Aspects of Clinical Decision Support Systems

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ABSTRACT

The envisioned role of computer programs in health care is perhaps the most important. Everything we know today in medicine might not have been possible without the valuable contribution of computers. Medical knowledge in modern health care is vast and constantly changing, as well as expanding. The provisioning of Clinical Decision Support Systems (CDSSs) would enable the discovery of patterns in health data which might be important for the fight against incorrect diagnosis. Medicine uses empirical knowledge about superficial associations between symptoms and diseases. Uncertainty is a central, critical fact about medical reasoning. Many of intelligent CDSSs are based on the fuzzy set theory, which describes medical complex systems mathematical model in terms of linguistic rules. Considering the fuzzy nature of the data in a medical environment, it becomes obvious that the ability of managing uncertainty turns to be a crucial issue for CDSSs.

Since the potential of medical decision making was first realized, hundreds of articles introducing CDSSs have been published in the last three decades. But even today, only few systems are in clinical use. Even fewer are in use outside their site of origin.

This paper addresses, works out advantages and disadvantages of several approaches and compares them against possible alternatives. Finally, experiences, gained by clinical use of two introduced systems, are used to analyze the little use of CDSSs in today's clinical routine practice.

Keywords: Knowledge acquisition, medical decision support, fuzzy control, medical applications.

1. INTRODUCTION

Over the two past decades, medical treatment has made enormous progress, resulting in new medical data about the patient's condition and an increase in the complexity of medical protocols.

A computerized Intensive Care Unit (ICU) especially is an extremely data-intensive environment, resulting in enormous databases. Physicians and nurses are still performing time-consuming manual data analysis for making the most optimal medical decision for each individual patient [1-5]. Moreover, current ICU platforms are not offering an infrastructure for decision support, data-driven guidance, infection surveillance or modeling of critical illness. The provisioning of a Clinical Decision Support Systems (CDSS) in such an environment would enable the discovery of patterns in health data which might be important for the fight against nosocomial infections, incorrect diagnosis, unnecessary prescriptions, and improper use of medication.

In addition to the huge amount of data, in this special environment, the complexity of these biological systems makes the traditional quantitative approaches of analysis inappropriate. Medicine uses empirical knowledge about superficial associations between symptoms and diseases. Also, many data, symptoms, or diagnosis can be affected by incompleteness, subjectivity, and inaccuracy. In many areas the main characteristic of medical information is uncertainty.

In other words real world knowledge is characterized by uncertainty, incompleteness and inconsistency. Fuzzy set theory, which was developed by Zadeh [6], [7], makes it possible to define inexact medical entities as fuzzy sets. Considering the uncertainty or fuzzy nature of the data in a medical environment, it becomes obvious that the ability of managing uncertainty turns to be a crucial issue for CDSSs. The implications of this approach, equal with or without the fuzzy set theory, where promised to be that CDSS or Decision Support Systems (DSSs) in general deal with complex and difficult problems, and make better and more reasoned decisions. Over the years' the experience has shown that the expectations were not always fulfilled.

This paper surveys on two applications the capabilities as well as limitations of CDSS. The systems are established as real-time applications in an ICU and have reached the state of extensive clinical integration and testing at the Vienna general hospital.

2. DECISION SUPPORT SYSTEMS

Generically DSS are any type of application that support the decision making process. A DSS receives a certain amount of data as input, processes it using a specific methodology and offers as a result some output that can help the (physicians) decision-makers [5], [20]. A typical therapeutic cycle in a simplified view is shown in Fig.1.

In principle a DSS can be classified into the following six frameworks [21]: Text-, Database-oriented, Spreadsheet-oriented, Solver-oriented, Rule-oriented, and into a Compound DSS. A compound DSS is the most popular classification for a DSS [22], [23]. It is a hybrid system that includes two or more of the five basic structures of DSSs. The input data could be clinical, administrative or financial. In addition, the input data can also be a signal automatically acquired from medical devices. Depending on the methodology used by the DSS some additional data should also be available such as certainty factors for uncertainty handling by either symbolic or connectionist based DSS.

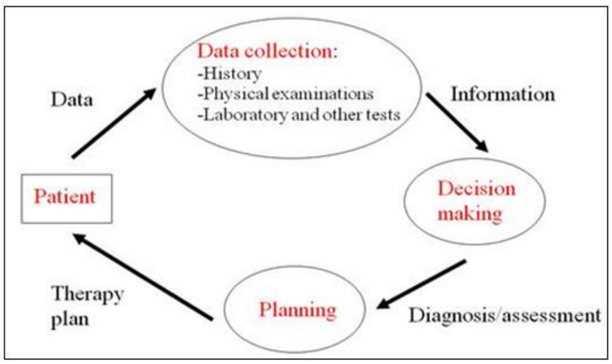

Figure 1: The Diagnostic-Therapeutic Cycle (a simplified view)

Expert or knowledge-based systems are another type of DSS capable of being programmed to perform decision making at the level of a domain expert. These systems represent the most prevalent type of DSSs used in medical clinical practices today [19].

Though CDSSs can include different components, and though domain knowledge can be structured in a variety of ways, certain elements are common to all: a user interface, a knowledge base, a database, a knowledge acquisition facility, and an inference mechanism.

2.1 Clinical Decision Support and Fuzzy Control

The concept of fuzzy set theory, which was developed by Zadeh (1965), makes it possible to define inexact medical entities as fuzzy sets [6]. The Fuzzy set theory [7], [23] derives from the fact that most natural classes and concepts are of fuzzy rather than crisp nature. On the other hand, people can approximate well enough to perform many desired tasks. By generalization of usual set theory an object cannot only be seen as an element of a set (membership value 1) or not an element of this set (membership value 0), but it can also have a membership value between 0 and 1. Therefore fuzzy sets defined by their *membership function* μ which is allowed to assume any value in the interval [0, 1] instead of their characteristic function, (Fig. 2).

A more far-reaching concept of modeling relationships was introduced by Sanchez 1979. Sanchez postulates the concept of "medical knowledge" based on a relationship between symptoms and diagnoses [14], [27].

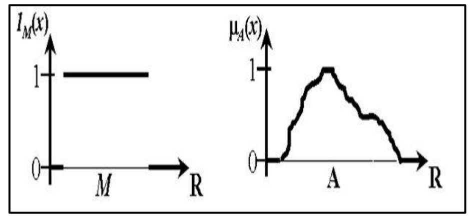

Figure 2: Characteristic function of a set *M* and membership function of a fuzzy set *A*.

Using this composition formula as an inference rule, Assilian and Mamdani developed the concept of f*uzzy control* in the early 1970s [12].

Mamdani's development of fuzzy controllers in 1974 gave rise to the utilization of these fuzzy controllers in ever-expanding capacities [13], [24]. What is needed is a system which can process quantitative and qualitative data of varying levels of precision and, by reasoning, transform this data into opinions, judgments, evaluations and advice. These new intelligent Fuzzy CDSS must be able to expect a tolerance for imprecision, uncertainty, and partial truth to achieve tractability, robustness, low solution cost, and better rapport with reality.

2.2 PDMS based Medical Applications

Based on the use of a Patient Data Management System (PDMS) the medical applications SIRS Detection and FuzzyKBWean are realized in the cardiothoracic ICU at the Vienna general hospital.

The PDMS is in routine clinical use in the cardiothoracic ICU and collects data from all available monitoring devices in intervals of 1 minute [8-10]. The system came up to more than 2 million data entries; laboratory data and blood gas analysis was done according to institutional standards; the data of daily balance and treatment was recorded every day (Fig. 3).

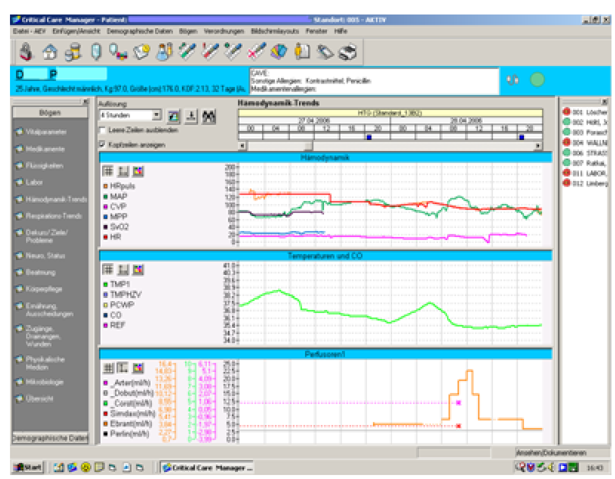

Figure 3: Cardiothoracic PDMS-chart, University Hospital of Vienna

The PDMS is the platform, the data-source, for several CDSSs, used at the General Hospital of Vienna.

2.3 Early SIRS detection

The syndrome of generalised inflammation is defined as Systemic Inflammatory Response Syndrome" (SIRS) or severe SIRS if hypotension is present simultaneously. After major surgery many patients develop signs and symptoms of generalised inflammation. The term's SIRS, sepsis, septic shock and MODS (multi organ dysfunction syndrome) are used to describe the different extents of inflammation and infections [11]. SIRS was proposed to define sepsis and its sequelae clearly in 1991, in order to make early detection of the disease possible, and to improve the ability to compare innovative potential diagnostic modalities by standardizing terms. Clinicians are facing the challenge to differentiate between post-operative inflammation a condition considered to be benign and early signs of infection [15-17].

Regardless of etiology, SIRS manifests itself through two or more of the following symptoms (Table I).

Sepsis is defined as SIRS when the systemic response is the result of an infection [15]. The development of a SIRS and sepsis are well known complications after cardiothoracic surgery. The management of sepsis based on elimination of the causative infection by surgery, antibiotics, and supportive treatment has not sufficiently changed the mortality rate over the past decades.

TABLE I: SIRS SYMPTOMS

- heart rate > 90 per minute
- body temperature < 36 or > 38 °C
- respiratory rate > 20 per minute or pCO_2 < 32 mmHg
- white blood cell count (WBC) < 4 or > 12 billion cells/liter

Sepsis remains an important and life-threatening problem and the most common cause of death with mortality between 20 to 50% for severe sepsis and 45 to 80% for septic shock [16], [18]. The progression from sepsis or severe sepsis to a septic shock with its increased mortality may be prevented by the initiation of appropriate therapy.

Implemented as a CDSS we tried to use SIRS in the ICU as a predictive tool, to prevent the risk of sepsis.

We determined in the first phase the moment of the first occurrence of SIRS and severe SIRS. In the following phase, we determined the number of SIRS episodes on the individual patient and investigated the influence of this parameter on the outcome of patients. At last we tried to discover a possibly existing relationship between the treatment and the development of SIRS in order to find an optimal time for the SIRS intervention. At the Vienna University Hospital 1925 patients were admitted during the time period mentioned above. Among those patients, we identified some cases as the second and some as the duplicate admission of the same patients. The admissions in succession of the same patients were considered as one admission, if the pause was less than 24 hours. Otherwise they were considered as two independent admissions. Severe SIRS was defined as SIRS with at least 2 of the following criteria for organ dysfunction as defined in the SOFA score [18], shown in Table II.

TABLE II: SIRS SEVERE CRITERIA

- systolic arterial pressure (SAP) < 90 mmHg or mean arterial pressure (MAP) < 70 mmHg or dopamine medication
- PaO_2/FiO_2 < 400
- bilirubin greater than or equal to 1.2 mg/dl
- creatinin greater than or equal to 100 mmol/l or urine output < 500 ml/day
- platelet count < 150000/mm^3

For prediction of severe SIRS, the knowledge base was constructed with the following input variables: body temperature, heart rate, pCO_2, WBC, SAP, MAP, PaO_2/FiO_2, bilirubin, creatinin, platelet count, and CRP. The output variable was the presence of severe SIRS in the following two hours.

2.4 Ventilator Weaning Application

The majority of patients requiring mechanical ventilation in the intensive care unit are safely weaned from mechanical ventilation within a short period of time.

Patients require mechanical ventilation during surgery, when they are anaesthetized, and must be slowly weaned from mechanical ventilation after major surgery to a point when they can breathe spontaneously. At this point, the patients can be extubated. In other words, the tube that is placed in the trachea to ensure proper ventilation is removed [8], [10]. The aim of an improved weaning process would be to make the transition from controlled ventilation to total independence (extubation) as smooth and brief as possible.

2.4.1 FuzzyKBWean Application

The in the ICU implemented CDSS FuzzyKBWean is an open-loop application that contains the knowledge and expertise of experienced intensive care physicians in computerized form.

It offers decision support for ventilator control during the weaning process of patients after cardiac surgery. The respirator changes effected by the physician have to be entered into FuzzyKBWean as a feedback for this open-loop system. The ventilator mode used for weaning must allow spontaneous breathing and a gradual reduction of the amount of ventilator support [8], [9].

The BIPAP (Biphasic Positive Airway Pressure) mode is a mode equipped with a standard ventilator [10]. This mode allows spontaneous inspiration during the entire respiratory cycle and, consequently, a very smooth and gradual change from controlled to spontaneous breathing. The fuzzy knowledge bases consist of variables, values, and rules. The variables represent the physiological parameters of the patient and the respirator settings. The values are described in linguistic terms that are formalized by fuzzy sets.

2.4.2 PDMS Data Input

The respirator settings and physiological parameters are taken as input at one-minute intervals from the Patient Data Management System (PDMS) Picis®. The PDMS is in routine clinical use, at the cardiothoracic ICU of the General Hospital of Vienna, and collects data from all available monitoring devices. The system analyzes these data and makes suggestions for appropriate respirator setting adjustments. The attending intensive care specialist (physician) is free to decide whether he will follow the given advices.

3. RESULTS AND DISCUSSION

3.1 Early SIRS Detection

With the current system it could be showed that SIRS was present in 1544 patients (92.2%), SIRS with hypotension (SAP < 90 mmHg or MAP < 70 mmHg) in 1315 (78.6%) and severe SIRS in 1175 (70.2%) of the total of patients. The time points of first fulfilment of SIRS and SIRS severe are shown in Table III.

TABLE III: FIRST FULFILLMENT OF SIRS SEVERE

time delay after surgery (h)	patients	severe SIRS	severe SIRS / severe SIRS total (%)
<6	1207	669	56.9
6 – 12	150	233	19.8
12 – 18	64	76	6.5
18 – 24	48	55	4.7
24 – 30	20	30	2.6
30 – 36	10	21	1.8
36 – 42	16	22	1.9
42 – 48	7	15	1.3
48 – 54	4	10	0.9
54 – 60	4	4	0.3
60 – 66	2	4	0.3
66 – 72	2	6	0.5
>72	10	30	2.6
total	**1544**	**1175**	100.0

The analysis of the treatment of the patient population also showed that the repeated episodes in the SIRS process are also a crucial factor of rising costs for the ICU, because the patients with several SIRS episodes received significantly more frequent and longer medical treatment than those patients who had no SIRS or only one SIRS episode. The resulting mortality SIRS to severe SIRS is shown in Fig. 4.

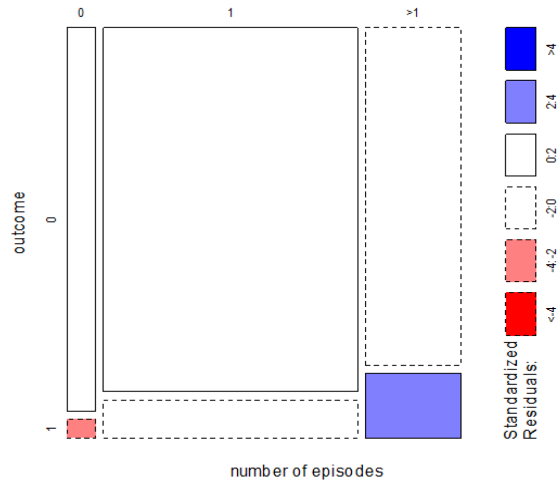

Figure 4: Mortality from SIRS to severe SIRS.

3.2 FuzzyKBWean System

The bedside real time application of FuzzyKBWean is shown in Fig. 5. The user interface has two main- units. The online (real time-data) unit, and a so called history (data base related) unit. It is possible to toggle between these units, so that always one or both of them have the focus. The top panel displays actual values and proposals, middle panel allows data review from any previous time point and, bottom panel displays key variables of the ventilation process together with the proposed new settings.

Figure 5: FuzzyKBWean frame application

The system is continuously being tested with prospective randomized cases currently undergoing treatment. It can be found that the clinical staffs react with a longer delay to hyper- or hypoventilation then the program does. The mean delay in case of hyper- ventilation was 127 minutes, Standard Error of Mean (SEM) 34; the corresponding value for hypoventilation was 50 minutes (SEM 21). The obtained results confirm the applicability

of FuzzyKBWean to represent medical knowledge, thus rendering the weaning process transparent and comprehensible. Periods of deviation from the target are shorter with FuzzyKBWean.
Due to the system is an open loop system, and therefore manual settings of the ventilator cannot be very precise, the utilisation is poor. Only a closed-loop application, i.e. a direct connection between the system and the ventilator, would allow smooth adaptation continuously.
To increase the usability of an open-loop system a more intuitive user interface has been developed.
In order for physicians to be able to make weaning decisions at the bedside, they need to be able to easily retrieve, digest, manipulate, and utilize information relevant to the decision making process. An interface approach that visualizes the actual patient status in the current weaning variation of time is shown in Fig. 6.

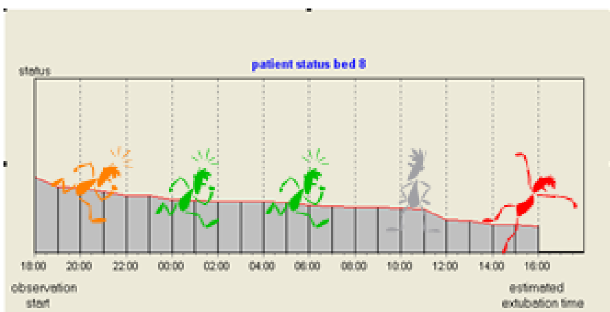

Figure 6: Progressive weaning and patient actual status

The goal is to find out an intuitive user interface that is as simple as possible and even so gives the physician a good perception where the patient is currently positioned in the weaning variation of time.

4. CONCLUSIONS

When CDSS or DSS in general where initially developed, each knowledge base and inference mechanism required programming before the knowledge base content could be written. As the field evolved, researchers found that it was possible to separate the inference mechanism from the domain specific knowledge and databases. This key design feature became responsible for the commercial success of decision support systems. Producing standard inference mechanism and knowledge bases made it possible to unplug one knowledge base and then connect a different one.
In medicine it is the uncertainty found in the process of diagnosis of disease that has most frequently been the focus of applications of fuzzy set theory. Two fields of fuzzy applications were developed since the nineteen seventies: intelligent patient monitoring systems and computer assisted diagnostic systems. Both developments of Zadeh's rule of max-min composition, namely fuzzy relations and fuzzy control, have been applied in these areas. As mentioned above, computer-assisted systems using fuzzy methods will be better able to manage the complex control tasks of physicians than common tools. Most control applications in the hospital setting have to be performed within critical deadlines.
Fuzzy Logic in medicine is still a largely untapped area that holds great promise for increasing the efficiency and reliability of health care delivery. The principles behind fuzzy logic are straightforward and its implementation in software is relatively easy.
Based on the literature, current computer-based clinical CDSS or Fuzzy-CDS systems (FCDSS) are limited in application. Roughly seventy known proprietary medical CDSS exists. Only ten out of seventy CDSSs geared towards routinely use. There is no information available about a real daily average usage of these systems.
A well-designed CDSS should have the potential to assist physicians who can and do use it as often as possible in the daily routine work. In some situations physicians learns from using a CDSS about criteria, facts or process issues that need to be considered in a specific decision situation. CDSSs encourage and promote "rationality" in decision making. CDSSs are intended to support not replace physicians, so the users need to consciously interact with a CDSS to use it effectively.
A big issue is that the expectation needs to be created that the physicians are the ultimate authority and that the physicians can anytime "over rule" or choose to ignore analyses and recommendations of the CDSS.
The greatest anticipated benefit of a CDSS lies in the constituency and uniformity in applying decision criteria of a given situation. Physicians have difficulty making decisions because they cannot exhaustively consider every factor relevant to the decision, due to either limited memory or limited information.
Anticipated limitations of CDSSs are that an optimal physician's treatment requires that physicians be able to have the following information, in real time, if possible:
What is happening right now? What will happen in the future? What do I need to create the future I want? To answer these questions effectively, physicians requires data that are factual, factual inferential (why type questions) and predictive (what if questions). To date, the best support that a CDSS has been able to provide is data that answer factual and maybe some forms of predictive questions [26].
Physicians have no shortage of data available to them. Thus, physicians have found that currently available CDSSs are not able to meet their more complex information needs. As mentioned above one big argument of the rare utilization at this time is that most of the CDSSs have not progressed beyond the prototype stage.
There are no standards or universally accepted evaluation or validation methodologies to ensure that the system's knowledge base is complete and correct.
Further questions about CDSSs are: Does the use of a CDDS improve the quality of decisions produced? And are the economic or other benefits, as for instance patients comfort, attributable to the use of the CDSS?
The absence of a well defined or universal evaluation methodology makes these questions difficult to answer.

To date, an examination of the literature indicates that there is virtually no information available related to the cost or cost effectiveness of CDSSs.

Most of the CDSSs are university-based developments, and still in prototype stage. These costs regarding the initial investment of CDDSs tend to be hidden and therefore difficult to access.

This frightens or hinders the industry's interest in funding and encouraging the development of CDSSs in health care in general [25].

Still, many physicians have a real positive outlook on the potential for these systems, particularly relating to practitioner performance. However, until the use of CDSS is a routine as the use of the blood pressure cuff, it is important to be sensitive to resistance to using these systems.

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