A Modular Clinical Decision Support System

Clinical Prototype Extensible into Multiple Clinical Settings

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Abstract— **Traditionally, Clinical Decision Support Systems (CDSS) collect patient data from physiological monitors and other sources, providing clinicians with derived instructions and information to aid treatment planning. With advancements in telecommunication networks, CDSS functionality can be extended over distances, and accessed remotely (e.g. by appropriate healthcare providers not available in the patient's immediate surroundings). This paper discusses a modular CDSS that features real-time continuous patient monitoring, high-fidelity analysis and incorporation of clinical guidelines for decision support. A modular CDSS prototype was designed, implemented and tested in a pediatric intensive care environment, by incorporating a guideline for pediatric traumatic brain injury (TBI). System outputs show successful aggregation and analysis of continuous and periodic data, and automation of guidelines by recognizing deviation of patient's condition from normal states. The modular design will allow extension into pre-hospital treatment environments by taking advantages of advances in pervasive monitoring.**

Keywords - Pervasive Healthcare, Continuous Monitoring, Real-time Monitoring, Clinical Guidelines, Visualization.

I. INTRODUCTION

Clinical Decision Support Systems (CDSS) have been developed and tested for the past four decades, with mixed indication of effectiveness. These systems are based on computer systems which handle patient data, manage clinical logistics, and provide decision support, occasionally enlisting the help of clinical guidelines [1][2]. They have tremendous potential to contribute to primary healthcare, where growing consumerism and patient expectations are placing higher demands. With the explosion of telecommunications technology, processing power and storage capabilities, these systems are no longer confined to traditional clinical settings (e.g. hospitals and clinics), for which most systems are being developed, and can be extended over telecommunication networks for pervasive healthcare. Although opinions, frameworks, and roadmaps for CDSS are abundant, the field remains embryonic[3][4][5]. As such, the design of CDSS should be considered with foresight by enforcing modularity to accommodate distribution of components into different physical areas. These considerations are taken into account for the design of a prototype CDSS for TBI in a critical care setting extensible to external environments (e.g. pre-hospital settings), where the patient is away from clinical expertise.

II. METHODS

The distance between the patient and the clinician make CDSSs even more important as providers can rely on them to provide insight into the patient's condition in the absence of first-hand examination and observation. In this case, data regarding the patient's condition needs to be collected through wearable sensors or other non-invasive devices [6]. An effective CDSS should aggregate and analyze the data, comparing it with specifications in clinical guidelines. All relevant results, both relevant data and information to support decisions, must then be distributed over a secure network connection. At this point, the information must then be accessible for visualization from any location in a format suitable for relevant and authorized providers (Figure 1).

To assist the providers making treatment decisions, we built a CDSS in 4 modules: 1) Data Collection, 2) Analysis, 3) Guideline automation and 4) Visualization.

A. Clinical Functionality

Data Collection: This prototype requires three sources of patient data: 1) bedside monitors outputting physiological data, 2) hospital databases of laboratory results, and 3) clinical observations. The first data source is output continuously in real time (every 5 seconds), whereas the latter two are entered periodically. Examples of data collected include mean arterial blood pressure, cerebral perfusion pressure (CPP), and intracranial pressure (ICP). Examples of laboratory data are blood CO_2 and O_2 levels. The clinical observation database receives data including toe temperature and Glasgow Coma Scale. Each value collected into the system is intelligently filtered for non-sensical values (eg. negative heart rates or blood pressure or ICP values over 10 0mmHG), which may indicate sensor or device malfunctioning.

Analysis: Once data is deemed valid, an analysis is performed on the updated dataset to update the decision support fields accordingly. This program analyses the patient's individual condition in terms of 5 functional systems:

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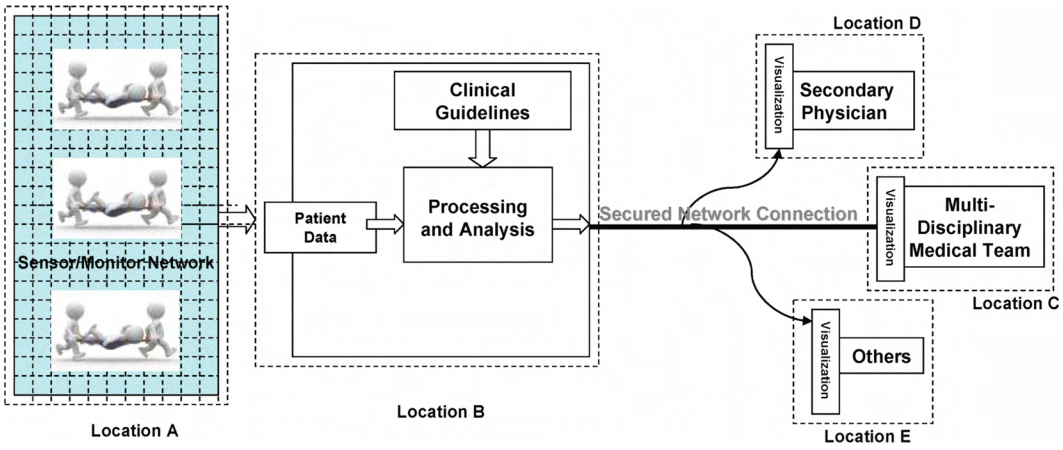

Figure 1 Overview of Pervasive Intensive Care Environment

brain, renal, hemodynamics, nutrition and respiratory, chosen based on the parameters discussed in the pediatric traumatic brain injury guidelines[7]. Thresholds for each parameter are calculated for the individual patient based on their demographics (such as age and height for systolic blood pressure), or those suggested by clinical guidelines, and compared to the latest collected values. Trend analysis is performed on applicable parameters to monitor for deviations from normal conditions and alert the provider as necessary. This is necessary in all clinical settings where the provider may be devoted to a single patient, and is especially crucial in pervasive environments where the provider is not even in the vicinity of the patient to see acute conditions. All patient data collected is logged and can be retrieved by any participating clinician for review during the patient's stay or for retrospective reviews after discharge.

Guideline automation: After comparing the patient's condition to computed values suggested by clinical guidelines, the system automatically suggests treatments from the guidelines. To implement this feature, we carefully examined the TBI guidelines and translated those into a rule base. The system traverses through the guideline, comparing real-time patient data and analysis to what was suggested in the guidelines, and displays matching treatments. For example, when the patient's ICP value exceeds guideline levels, the system will alert the physician and guide them through the series of treatment steps described by the guideline. The CDSS calculates all dosage levels, and monitors patient parameters to alert the physician about the progress of the treatment, and when sufficient conditions have been met to progress to the next treatment.

Visualization: A visual display was implemented to present the outputs of the CDSS. The display is organized into the functional groups consistent with the analysis program, and was designed for efficient information delivery. Each section has a header section, which changes color to reflect the patient's condition: green for values within guidelines and red for values outside guidelines (Auditory cues can also be programmed into the CDSS). Treatments for each functional group are presented in each area. All treatments suggested are individualized for the patient and contain patient specific values such as dosage levels embedded within the statements.

Additionally, all patient data is available in graphical or tabular values and can be selected for review. Traditionally, providers can glance at monitors or clinical records for a snapshot of the patient's condition periodically or when they're alerted. Continuous data provide much deeper insight into the patient's condition, especially when graphed [8]. These graphs allow providers to observe trends and watch for patterns that provide insight on the patient's reaction to treatments and overall condition. Proactive treatment for critical values may be much more effective. For example, dashing to lower ICP levels only when they reach 20 mmHg may be much more difficult to handle, compared to lowering ICP as it is approaching 20 mmHg. The graphs can even be manipulated to display as few or as many graphs as possible, allowing a physician to view one parameter at a time (ICP), or a combination of parameters (ICP, CPP, Urinary Output, and Heart rate) to see interrelationships.

B. Software Architecture

The software framework handles the tasks of data acquisition and validation, visualization, and treatment management in order to enable the development of protocol guideline modules as "plug-ins" to the framework. The automation of these clinical guidelines is implemented through standard procedural programming. The system utilizes an asynchronous data-driven design to support real-time information flow and user interaction. All components of the framework are modular and easily extendible, allowing for new data sources, visualization methods, and protocols to be inserted. The system is configured by assigning each protocol a manager that handles decision communication with the rest of the framework. A set of classes has been created to allow communication between the different modules along with persistence of all data, decisions, and treatments to an internal

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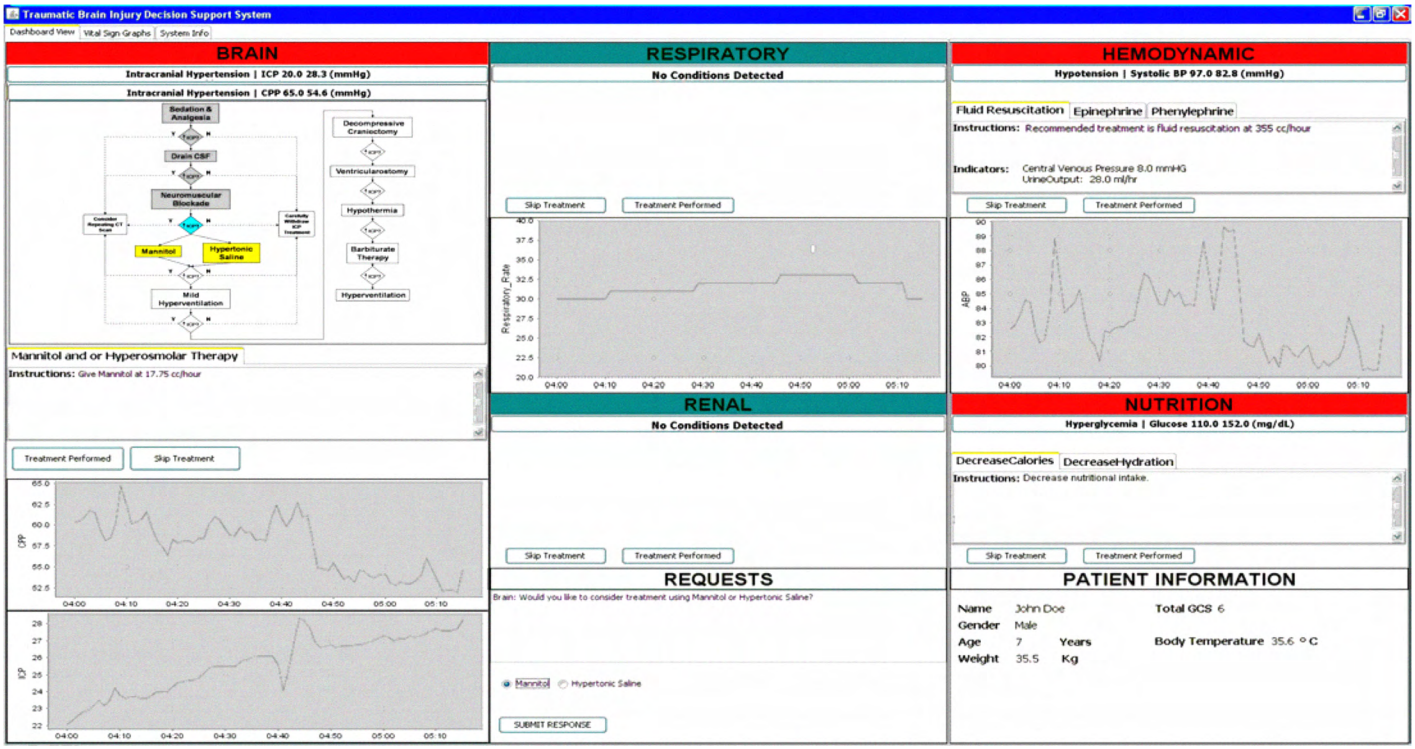

Figure 2 CDSS Output

database. In the Traumatic Brain Injury prototype, two data acquisition modules are used in the framework, one for real time patient data from the GE BedMaster software, and another for lab test results and patient medical records from the Eclipsys database (Patient data from manual entry).

III. RESULTS

A. Data Aggregation, Analysis and Visualization

A screenshot of the system output is shown in Figure 2. The display is divided into different panes. This diagram shows the status of a patient, with elevated ICP and CPP levels, hypotension and hyperglycemia.

The brain section displays a flowchart suggested by the TBI guidelines for lowering ICP, as the system guides the provider through the suggested steps. Currently, the system is suggesting mannitol or hypertonic saline, options provided by the clinical guidelines, and is asking the provider in the middle bottom section for their choice of treatment. The CDSS will then proceed to monitor the patient to see if ICP has been lowered, and/or if serum osmolarity level reaches 320 or 360 depending on whether mannitol or hypertonic saline therapy was selected. If the ICP remains high after these levels are reached, the system will suggest mild hyperventilation. The remaining sections follow the guideline in a similar manner.

In each section, graphs of key parameters are also provided to place the patient's condition in context. For example, ICP and CPP are default choices in the brain module, while ABP and respiratory rate are chosen for the hemodynamics and respiratory modules.

In the heading of each module, the condition is identified and displayed with the threshold value that was crossed and the patient's actual value. This data provides transparency to the CDSS's decision support. In the hemodynamics module, hypotension was identified. The target systolic blood pressure was computed to be 97mmHG for this patient[9], and the patient's systolic blood pressure was 82.8mmHg.

B. Monitoring Deviation from Clinical Guidelines

In an attempt to demonstrate the utilization of the program, 3 core parameters in the treatment of pediatric TBI were graphed for a single patient, who unfortunately deceased (Figure 3). These values came from continuous monitors which were accessed by the software, and span a section of the patient's stay most relevant to this paper. Solid lines on the graphs indicate derived boundaries for the 3 variables as recommended by the guidelines. The break in the data represents the time where the patient was taken for a CT scan. The patient was receiving Epinephrine at the beginning of this time interval, and adjusted as needed such as at Rx-a. Vasopressin was administered at 2:54am as indicated by Rx-b and Thiopental was administered 5:25am and repeated 3 more times, the last at 6:30am. Shortly after, the patient was taken for a CT around 8am. In contrast, the software will notify the clinician of any deviation instantaneously, and suggest treatments according to guidelines. For example, as soon as ICP exceeded 20mmHG, an algorithm would have been initiated to aggressively lower ICP. The measures include sedation and analgesia, draining CSF etc as recommended by the guidelines. Specifically, before the child was taken for a

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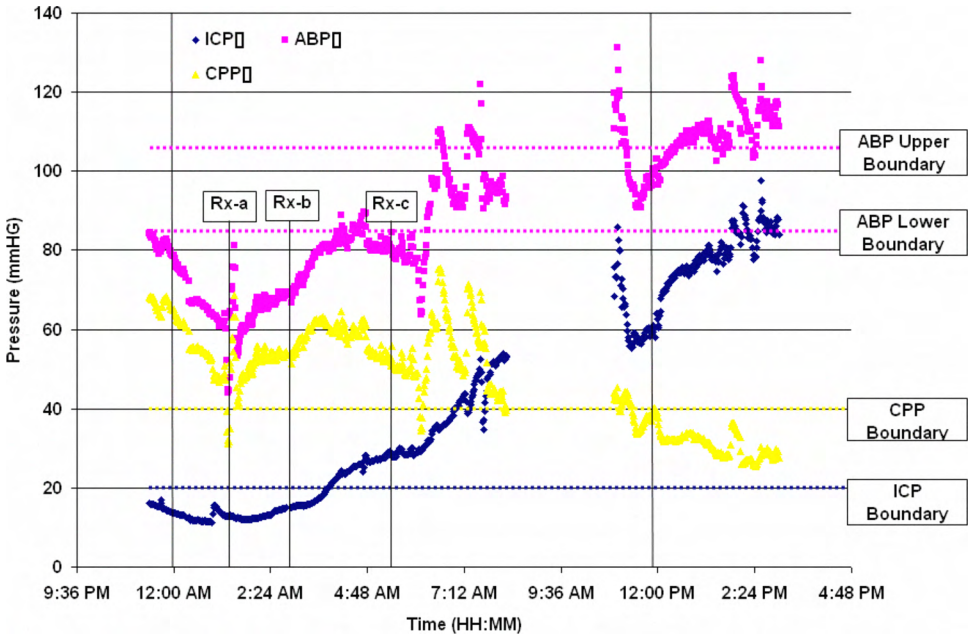

Figure 3 Pediatric TBI Patient's Deviations From Clinical Guidelines Versus Clinical Treatment

CT scan, a barbiturate coma would have been suggested. Again, one feature of the software is to remind clinicians at appropriate times, and ask for reasons for protocol deviations. It is possible, that with enough captured logic for these deviations, guideline revisions will be more evidence-based.

IV. Future Work and Vision

Much consideration has been done to make the system scalable and modular. Although the prototype demonstrates the integration of data, analysis, guideline automation and visualization, further work is planned to improve the CDSS. Currently, only the TBI guidelines are programmed into the CDSS but more clinical guidelines will be gathered and programmed to provide multi-organ system monitoring of as many conditions as possible (e.g. more robust hemodynamic CDSS and mechanical ventilator CDSS). This will call for monitoring of even more continuous parameters. Lessons can be learned from previous projects which incorporated guidelines into CDSS [10]. Crucial for pushing the CDSS into the pre-hospital settings will be the use of non-invasive and/or "easily invasive" sensors.

Finally, with all the information available from multiple patients, many studies can be conducted, both retrospectively and in real-time, to identify patients with "like conditions" and/or who have followed "like trajectories". These population based patterns may be extremely useful to both medical and non-medical staff.

V. Conclusion

For pervasive computing to have patient care impact, real-time, multi-parameter, multi-database, CDSS must be possible. We designed and implemented a multi-parameter CDSS, with distributable components, that takes advantage of telecommunications and is extensible to decision support over a pervasive healthcare environment. This pilot project demonstrates the viability of this concept, and forms the basis for a comprehensive multi-organ CDSS for pervasive healthcare.

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