

Evaluation Factors of Clinical Decision Support System in u_Healthcare Service

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Abstract—Automated intelligent, clinical decision support systems generally promote to help or to assist physicians and patients regarding to prevention of diseases or treatment of illnesses using computer represented knowledge and information. In this paper, assessment factors affecting the proper design of clinical decision support system were investigated. The required procedure steps for gathering the data from clinical trial and extracting the information from large volume of healthcare repositories were listed, which are necessary for validation and verification of evidence-based implementation of clinical decision support system. The goal of this paper is to extract useful evaluation factors affecting the quality of the clinical decision support system in the design, development, and implementation of a computer-based decision support system.

Keywords—Evaluation, Clinical Decision Support System.

I. INTRODUCTION

THE widespread use of computer and information technology changes not only the patterns of diagnosis and treatment of the patient at hospital setting, but also self-care at home and even at the working office in continuous management of health care with direct or indirect physician's contact. Moreover, the rapid advances in mobile technology provide the healthcare service even on moving status at any time at any place, which is called as the u-healthcare (ubiquitous healthcare), or mobile-healthcare. Moreover, the high computational processing power of the mobile phone and the accessibility to large volume of data set through the internet can pave the way for the healthcare applications to be knowledgeable and automated.

Due to the technology reformation and social networking demand, the advent of computer processed automated system, clinical decision support system, is necessary means both for the medical personnel, and for general users including patient and healthy people. New methods of clinical decision support system in combination with medical expert knowledge and artificial intelligence software technologies can give new impetus to the medical treatment and care management [1].

The well known clinical support system used in hospital are CAD (Computer Aided Diagnosis) in radiology department, automated arrhythmia detection system in cardiology department, and drug management system (inspection of drug-drug interactions, maximum allowable dose, alternative medications, etc) [2]. Many types of CDSS systems for

u-healthcare services are developed, and are still serviced to users: alerting the medical personnel to situations of concern, giving supplementary information for the previous medical decision, suggesting the direct intervention to a care giver, and retrospective care quality reviews [3]. It is generally regarded that the aim of the clinical support system is to provide an opportunity to improve care both to care giver and patients. The first step for the initial clinical support system is to capture the knowledge of the clinician [2]-[5], but sometimes the knowledge is not at hand. In some situations, some healthcare information can be gathered, processed and decision-made without legal and regular inspection. Patient demographics information was not securely protected. Patient healthcare information was not properly managed in the process of deriving computer processed decision, and was even gathered without person's legal consent agreement.

In this paper, assessment factors affecting the proper design of clinical decision support system were investigated. The required procedure steps for gathering the data from clinical trial and extracting the information from large volume of healthcare repositories were listed, which are necessary for validation and verification of evidence-based implementation of clinical decision support system. The goal of this paper is to extract useful evaluation factors affecting the quality of the clinical decision support system in the design, development, and implementation of a computer-based decision support system.

II. MATERIAL AND METHOD

A. Clinical Decision Support System

Clinical decision support system is the process of clinical decision making based on the evidence-based medicine [2]. Clinical decision making system has a potential to reduce medical errors and to improve healthcare quality and efficacy [2]-[5]. In conjunction with clinical support system, an evidence-based medicine can prompt it an efficient means of deriving the useful clinical decision making based on the scientific, medical evidence, which can result in the substantial improvement of healthcare quality [2]-[4].

An output of the clinical decision support system usually take the form of alerts, and reminders, diagnostic assistance, therapy planning, prescribing decision support, information retrieval, and image and bio-signal recognition and interpretation [2].

In clinical decision support system, by means of the computer-embedded knowledge and information, automated intelligent system generally promote to help or to assist physicians and patients regarding to prevention of diseases or

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treatment of illnesses [2], [5]. Thus, the design of clinical decision support system requires either medically evidenced clinical knowledge to support the clinical decision making process or the use of the known medical knowledge, which is necessary to support or assist the medical personnel and general users in healthcare domain through the computer-assisted decision making.

Generality, the effectiveness and usefulness of the decisions or steps generated by clinical decision system is highly dependent on the correctness of the gathered information to derive the decision making through the computer-automated process. Hence, the verification and the validation of gathered data for scientific, medical evidence is indispensable. Correct procedures and experimental design should be carefully managed before starting the clinical trial, necessary in evidence-based information gathering.

B. Procedures in Clinical Decision Support System

The running steps in the clinical support system consist of the two [2]-[5]. The first step is to gather information from various sources. It can be entered manually or electronically. Portable healthcare devices having the wired or wireless communication facility collect healthcare data either continuously (real-time ECG monitor) or on intermittently demanded instant (temperature, or glucose meter). Particularly, in hospital, the clinical decision support system interfaces to the hospital information system with standard protocols such as HL7 (Health Level 7) and DICOM (Digital Imaging in Communication and Medicine) 3.0. Wide spread penetration of EMR (Electronic Medical Record) and PACS (Picture Archiving and Communication System) in the hospital can facilitate an efficient means of accessing the patient information in digital format if the patient secure information is properly handled. For home users, medical devices should be IEEE 11073 compliant for interoperable operation between the device and hospital information system. Gathered information including demographic data may be from user entering process, electronically transferring process from network connected device, and system interface process from hospital information system [2]-[5].

The second step is to convert the gathered information into new information that is intended to support a clinical decision. The large volume of gathered information by lazy users (who are not well trained to operate the medical device and information system) can contain lots of wrong data and missing data. Improperly handled data can lead to the wrong decision making. Even for the data gathered at hospital can contain wrong typed errors. Either improperly handled data or missing data correction should be corrected before inputting gathered data to the decision making routine. In addition to data correction, the anonymization is required to protect patient critical information, when the clinical decision making systems interface to the hospital's large volume of repositories through the hospital information system. Also, the gathered data should be converted to new information format that helps in making clinical decision in a comprehensible way. In that case, clinical

data repository should be constructed to protect patient information and should be reformed as well organized format representation for efficient and rapid access of large volume of data. The decision making procedures are conducted in the computer automated algorithm using converted format data. Fixed or iterative algorithm, formula, data-base look ups or comparisons to establish clinical rules or associations are performed in the computer-automated decision making process. In the long run, the outcome of the decision making can be presented at a mobile application, web-based service application or desk-top application [2]-[5].

C. Factors in Clinical Decision Support System

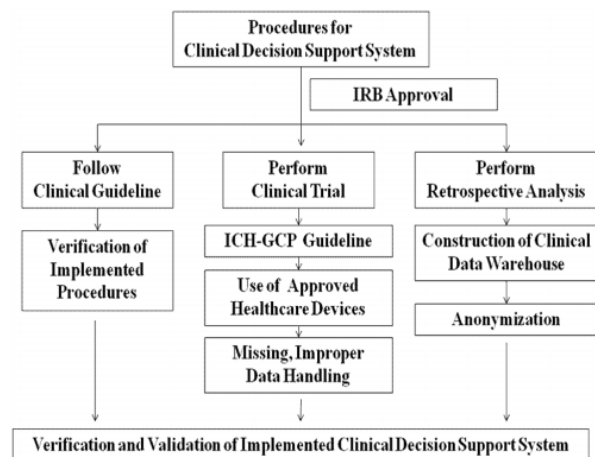


Fig. 1 Three analyzing procedures of clinical decision support system for verification and validation

The information for clinical decision support system can be obtained by clinical trial with IRB (Institutional Review Board) permission if clinically acceptable evidence or knowledge were not well established. The test by clinical trial through IRB should be based on the principles; independence, competency, justice, continuing effort, and transparency [2]-[5]. The necessity of the clinical trial, and the scientific significance should be carefully inspected before performing clinical trial, because it is for the human. Clinical trial should follow either the international ICH-GCP (International Conference on Harmonization-Good Clinical Practice) or local-domestic GCP; (a) general information, (b) background information (c) trial objectives and purpose, (d) trial design, (e) selection and with drawl of subjects, (f) treatment of subjects, (g) assessment of efficacy, (h) assessment of safety, (i) statistics, (j) direct access to source data and documents, (k) quality control and quality assurance, (l) ethics, (m) data handling and record keeping, (n) financing and insurance, (o) publication policy, and (p) supplements [6].

The clinical decision support system should be tested for verification and validation. Human problem solving, decision making procedures are not easily represented within a computer, as well as clinical decision support system can have engineering

artefacts [3]. Moreover, it is difficult to investigate the interaction of rules and computer automated algorithms. Quality assurance (assured medical procedure), safety (reduction of medical error), regulation (compliance with standards), and operational efficiency (user acceptance) should be included in the testing procedures [3]. The inference algorithm, comparison operation (established clinical guideline) or formula (evidence based rule) employed at clinical decision support system should be tested by means of large volume of testing vectors, which can be generated either by computer synthesis or real clinical data. Modular, functional, integration running test should be performed to guarantee the correctness of internally operated decision making procedure. Clinical usefulness and correctness can also be validated by blind pair-wise comparison by medical experts. Statistically, minimum false positive ratio, and minimum false negative ratio are inspected under test condition control. Also, whether the inclusion of clinically improper data handling or not should be checked. For software reliability and later audit, date and time stamp handling, missing data handling and unclear data handling should be documented and validated. The measurements should be randomized or blinded to minimize or avoid bias, and the level of significance should be recorded to represent the statistical efficacy of testing procedure.

In addition to clinical trail, and test of clinical decision rules, errors that can be introduced at clinical decision support system should be managed for good clinical data gathering [2]-[5]. The medical devices used at clinical decision support system should be approved by government agency (for example Ministry of Food and Drug Safety). Errors associated with medical devices can contain improper measurement error, improper data transmission occasionally happened during wireless transmission and jammed environment, failure of connection initiation, device failure, device malfunction, battery failure, and user's incorrect operation. The clinical support system inference engine should have functions to notify users for improper operation; automatic alarm for improper data, improper alarm for mal-functioning procedures, the occurrence time of improper operation and improper operation of decision-making inference engine.

When large volumes of data are required in the clinical decision support system from the existing database, such as electronic medical records repository that was composed by patient care procedure at the hospital, the clinical data repository should be well organized with pre-defined format and with anonymous data entry [7]. The retrospective analysis using existing data base has the branch in clinical trial for the validation of the clinical decision support system. Although the importance ordering of healthcare items for selecting the privacy protection with well-defined rule is difficult, the patient demographic information (name, identification number, etc) and patient health items enabling the individual patient identification should generally be regarded as protected items. Hence those direct items should be anonymized. The indirect items, that enable the individual identification by the

combination of several items together, are also anonymized. As a result, chart review and relevant item discovery can be done anonymized fashion.

II. CONCLUSION

In conclusion, the automated software procedures for clinical decision support system should be accurate enough with minimum false positive ratio, and false negative ratio. For resolving patient safety and confidential issues against the extracting patient health data from large volume of data repositories, the clinical decision support system should be trusted and secured. The patient information extraction policy from repository should be under the control of management security, technical security, and physical security based on confidentiality, integrity, and data protection. For information exchange among heterogeneous healthcare repositories, the healthcare devices used in clinical decision support system should be institution approved and in normal operation including wireless data transmission capability as well as should be reliable and accurate with easy user interface, and interoperable (requirement of IEEE 11073 standard, HL7 standard, and DICOM standard). For data integrity and accuracy, the designed clinical decision support system should compromise missing data, improperly measured data and miss operation data.

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