

Ethical Issues and Safety in the Use of Clinical Decision Support Systems (CDSS)

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ABSTRACT: *The number of clinical applications used in the medical field to reinforce and support physicians in the application of their medical knowledge keeps growing tremendously. But some of the problems that occur at the same time are the efficiency of those applications and the ability of the practitioners to make the right choices regarding the feedback they received from their utilization. Clinical Decision Support Systems (CDSS), also called Medical Decision Support Systems (MDSS), belong to the wide category of those clinical applications. They must be used only for secondary care purpose, and if not, the risks of malpractice due to CDSS medical based diagnoses are greater. The main concern here is the reliability of CDSS which use is supported by both hardware and software components. The reliability of CDSS can be improved by integrating fault-tolerance and redundancy in their design features so as to increase their efficiency and reduce medical errors. This helps to prevent or reduce the number of accidental cases due to malpractice and also, to mitigate potential health care risks.*

KEYWORDS: *coding, clinical-decision-support-systems, fault-tolerance, medical, reliability.*

I. INTRODUCTION

Clinical Decision-Support Systems (CDSS) belong to the wide range of expert systems used in medical practice, for in-patient care and other medical needs, to support a physician's clinical knowledge for a diagnosis. These technologies can positively or negatively impact in-patient quality of care [1]. With the increasing number of related risks and problems that they are likely to expose people to, lawyers, computer scientists, healthcare professionals and others concerned by the activities in the medical field, have condemned their use [2].

The use of Computer Assisted Coding System (CACS) in association with regular CDSS could have helped to reduce medical errors rate. Used by health care personal to analyze health care documents, CACS use natural language processing (NLP) to produce significant medical codes. These are two of the various effective clinical applications used to reduce medical errors in the diagnosis of in-patient care. But none of those clinical applications can be used without data existing in electronic health records and computerized programs written to use those records. Because they cannot be used in isolation, the reliability of these decision support applications generate specific requirements that they must fulfill and among them, their ability to accept fault-tolerance. Also, a performance requirement of both CDSS and CACS is that their design features must include efficient mechanisms for caching data retrieved from various health care networking file systems.

II. GLOBAL DESCRIPTION

1.1. What is a Clinical Decision Support Systems?

An ideal CDSS is a fault-tolerant system or at least, a system with fault-tolerance incorporated, which would execute even if an hardware failure or a software error occurred. Also, the design features of such a CDSS must include high redundancy. A combination of information redundancy with static and dynamic hardware redundancy is one of the best way to ensure the accuracy of data found in the knowledge base.

CDSS can be just reminders to a doctor or electronic alerts to their patients whenever needed. The best clinical decisions are evidence based and they support a specific clinical case [3].

A basic ethical issue could occur if the physician refused to take into account the preferences of their patients [4]. This could alter their mutual relationships with their patients.

A computer-assisted therapy based on a feedback from a deficient CDSS or a CDSS that has been misused by a confused or untrained physician is likely to be ineffective and health harmful. Even if it is a case of clinical malpractice, it is difficult to legally prove it. For this reason, it would be considered an ethical issue. The breach of the security and thus, the confidentiality of patients' health care data when processing those data over the internet or during a chat session of the physician with his patient It is obviously an ethical concern that need to be promptly and safely addressed .

Some of the questions to ask here are:

- To what extent should we rely on the reasoning skills of a physician who, like any normal human being, could be confused and unable to interact properly with their CDSS?
- what could explain a potential deficiency of a medical knowledge management system?
- is it good enough for a CDSS to meet medical standards to be an effective decision support mean?
- if such medical systems are reliable, to what extent is it appropriate to use them and to solve what specific health care problem?
- are these programs always safe to use for humans and who should be held accountable if their use generated some clinically harmful issues?
- do physicians need their patients' permission before using them?
- is it legal, ethical to use them and if yes, how should physicians use them?
- what is the best way to handle in care-patients' confidentially and what happen in case of a breach of this confidentiality?
- how to set an appropriate balance between patients' privacy and the right for health care personal to access and release their patients' health and treatment records?
- are the boundaries between ethical and legal medical issues well defined?
- How to reduce the frequency and consequences of medical errors due to the use of decisions support systems?

Most of those questions could be answered regarding local and federal regulations about malpractice jurisprudence and legislation, information systems support legislation, internal policies of the health care providers, but not all of them can be completely answered. It is also important to mention that no consensus has been reached yet about an appropriate use of CDSS so as to avoid ethical issues generated by an inappropriate use or technical malfunctioning of these tools.

The amount of electronic patient records has increased tremendously throughout years and with it, a diversification of medical assisted diagnosis techniques. In fact, clinical information provided by each CDSS is used to interpret, diagnose and address a specific medical concern. It has been proven that an appropriate use of CDSS improved physicians' performance by providing more accurate and faster diagnoses and therefore. This reduced health care costs significantly.

A basic CDSS has normally two basic parts:

-the first component is the medical knowledge base component which stores information about specific common clinical patterns. It is the knowledge base.

-a set of algorithms designed to recognize the patterns stored in the medical knowledge base. It is the medical software component.

But CDSS that do not have the knowledge base part use machine learning for clinical information analysis and those using only the knowledge base rely on health care search engines and health care providers websites.

1.2. how does it work?

The Physician use the CDSS to ask basic questions his patient must accurately answer and the MDSS matches those answers with patterns within the knowledge base (database) to provide a first diagnosis.

Data mining[5] is the common data management technique used by care providers to analyze a patient's medical history to get information to use with the CDSS. It is used to sort the available health care information of a patient to identify pathological patterns and to match them with those found in the knowledge base or if not, with machine learning. Predictive Analytics is one of the attributes of Data Mining that allow clinical practitioners to effectively analyze relationship between patterns and to forecast health issues their patients are likely to experience in the future.

When it exists, the knowledge base must be updated on regular basis for accuracy. This is possible only by integrating the CDSS with the medical workflow of health care providers or operational health care organizations.

1.3. What are some of the trade-offs and constraints related to the use of a CDSS?

Medical standards are guidelines, protocols and insights that help treat a disease and promote health care. From a utilitarian's perspective, any clinical action or medical decision should be aimed in such a way as to provide the best possible care without restriction. The design features of each CDSS should emphasize those requirements to promote the quality of health care. The feedback from a CDSS should not be a substitute to the

physician's clinical knowledge but rather a set of additional pieces of medical advices that supplement or augment this knowledge. Overall, it must be an accurate response to the physician's need for decision support to promote healthcare. The design features of a CDSS should also promote its adaption and integration to the clinical environment where it is to be used.

A CDSS has a computerized database with a huge amount of clinical knowledge that a doctor would never be able to learn and assimilate. The medical knowledge base is organized in such a way that the doctor can see a large number of his patients without facing a conflicting schedule problems.

1.4. What are some of the related well-known weaknesses?

CDSS don't tell what treatment should be applied and they cannot suggest when to end a treatment. The knowledge base of CDSS describes the symptoms of a potential health issue but doesn't tell what to do to solve the problem. Thus, side effects of a cure might not have been invoked in the knowledge base through existing patterns.

The interpretation of some clinical information might vary depending on the context, due to demographic and cultural changes. Thus, the chances of misinterpretation of a health issue if some psychological aspects of a pathology are not well addressed increase.

There are also some limitations due to the size of the electronic health database the CDSS relies on. Some CDSS might not be able to handle appropriately with huge database.

The design features of a MDSS could be a significant barrier if they do not offer a convenient and appropriate user interface.

It is also relevant to always question the reliability of the knowledge base before making a clinical decisions.

The tremendous amount of possible diagnoses and clinical healing strategies keeps increasing and MDSS cover only a small part of the related knowledge base. The user interface of a MDSS exhibits some limitations because it uses only input data, which are quantitative, while some relevant data such as the state of mind of a patient might be only qualitative.

1.5. What are some of the factors that impact CDSS implementation?

CDSS are not effective when the clinical practitioners who use them are not well trained to understand and make an accurate interpretation of the outcomes. It becomes then harder to distinguish between personal judgment and the scientific information returned by the CDSS. Bad interpretations of the information lead usually to bad decisions, then, the chances of malpractice occurrences are much higher. Experienced end-users who have been well trained and are technically supported are more likely to provide a meaningful and accurate interpretation of a feedback from a CDSS.

The availability of a patient medical record which is a legal document when no permission has been granted, could be a serious barrier to an effective utilization of a CDSS.

III. CONCLUSION

With the exponential growth of electronic health records with a huge amount of medical information, coders experience more complex procedural work. This has increased tremendously the number of medical errors and thus, the chances of an inaccurate interpretation of the feedback received from CDSS. Also, in presence of technical malfunctions, the chances to achieve the expected health care goals are reduced because the physician is more likely to provide by accident his patients with an unsafe and harmful quality of care. There is a crucial need for an accurate medical safety database with user's manuals that address also technical malfunctions of CDSS. Medical errors could be reduced if there exists rigorous fault-tolerance requirements. Support systems must be connected and communicate in an effective manner.

CDSS are life-critical systems which must be rigorously tested several times if needed through various clinical trials to ensure safety and an effective use of the applications.

The protocol used to communicate laboratories data must be reliable and moral.

Overall, medical practitioners must be able to use common sense to make effective decisions even under pressure, whenever and wherever it is needed. This requires good problem solving skills and their willingness to acknowledge their intellectual limitations about some clinical topics.

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