



POSITION STATEMENT

ENCOURAGING DEVELOPMENT OF OPTIMAL HEALTH RECORD SYSTEMS

*Adopted by the IEEE-USA
Board of Directors, 11 Nov. 2011*

IEEE-USA supports appropriately designed and developed Electronic Health Record (EHR) Systems as a means of improving patient care, reducing medical errors, and enhancing the quality, safety and cost effectiveness of healthcare delivery, with assurance of the dynamic integrity of the healthcare record, and all related work products.

Below is a summary of the major IEEE-USA recommendations to achieve optimal design and development:

1. EHR Systems should comply with three sets of evolving federal criteria. First are the “Meaningful Use” criteria; second are HIPAA privacy and confidentiality standards; and third are the currently developing usability requirements for critical tasks in the clinical workflow as suggested in ISO 25062 and NISTR 7742 (see background section for further information).
2. EHR Systems should achieve immediate compliance with current criteria and urgent adoption of future and amended criteria as they are finalized.
3. EHR Systems structural and performance parameters should be included in accreditation and licensure requirements and in agency/organizational requirements within healthcare systems not subject to accreditation.
4. EHR Systems should generate a Current Clinical Summary (CCS), on request, at any point in time.
5. EHR Systems should generate an approximate or complete Lifetime Health Record (LHR), based on the medical history available within the health facility.

The detailed IEEE-USA recommendations are as follows:

1. The EHR System should be standards-based, interoperable and designed to provide quality and “Meaningful Use” measures, as specified by the Office of the National Coordinator for Health IT and the Center for Medicare and Medicaid Systems (CMS).
2. EHR Systems should be programmed to incorporate HIPAA security, privacy and confidentiality guidelines, including capture and implementation of each patient’s specific instructions and consents, with regard to both medical procedures and information sharing.
3. EHR Systems should meet anticipated usability requirements, as described in the IEEE-USA Position Statement on “Design for Use Issues in a Health Care Environment”¹ and measured as described in ISO 25062 and NISTIR 7742. These requirements should assure that the EHR System is designed to be user-friendly and not slow or otherwise complicate the work of the practitioner.
4. In addition to the requirements for Meaningful Use, HIPAA and usability, EHR Systems should be configured to provide the following benefits, in the context of meeting accreditation and licensure standards, with provision for similar action by federal authorities for federally sponsored healthcare systems not subject to accreditation:
 - The EHR System should meet the documentation, communication and coordination needs of patients, healthcare facilities, physicians, nurses, and other health professionals. This functionality will include, but not be limited to, system capacity to generate up-to-date CCSs and best possible LHRs on request, at any point in time.
 - EHR Systems should be designed to support quality of care, patient safety and medical error studies.
 - EHR Systems should be designed to support cost-containment studies relating to underuse, overuse, and appropriateness of use of preventive, diagnostic and therapeutic services.
 - EHR Systems should incorporate and facilitate use of patient questionnaires to address unmet service needs, standardized health status measurements, and health risk assessments.
 - EHR Systems should have procedures in place to periodically update the system, in response to new and changing quality standards, new medical procedures and terminology, and ability to communicate with other EHR Systems.

- EHR Systems design should anticipate future development of simulation models, which would then be used to compare quality of care, costs and outcomes projected by the idealized simulation model to the actual quality of care, costs and outcomes generated by the healthcare facility.

This statement was developed by the IEEE-USA Medical Technology Policy Committee and represents the considered judgment of a group of U.S. IEEE members with expertise in the subject field. IEEE-USA advances the public good and promotes the careers and public-policy interests of the more than 210,000 engineers, scientists and allied professionals who are U.S. members of the IEEE. The positions taken by IEEE-USA do not necessarily reflect the views of the IEEE or its other organizational units.

BACKGROUND

The EHR, CCS and LHR are new products made possible by advances in computer technology within EHR Systems.

- a. The CCS and LHR are reports to be made accessible through regional and national communication networks.
- b. CCSs and LHRs should be able to be communicated and understood within and across healthcare systems.

There are multiple levels of responsibility that pertain to EHRs, EHR Systems and the networks used to share EHR-related data:

- c. The entity generating the CCS or LHR is the party responsible for its accuracy, completeness and timeliness. This entity is also responsible for generation of reports and studies relative to quality of care, cost containment, etc.
- d. The entity providing a system for transmission of the data is responsible for assuring the integrity of the record en route.
- e. The entity receiving the record is responsible for assuring that the material received is immediately made available in useable form to the physician or other health professional caring for the patient.

Personal Health Records maintained by the patient may be modified by the patient in ways that decrease its value to subsequent healthcare providers. For example, the patient may remove or alter entries related to sexually transmitted diseases, behavioral disorders, and other stigmatizing conditions. Such errors or omissions could prove important from medical and liability perspectives.

Glossary of Key Terms and Phrases

Accreditation is a form of voluntary certification conferred by a healthcare accreditation system that declares that a healthcare plan or institutional healthcare provider (hospital, nursing home, or other) meets quality standards established by one of the three American Accreditation Systems: JCAHO, NCQA or URAC. Many states accept accreditation as compliance with licensure standards. Use of accreditation as a vehicle for assurance of implementation of IEEE-USA recommendations is recommended, because health insurance and healthcare delivery system administrators are accustomed to implementing accreditation requirements for marketing purposes, and to comply with licensure standards.

Since accreditation standards relative to EHR Systems are sure to evolve over time in response to advances in technology and policy, IEEE-USA anticipates future issuance of additional recommendations for inclusion in accreditation standards.

All American healthcare delivery systems should meet the same quality standards. "All systems" include federally sponsored healthcare delivery systems not subject to accreditation. IEEE-USA urges the Office of the National Coordinator for Health IT, the Center for Medicare and Medicaid Services (CMMS), the Veterans Administration, Indian Health Service, and the healthcare delivery programs of the uniformed services to adopt the IEEE-USA recommendations presented herein.

Certification for Meaningful Use means that the product meets federal standards under Title 45 of the Code of Federal Regulations (CFR) Part 170. This certification will meet the Meaningful Use criteria for Phase 1. Certification for Meaningful Use is a federal level certification used to qualify for ARRA/HITECH funding for implementing EHRs. An EHR that meets these criteria is standards-based, interoperable, and able to provide certain quality measures.

Current Clinical Summary (CCS) is a report generated from EHRs and the LHR for the purpose of providing other providers pertinent medical history, current problems/diagnoses, medications, current regimens of care and health insurance coverage. The CCS should include most recent blood pressure, pulse, temperature, pertinent abnormal physical findings, laboratory, x-ray and other results of recent diagnostic studies. It should also include contact information for providers (hospitals, doctors, pharmacies, etc.) currently involved with provision of care to the patient.

Electronic Health Record System (EHR System) is an overall term that includes all system products and components; related billing/finance, scheduling, and process/activity records; and storage modalities.

The **Electronic Health Record (EHR)** replaces the traditional paper medical record and adds multiple new and related functions, including reminders, warnings and components for ordering pharmacies, labs, x-rays, etc. An EHR is maintained by each provider (doctor, clinic, facility, pharmacy, health plan, etc.) to record and guide the care provided to the patient by that provider. EHR supports activities related to quality assurance, patient safety, medical error detection and public health surveillance.

HIPAA: The Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) protects health insurance coverage for workers and their families when they change or lose their jobs. It encourages widespread use of electronic data interchange and imposes requirements for security, privacy and confidentiality of health-related records and record systems.

ISO is the International Standards Organization. **ISO 25062** began as an American National Standard ANSI/INCITS 354 Common Industry Format (CIF) for Usability Test Reports. It was then revised and elevated to an ISO international standard. It imposes uniform standards for reporting on the usefulness of record keeping systems relative to the ability of the record keeping system to enhance the effectiveness and efficiency of the user. **NISTIR 7742**, as developed by the national Institute of Standards and Technology of the US Department of Commerce, adapts ISO 25062 to the healthcare setting..

Licensure is authorization to practice medicine or otherwise engage in healthcare delivery. Licensure is a state activity for non-federal healthcare entities in every state.

Lifetime Health Record (LHR) is envisioned as a report that the EHR System can generate at any point in time, when a healthcare provider, or a patient, may need such detailed data to manage health-related affairs. When generated by the EHR System for use by a healthcare provider within, or external to, the parent healthcare system, this record could also be referred to as the “**Medical Home Record.**” When generated for personal use by the patient, it could be referred to as a “**Personal Health Record.**” To the extent possible, this report would include “cradle to grave” medical history, records of immunizations, and other preventive services, health-risk data, health-status data, and current use of health-related products. Ideally, the LHR would be a longitudinal record of the information in the EHRs of all the healthcare providers of the patient, validated by the individual providers (for example, by electronic signature). Given the fragmentation of the American healthcare delivery system, ideal LHRs will be hard to secure outside healthcare delivery systems, which have served the patient for many years as a medical home.

A “**medical home**” is a doctor’s office, clinic, health maintenance organization (HMO), accountable care organization (ACO), or government healthcare provider that oversees and coordinates all of the medical care being provided to a given patient or family.

Medical Home Record (see “Lifetime Health Record,” as described above)

The term “**patient safety,**” refers to elements of the system alerting clinicians to potential problems. These elements include, but are not limited to, alarms from monitoring devices, reminders as to treatment protocols, warnings of potential drug interactions, and alerts related to major laboratory findings.

Personal Health Record (see “Lifetime Health Record,” as described above)

The term “**quality of care**” refers to process standards for delivery of diagnostic, therapeutic, or clinical preventive services.

Questionnaire: Health status (energy level, psychological and physiological fitness): These questionnaires can provide data not otherwise available to guide patient management. Responses suggesting a lower than expected level of wellness should lead the doctor or nurse to consider whether the prescribed treatment regimen is not working as intended, possible depression, a hidden malignancy, or undiagnosed medical disorder. These questionnaires can provide information of value in assessing overall quality of care. Patients can quickly and easily complete the questionnaires in waiting rooms on machine-readable paper forms. The results can be incorporated into the EHR as an addendum to the physician notes for that clinic visit. All patients should be encouraged to complete such questionnaires at each visit.

Questionnaire: Risk profile (family history, smoking, diet, exercise, etc): Results can be used to guide health education and counseling activities and to assess changes in risk profile over time. Versions are available for pediatric, teen, adult and elderly patients, and for patients suffering from a number of chronic diseases. Frequency of administration will vary from every few months for pregnant women, infants and selected chronic disease patients, to every few years for otherwise well adults. These should be voluntary on the part of the patient, with precautions taken to assure that the data are not taken out of context to discriminate against patients relative to health insurance or employment.

¹ See IEEE-USA Position Statement, Design for Use Issues in a Health Care Environment, 20 Nov. 2009. Available on-line at <http://www.ieeeusa.org/policy/positions/designforuse1109.pdf>.