation and usage of those architectures. It draws on terms used in the information engineering literature and standards.

**Issues Relating to Textual Representation of Patient Data for the EHR**

The standards in this group of standards are directed at the principles and details of textual information captured during patient care most generally by dictation from practitioners for some part of the Basic Care Scenario. In printed paper forms the dictated and transcribed text can be incorporated into paper record systems currently operational. Alternatively, the textual “Documents” can also be
stored within EHR systems in the data elements defined in Practice E-1384. These standards provide common conventions for quality management of the capture of such data.


In integrating the conventional transcription of dictated textual observations, data and interpretations used in paper record systems into an EHR environment, common principles for maintaining the confidentiality and security of patient data must be employed and applied to the transition process whenever it occurs. This standard documents those principles.

**E1959 Standard Guide for Requests for Proposals Regarding Medical Transcription Services for Healthcare Institutions**

This standard deals with the management process for acquiring Medical Transcription Services to serve a healthcare enterprise and provide input into EHR components of that enterprise’s information architecture. It is one aspect of the application of Life Cycle Management principles to that information architecture.

**E2117 Standard Guide for Identification and Establishment of a Quality Assurance Program for Medical Transcription**

A key aspect of managing the quality of transcribed textual data incorporated into the EHR component of a healthcare enterprise’s information architecture is a quality assurance program specifically directed at this capability. This standard describes the principles in establishing such a program for this component.

**E2184 Standard Specification for Healthcare Document Formats**

This standard develops the steps for defining specific formats for textual data elements for EHRs and other aggregates of EHR abstracted data for various business model purposes of a healthcare enterprise. It assists the enterprise in developing a comprehensive plan for integrally managing both Patient Care and Resource Management information and the use of XML capabilities in its communication.


This standard provides specific guidance for managing the exchange of voice data produced by independent contractors developed as part of the healthcare enterprise business plan in a fashion that ensures integration and control of
security and privacy during the communication process and the eventual posting of such data to the EHR.

**E2344 Guide for Data Capture through the Dictation Process**

This standard addresses the principles for designing and managing the capture of dictated textual data generated during patient care and eventually posted to the EHR or paper record as part of the design of the enterprise’s information architecture.

**E2364 Standard Guide to Speech Recognition Technology Products in Health Care**

This standard addresses the principles of using speech recognition technology in the production of textual patient data during Patient Care and posting it to the EHR as part if the healthcare enterprise’s information architecture.

**E2502 Guide for Medical Transcription Workstations**

This standard addresses the attributes of workstations from capturing text through transcribed dictation in healthcare settings.

**Issues Relating to Context-Insensitive Referential/Knowledge-base Data**

This group of E-31 standards are directed at conventions for the associated and linked collections of knowledge and terminology from underlying basic and clinical science disciplines that can be “pointed to” from within an EHR patient record.

**E2182 Standard Specification for Clinical XML DTDs in Healthcare**

This standard describes specific approaches to assembling structured textual abstracts of data relating to the EHR using XML communication formats for identified representative segments of the record. This document addresses the formatting of the subject matter.


This companion document to E-2182 addresses technical approaches to designing and implementing appropriate communication formats such as those in its companion document.

**E2210 Standard Specification for Guideline Elements Model (GEM)-Document Model for Clinical Practice Guidelines**
A key “Core Competency” identified in the IOM 2003 report “Health Professions Education: A Bridge to Quality” was Evidence-based Practice. This standard details how to use the GEM common conventions for representing appropriate knowledge structures for evidence-based practice with XML conventions.

**Issues Relating to the Use and Management of EHRs in the Enterprise Business Model**

The EHR exists as an information sub-domain within a healthcare enterprise that has a working business model. Thus, the full benefits of an EHR are realized when the elements of its business model optimize first the Patient Care functions and then the supporting Resource Management functions. A key aspect of those functions has to do with managing the Privacy, Confidentiality and Access to patient data that are both parts of the EHR and of the communication processes involving patient data. This class of standards addresses guiding principles for those functions. They therefore complement the other E-31 standards that define the EHR.

**E1762 Standard Guide for Electronic Authentication of Health Care Information**

This Guide gives general guidance for the methods of authentication of specific groupings of healthcare data.

**E1869 Standard Guide for Confidentiality, Privacy, Access, and Data Security Principles for Health Information Including Electronic Health Records**

This Guide presents the basic principles related to protection particularly of individual healthcare data that may be in EHRs but also may be part of collections of abstracted data being used for research or administrative purposes in population health.


This standard addresses the initial key access problem in health information architectures of identifying and authenticating a user who is entering the system and assigning authorized roles and privileges that the user can conduct when allowed access.

**E1986 Standard Guide for Information Access Privileges to Health Information**
This standard addresses the various aspects and the principles of business practices within healthcare enterprise that affect access by individuals to confidential healthcare information. It addresses the key EHR attributes and the roles of individuals who may need access to these data during the Patient Care or Resource Management processes

**E1987 Standard Guide for Individual Rights Regarding Health Information**

This standard addresses the rights of the individual patient with respect to how the data captured in the EHR and other data structures must be protected as a responsibility of the healthcare enterprise.

**E1988 Standard Guide for Training of Persons who have Access to Health Information**

This standard addresses how a healthcare enterprise should educate and train its members to ensure protection of individual patient data used in either Patient Care or Resource Management. Competency in information protection is a specific benefit for the organization.

**E2017 Standard Guide for Amendments to Health Information**

Because information captured either in Patient Care or in Resource Management may suffer errors when originally recorded, an explicit process for amending that original entry must be developed by healthcare enterprises and be included in the information management processes and toolsets. This standard presents the principles needed.


Because recorded health information in electronic formats can be modified after original recording, a technical encryption mechanism is needed, based upon the original electronic “signature”, to authenticate that the observed data has not been in any way modified. This capability must then be a part of the EHR and the healthcare enterprise information architecture.

**E2085 Standard Guide on Security Framework for Healthcare Information**

Healthcare enterprises must develop a comprehensive business process and technical infrastructure framework in order to protect its information architecture and this standard presents the general principles for its creation.

**E2086 Standard Guide for Internet and Intranet Healthcare Security**
This standard deals with the details of the specific components of the information architecture that use Internet and Intranet communication technology. It addresses the organizational as well as technologic considerations that the enterprise must address.

**E2147 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems**

A specific task in managing access to information in the protection of privacy and confidentiality, as well as security, of the healthcare enterprise’s information assets, is a system of logs to record what individuals have accessed what information for what purpose. This standard gives specific guidance about the tools and procedures for establish such logs.

**E2211 Standard Specification for Relationship Between a Person (Consumer) and a Supplier of an Electronic Personal (Consumer) Health Record**

This Specification gives a specific description of the relationship between a healthcare enterprise EHR data structure for patient care data and a Supplier organization who may arrange to provide for a patient an online abstracted synopsis of the patient’s data from several such healthcare enterprises. This document provides information to those individuals or organizations that may be considering such arrangements.

**E2212 Standard Practice for Healthcare Certificate Policy**

This Practice identifies the technical behaviors of communicating components within the technical components of health information architectures and how they should be arranged and supervised.

**E2369 Standard Specification for the Continuity of Care Record (CCR)**

This recent Specification gives a particular and detailed description of the data, and its organization into structured textual forms, that are destined for communication between healthcare enterprises and that may not be interoperable otherwise. This Specification describes the detail for abstracting the data contained in the attributes of the EHR documented in Practice E-1384 and organizing and composing it into a textual view for transfer to other care settings which may not utilize a structured electronic representation of patient data. The textual form is used in order to provide a familiar cognitive format for information exchange that is maximally useful to practitioners currently operating in traditional care settings. It complements the EHR by allowing explicit extraction and composition for communication among such care settings. This structured text can be explicitly mapped to the data elements given in Practice E-1384 and,
therefore, expresses a common convention for this alternative representation of the patient data.