Standard Guide for Properties of Electronic Health Records and Record Systems[1]

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1. Scope

1.1 This guide covers the current understanding of the requirements for the electronic health record (EHR) that is using currently available technology to document clinical activities and related information generated during care of individuals.

1.2 This guide sets forth the fundamental principles for an electronic health record system, and its major attributes, with reference to the Automated Primary Record of Care (see Guide E 1384), which proposes content and organization of automated health care records generated in various clinical settings.

2. Referenced Documents

2.1 *ASTM Standards:*

E 1238 Specification for Transferring Clinical Observations Between Independent Computer Systems[2]

E 1384 Guide for Description for Content and Structure of an Automated Primary Record of Care[2]

E 1460 Specification for Defining and Sharing Modular Health Knowledge Bases (Arden Syntax for Medical Logic Modules)[2]

3. Terminology

3.1 *Definitions:*

3.1.1 *ancillary service visit*—appearance of an outpatient in a unit of a hospital or outpatient facility to receive service(s), test(s), or procedures; it is not counted as an encounter. (See Guide E 1384.)

3.1.2 *authorized health-care practitioner*—individual(s) licensed or certified (registered) to deliver care to patients.

3.1.3 *authorized users*—all those who have received explicit formal permission both from the person, or person's guardian, and from the operative authorities of the electronic health patient record system, to access specific data pertaining to that person. Authorized users may use the accessed data only for authorized purposes and are responsible for protecting any person-specific data from unauthorized access.

3.1.4 *clinical*—pertaining to patient care.

3.1.4.1 *clinical informatics*—the field that concerns itself with the cognitive, information processing, and communication tasks of health-care practice, education and research, including the information science and the technology to support these tasks.

3.1.5 *clinical encounter*—an instance of direct (face-to-face) interaction, regardless of the setting, between a patient and a practitioner vested with primary and autonomous responsibility for diagnosing, evaluating; or treating the patient's condition or providing social worker services, or a combination thereof. (Encounters do not include ancillary services, visits or telephone contacts.) (See Guide E 1384.)

3.1.6 *clinical episode*—a chain of events in a period of time during which clinical care is provided for an illness or a clinical problem, rendered either in an ambulatory or hospital inpatient setting. (See Guide E 1384.)

3.1.6.1 *electronic health clinical episode record*—the documentation in an electronic record of care given and services rendered during a series of encounters over a cohesive time period, such as during a hospitalization.

3.1.7 *disidentified health-care data*—health-care data that does not reveal the identity of the person or the care provider(s) (organizations or professionally licensed practitioners), or both. Disidentified health-care data are viewed as data with virtually no risk to the person's rights to privacy or to the health-care provider's rights to privacy (for example, pooled secondary diagnoses from a population of one thousand diabetics).

3.1.8 *documentation of a clinical encounter*— (with a person) typically includes description of the patient's past health history, clinical observations, diagnostic studies, health care interventions, medication history, the patient's clinical course and outcome, as well as care-related documents.

3.1.9 *computer-based information system*—a computer-based organized arrangement of hardware, software, data, and communication that provides storage and access to electronic records and functions as an orderly system.

3.1.10 *electronic health encounter record (EHER)*—documentation of the care given in association with a single clinical encounter.

3.1.11 *electronic health record*—(*1*) collection of data and information gathered or generated to record clinical care rendered to an individual. It is to be noted that the EHR is a virtual entity where the actual physical information may be distributed across various systems and geographies. (*2*) a comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information in electronic form, documenting the health care given to a single individual.

3.1.12 *electronic health record system (EHRS)*—an assemblage of technical, administrative, operational, communication, and computer-based automated functions organized to accept, process, store, transmit, and retrieve electronic clinical information for various purposes such as assistance in health-care delivery and evaluation.

3.1.13 *electronic health record system*—supports the EHR. It provides practitioner reminders and alerts, and it facilitates access to expert knowledge bases. The operative EHRS shall permit authorized health-care staff to enter, verify, manage, process, transmit, retrieve, view, or print, or a combination thereof; any or all of the EHR data. The EHRS shall permit the algorithmic creation of longitudinal electronic health care files. The EHRS shall allow authorized user access to EHR data for purposes such as clinical, educational, administrative, financial, quality improvement, utilization review, policy formulation, and research, as defined in the authorization agreement with each legitimate user. The EHRS shall protect the data from unauthorized access.

3.1.14 *electronic record*—data and information stored as a logical entity on computer-compatible media such as magnetic tape, disk, optical media, etc.

3.1.15 *granularity*—the size of the information grains that can be directly retrieved. The smallest discrete information entities determine the granularity of the record. The smallest unitary information is a clinical fact: the shortest form representing an observation, finding or statement.

3.1.16 *identifiable health-care data*—data directly related to a person's health care that are combined with, or can be readily associated with, the identity of the person, practitioner, setting, or program, or combination thereof. Identifiers typically include items such as person name, guardian, date of birth, home address, work address, date of admission, date of discharge, hospital identifiers, and practitioner(s) identifiers.

3.1.17 *longitudinal electronic health care file*—a chain of chronologically identified records on the same person documenting the care given at different times and perhaps in different settings.

3.1.18 *structured information*—finite data organized according to one or more sets of relationships.

3.2 *Synonyms and Terms Related to Electronic Health Record*—Recently, there has been a proliferation of synonyms and acronyms for concepts relating to an EHR. The terms listed below are all viewed as subsets of the electronic health record because they may not include some comprehensive aspects

such as the person's industrial health hazards, risk factors, genetic background, etc. A partial list of such terms includes:

3.2.1 Automated Clinical Record (ACR).

3.2.2 Automated Health-Care Record (AHR).

3.2.3 Computer-based Electronic Health Records (CEHR).

3.2.4 Computer-based Patient Record (CPR or CBPR), as used in the Institute of Medicine report.[3]

3.2.5 Computerized Patient Information (CPI).

3.2.6 Computerized Patient Record (CPR).

3.2.7 Electronic Patient Encounter Record (EPER).

3.2.8 Electronic Medical Record (EMR).

3.2.9 Electronic Health-Care Record (EHCR), emerging in CEN documents in Europe.

3.2.10 Electronic Patient Record (EPR).

3.2.11 Paperless Health Care Record (PHR).

4. Significance and Use

4.1 Ever since the early 1960s, when the first digital computers became commercially available, numerous important efforts have been made to transfer patient information care documentation recorded on paper to electronic health records. Initially, highly structured questionnaires, in the form of checklists, were tried.[4] In some later attempts, the computer served as a repository of data and free text, but without processing of the narrative portions. This type of system represents an early form of computer storage. Recent advances in automation of clinical text processing have helped to change the perception of electronic health records and serve as a foundation of this guide.

4.2 Increased recognition of the need for automated access to clinical data, together with development of more sophisticated tools for managing these data, have focused intense interest on electronic health data. See the Institute of Medicine report entitled, "The Computer-Based Patient Record, An Essential Technology for Health Care."

4.3 Current experience with EHR is still limited. However, it seems important to define the fundamental characteristics of an EHR at this time in order to ensure some basic uniformity, compatibility, and comparability among developing EHRs and clinical data banks. In addition, a catalog of our current understanding of EHR characteristics can serve as a focal point for adding to this understanding.

4.4 During the history of automated clinical records, the goals have changed. Initially, one goal was to transfer the recorded information from paper onto the computer without much change in the role of the patient record, per se, or access to it. In sharp contrast, the currently evolving "new generation" of electronic health records is viewed as a major source of information for the entire health-care industry and for the patient community. This drastic change in the expected availability of EHRS calls for critical assessment of the various aspects of the electronic health record, which is the purpose of this guide, and for establishing a conceptual frame of reference

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[3] Institute of Medicine Report, "The Computer-based Patient Record: An Essential Technology for Health Care," Washington, DC, 1991.

[4] Gabrieli, E. R., "Automated Processing of Narrative Medical Text—A New Tool for Clinical Drug Studies," *Journal of Medical Systems*, Vol 13, 1989, pp. 95–102.

for understanding what is meant by the terms "electronic health record" and "record system," illuminating the granularity of information needed.

5. Criteria and Characteristics for an Electronic Health Record

5.1 *Input into EHR*— Input may be by an authorized person (human input) or electronically[5] from an automated system. Human input may occur using different devices such as a keyboard, pointing device, light pen, touch screen, bar code, or voice. Automated input may occur from patient monitors, laboratory instrument outputs, bar codes, CT scans, images, electronic data transfers, or other methods. Information may be generated from a wide variety of sources across the continuum of care.

5.2 *Data Source Identification*—The source of data and information entered shall be identified (source's role, location, and system used), and the associated date and time shall be recorded. This applies to human, instrument, and automated input. Source, in this context, refers to the computer system, instrument, or individual designated by the EHRS to enter data into the EHR.

5.3 *Input Validation*— Data and information entered into the EHR shall be appropriately validated. The validation mechanism shall state the data source.

5.4 *Transaction Accountability*—The EHRS shall maintain an incorruptible automated audit trail of all activities, system usage, and logging statistics. The audit trail should be sufficient to account for each instance of human and automated access and retrieval. For example at a minimum the EHRS should:

5.4.1 Provide audit trails sufficient to track accountability for each designated step/task in the clinical or operational process (for example, who, what, when, where),

5.4.2 Provide audit trails sufficient to track accountability for each access to a designated confidential record: to view, create, amend, or copy to external media, and

5.4.3 Provide audit trails sufficient to track accountability for all processing functions that create or modify EHR content.

5.5 *Permanence of EHR*—Validated health-care information shall be stored in a protected mode, disallowing any changes or deletions. Errors in the permanent EHR shall be correctable by means of a formal process and in the form of amendments only. Such amendments shall indicate at a minimum the initiator and authorizer of the amendment, date and time, and the reason for the amendment.

5.6 *Longitudinal Health Record*—The EHRS shall provide for logically viewing all components of the EHR for a single person as a single virtual entity, and each component shall be viewed as a part of a lifelong clinical file. To this end, nationwide compatibility of patient and practitioner identifiers and EHRs will be essential. Taking into account the temporal nature of the care process, the EHRS shall permit tracking changes in the person's health status and in the clinical understanding of the person's condition over time.

5.7 *Response Time of EHRS*—In support of user activities, the response time of the EHRS shall be rapid enough so as to support the various users' activities or train of thought.

5.8 *Accessibility of EHR Data*—Validated information shall be readily accessible to authorized users and to specific patients, if so requested.

5.9 *Reliability of EHR*—The EHR shall be generated and maintained with adequate assurance that it can be viewed as a primary source of information for all the activities it is intended to support. Provision shall exist to allow retention and continuous availability of data.

5.10 *Security of EHR*:

5.10.1 Adequate data security measures shall be maintained by the EHRS to protect the person's right to privacy while permitting efficient access to data needed by authorized users.

5.10.2 The EHRS security system shall be sufficiently flexible to permit an institutional data center to carry out its own unique set of security policies. The security system should be designed to be compatible with developing standards for privacy, confidentiality, and security.

5.10.3 For each access to data the EHRS security system shall:

5.10.3.1 Certify user identity and authorization level before allowing access,

5.10.3.2 Identify each person whose information is being requested,

5.10.3.3 Establish the role or relationship, or both, of the person requesting information to the object of such request: patient, practitioner, organization,

5.10.3.4 Record the date/time and location of EHR data access,

5.10.3.5 Record the nature of the EHR access: view, create, amend, or copy to external media,

5.10.3.6 Record the scope of access (for example, identified individual information, query concerning data values for an identified group of patients or persons, query concerning disidentified aggregate data values derived from a group of patients or persons), and

5.10.3.7 Have the capability for the user to enable logging to determine specific data fields accessed.

5.11 *Data Definition*— All items in an EHR shall have explicit data definitions stored in a data repository, with sufficient characterization of all mandatory and elective data fields and their data content to be consistent with specifications established by recognized standard groups (national and international), professional organizations, local health-care institutions, and accepted user groups. For example, at a minimum the EHRS shall:

5.11.1 Incorporate uniform core data sets,

5.11.2 Incorporate uniform data definition, naming, format, coding, and classification,

5.11.3 Incorporate uniform terminology and vocabulary;

5.11.4 Establish uniform identifiers (for example, person/patient, practitioner, location),

5.11.5 Incorporate an explicit data model with application subsets, and

5.11.6 Incorporate a composite data dictionary with application subsets.

[5] Gabrieli, E. R., "Computerization of Clinical Records, Grune, and Stratton," New York, 1970.