Remote Medical Evaluation and Diagnostics (RMED) - *A Testbed for Hypertensive Patient Monitoring*

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I. INTRODUCTION

Health care costs have surpassed $2 billion per day in the United States. For the Department of Defense faced with shrinking budgets, reduced medical staffs, and increased patient commitments this poses a particularly challenging problem. One solution being touted to allay this situation is the use of remote medical diagnostics. In its simplest form, remote medical diagnostics involves the collection, monitoring, and analysis of patient data from remote locations (home) via a communication device. Toward this end, the U.S. Army Research Laboratory (ARL) in collaboration with the St. Louis Veterans Administration Medical Center (VAMC) is developing a system is known as RMED for remote medical evaluation and diagnostics that combines remote monitoring capabilities with intelligent decision support technology.

The first area identified for use with the RMED system is hypertension. By one estimate there are over 58 million persons with hypertension or high blood pressure in the United States. Left untreated, the side effects associated with this disease are disastrous: coronary artery disease, congestive heart failure, stroke, renal disease, and retinopathy. At present, the most common method for managing and measuring hypertension requires office visits and the use of a sphygmomanometer (blood pressure cuff). Unfortunately this method requires a dedicated amount of a physician's time and does not guarantee correct results.

Required is a system that removes the constraints of having the patient in the doctor's office and at the same time provides the provider with a decision support tool to assist in diagnosis, evaluation and management of patient care. To be effective, the system needs to provide the ability to manage new patients (diagnosis), existing patients (reevaluation), and medicinal change patients (medicine fine tuning) scenarios. The system would improve health care management through improved data collection and analysis, reduce hospital visits, and provided valuable new insights into the effectiveness of current treatments methods. Outlined in this paper is an overview of the prototype RMED system, the preliminary results of an early pilot study and the future direction associated with this program.

II. WORKING PROTOTYPE

Capitalizing on the lessons learned from an earlier successful knowledge engineering program, the Turbine Engine Diagnostic Expert System [1], a team of computer scientists from the ARL along with a group of military physicians have designed and developed a working prototype of RMED for hypertension health care. At its highest level of abstraction, the RMED system can be viewed as a collection of three processes linked to a central knowledge base. Information flow between the processes and the knowledge base is depicted in Figure 1. The system combines the best of commercial off-the-shelf technology with advanced software engineering.

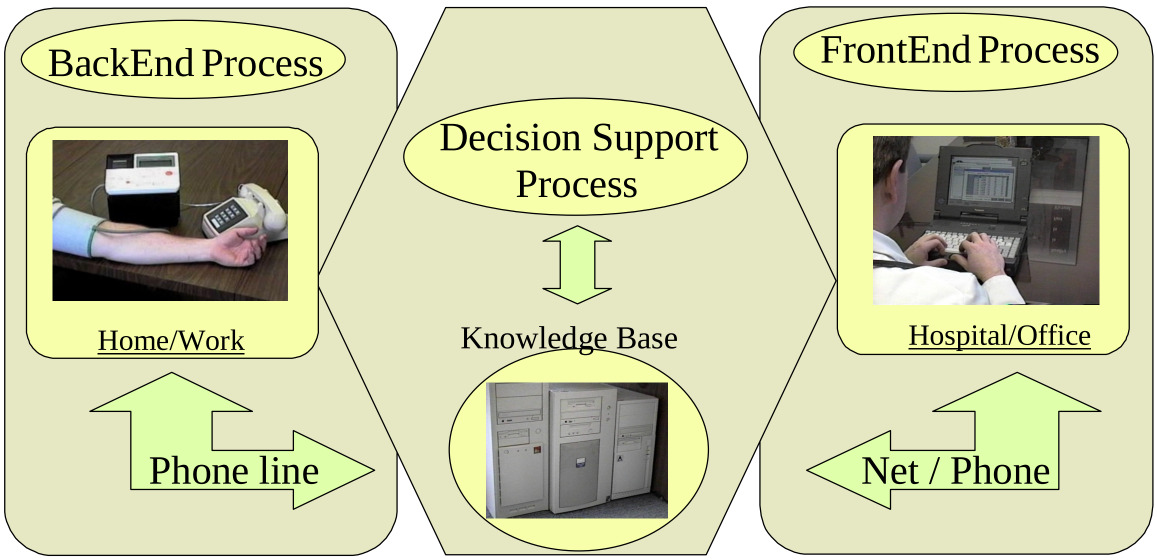

Figure 1: System Overview

BackEnd Process: For the backend process or *remote component* of the RMED system, ARL engineers successfully modified a commercial off-the-shelf (COTS) portable digital sphygmomanometer (blood pressure cuff), to allow connectivity with a smart-modem device. The backend process is the data acquisition module and links the COTS hardware to the knowledge base software. This portion of the system, along with its associated software, frees the doctor and patient from the constraint of mandatory hospital visits; allowing instead the patient to independently download "readings" to a centralized knowledge base. Once readings are received at the hospital the data are passed through a number of filters to determine appropriate action (i.e., pager alerts and e-mail).

FrontEnd Process: For the frontend process or *hospital component* of the RMED system, the physicians are provided a suite of software to assist in the evaluation, diagnosis and management of hypertension patients. As new patient data is downloaded, doctors are alerted to "red flag" situations, provided reports and graphs, and given access to the decision support tool that is still under development. The frontend of RMED is a graphical user interface (GUI) developed in Visual Basic and allows the provider access to all patient data. From the frontend, the provider enters new patients, prints reports and graphs, and performs basic statistical routines on the data. A sample of the frontend is shown in Figure 2.

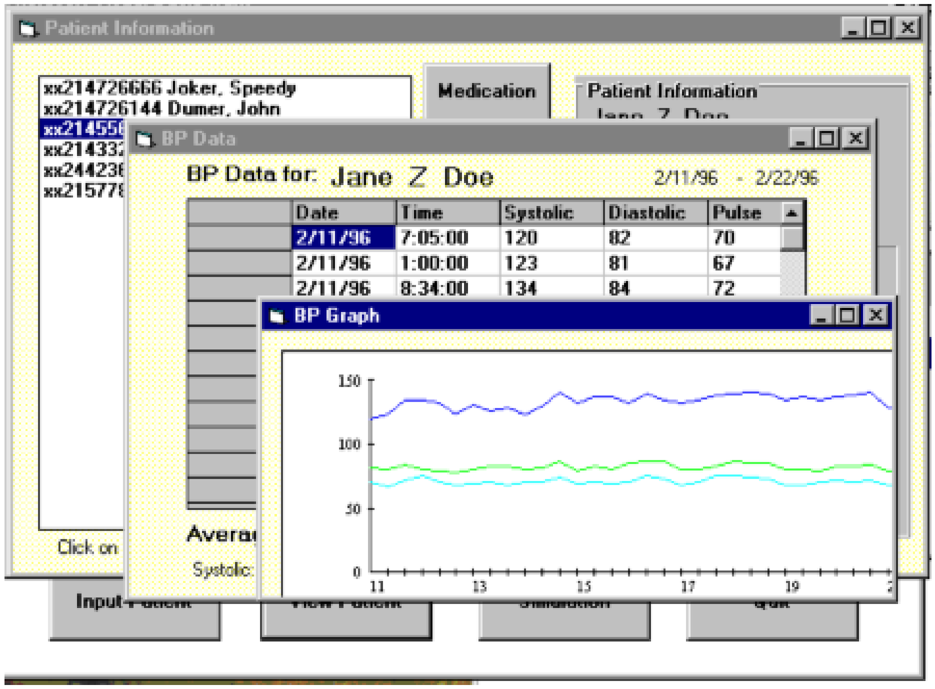

Figure 2: Sample FrontEnd Screen

Decision Support Process: The third and most challenging component of the RMED system is the decision support process. Within the decision support process or *patient profiler* of the RMED system is found the intelligence of the hypertension RMED project. Here lie the diagnostic and evaluation capabilities. The *patient profiler* is actually an extension of the frontend that gives the doctors the ability to efficiently and effectively diagnose new patients, reevaluate existing patients, and fine tune medicinal solutions. This portion of the program is still under development and the topic of the future effort section of this report.

III. PILOT STUDY

There is advantage to be gained from the increased precision, accuracy, and prognostic value of self-measured blood pressure [2,6,7]. Differences among blood pressure readings are noted in several studies according to where and how the readings were taken [1-6]. Differences are observed between home and clinic measurements and among methods: digital sphygmomanometer, ambulatory, mercury sphygmomanometer. And although the mercury sphygmomanometer is still viewed the gold standard owing to the many studies linking those readings to hypertensive illnesses, self measures are being recommended in studies of treatments for hypertension [3,4]. An ad hoc panel charged with reviewing the literature and making recommendations on BP measurement found that self-monitoring can be accurate for establishing baseline pressures, for evaluating the effect of antihypertensive medication. Further, self-monitoring may be statistically more reliable and more cost effective in patient care [6].

Table 1. Data Collection Schedule

		Day										
		1	2	3	…	15	16	17	18	…	30	31
Grp. A	Patient	Office	Home / RMED				Office	RMED / Home				Office
	1	3 BP	AM PM	AM PM	…	AM PM	3 BP	AM PM	AM PM	…	AM PM	3 BP
	2	"	"	"	…	"	"	"	"	…	"	"
	…											
	10											
Grp. B	1	"	"	"	…	"	"	"	"	…	"	"
	2											
	…											
	10											

The proposed RMED-hypertension system, a digital sphygmomanometer linked through a smart modem to a centralized knowledge base at the hospital, capitalizes on the benefits cited for self-monitoring and extends them by automatically data basing the home measurements and by allowing physicians to see and interpret measurements as they are remotely taken.

The purpose of the pilot program is to verify that the new system can automatically deliver reliable, self-measured BP to a centralized hospital component, where reliability is assessed relative to current measurement procedures.

Protocol

The recommended protocol provided to the St. Louis VA is based on two of the referenced studies [5,7]. Portions of the protocol follow. A data collection schedule is suggested in Table 1. We propose that 20 patients be included in a one-month pilot program. BP readings will be taken on these patients by a physician using a mercury sphygmomanometer, by standard home monitoring, and by the new automated home monitoring. Patients will be randomly divided into two groups of 10 (A and B). Ideal is that patients cover a range of BP readings consistent with those seen by the St. Louis VA. On day 1, a health professional measures BP for the 20 study participants. Patients should be at rest for at least five minutes. Three measurements should be taken and recorded. Group A patients are given the standard home monitoring system, patient logbooks and instructions. Group B patients are given the automated home monitoring units, logbooks, and instructions. During days 2–15, patients are asked to take their BP during 6–8 AM and 6–8 PM and record the readings in their logbooks. On day 16, patients return to the hospital and are again measured by a health professional in the same manner as on day 1. Patients turn in their logbooks for the first 14 days. Now, home measurement systems are switched between groups. Group B patients are given the standard home monitoring system and patient logbook and group A are given the automated home monitoring units and patient logbook. During days 17–30, patients are again asked to take their BP during 6–8 AM and 6–8 PM and record the readings in their logbooks. On day 31, patients return their home monitoring units and patient logbooks and are measured a final time by a health professional in the same manner as on day 1.

For each office visit, the three BP measures will be averaged. After testing for differences across visits, office BP will be pooled. For each home monitoring session, the 14 measures will be averaged separately for morning and evening time periods. Values within a patient are treated as correlated, and values across patients are treated as uncorrelated. These data will support comparisons among the three methods: office and home BP, office and automated (RMED) home BP, and home BP and automated home BP. Comparisons can be made using both morning and evening BP values. Data will also support comparison of automated home BP monitoring and patient logbooks. Standard deviations can also be computed over the 14 measurements taken by each patient using each home system during the morning and the evening and over the three office visit measurements. Comparisons of precision will also be made through standard deviation pairs after a log transformation to approximate normality.

To move beyond the pilot study, the automated home unit should show results, in accuracy and precision, relative to professionally taken readings "no worse than" the present home monitoring unit. For example, we might expect the automated home units to show a precision less than that of the standard home unit because operator (patient) variability in reporting is removed. We would also expect that the automated home units would show average BP less than the professionally taken measurements due to the "white coat" effect. Thus, either no significant differences should be observed or small significant differences should be in the right direction. If no *measurement* differences are concluded it is appropriate to move forward, because the new system provides, in addition to an equivalent measurement device, a hospital-located repository of data and decision support from the RMED software. The literature cited suggests that increasing monitoring data will improve care [6].

Analysis

A preliminary graphical analysis follows based on the patient data available at the time of the presentation.

Only 11 of the 20 patients participating had completed the study. We make a few observations. The next four figures are structured similarly. The recording method appears on the x-axis and a summary statistic (mean or standard deviation). Patient numbers range from 1 to 14, with patients 4, 5, and 10 missing. The order of recording method is shown by the line type. Dashed lines indicate the RMED unit was used first. Dotted lines indicate the traditional home unit was used first. Patients are separated by color within recording method order.

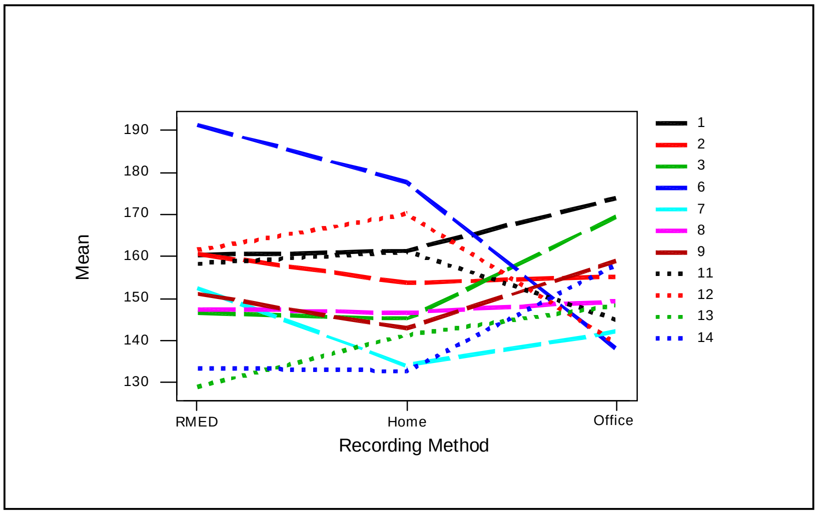

Figure 3: Systolic BP Mean by Recording Method

In Figure 3 we have the mean for the systolic BP for each patient using each recording method. Previous studies show the standard deviation to be approximately 16 mm Hg. Then, with approximately 28 observations, 3 standard errors can be considered about 9 mm Hg to provide a frame of reference. The figure shows some patients, for example patients 2 and 8, show little difference across recording methods. Some, for example patients 3 and 14, may be exhibiting the classic white-coat hypertension (office visits are higher). Patient 6 is unusual in this respect. He shows the lowest systolic BP during office visits. This patient has been in the care of the St. Louis VA for some time. His behavior in this study is consistent with past experience.

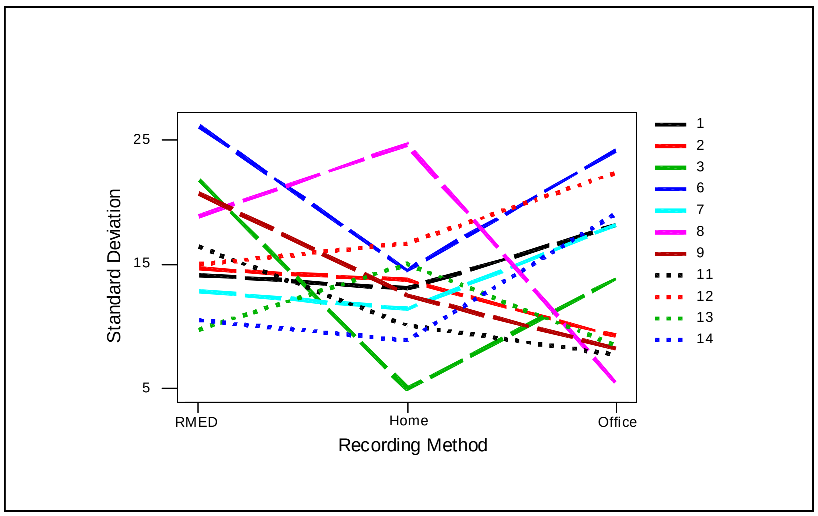

Figure 4: Standard Deviations for BP

In Figure 4, the standard deviations are shown for the systolic BPs. Patients 3 and 6 are interesting. They show markedly lower variation in home measurements as compared with RMED measurements.

Figure 5 and 6 show the diastolic BP readings. Based on previous studies, 3 standard errors is about 6 mm Hg. Diastolic BP readings appear to be more consistent over the three measurement approaches. Patients 3 and 6 again show a reduction in mean BP going from RMED to home measures. Generally we see a slight drop in standard deviation going from RMED to home measurements.

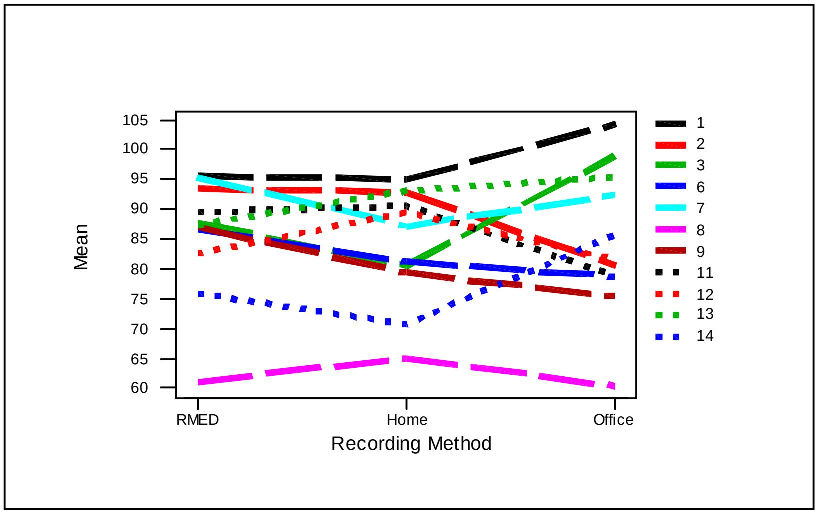

Figure 5: Diastolic BP Mean by Recording Method

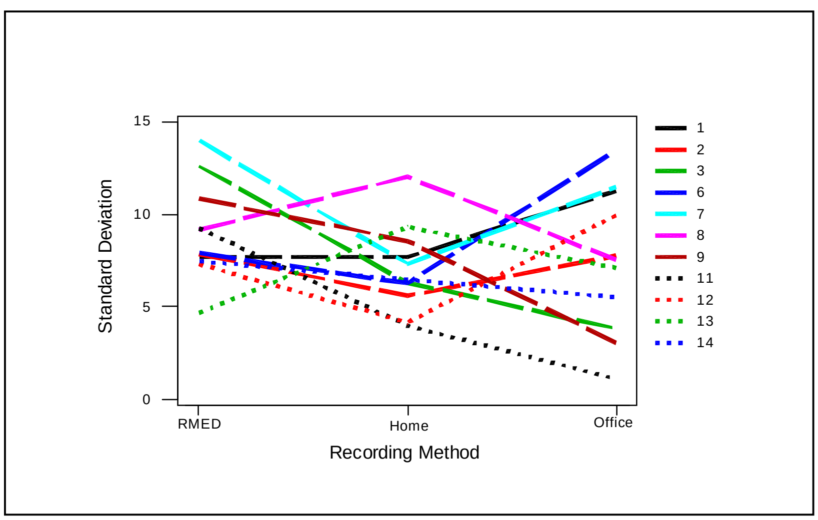

Figure 6: Diastolic Standard Deviation by Recording Method

Figure 7 shows the individual systolic readings recorded in order for patient 3. The first measurements were taken using RMED and the second half were taken using the traditional home measurement method. Notice the drastic reduction in standard deviation for the traditional home measurements. The device performance was compared with the results of another patient and found not to exhibit greater standard deviation. We conjecture that patient 3 accepted the mean measure given by the RMED unit and cooked the data for the home measurements. In their awkward attempt, they did not capture the standard deviation.

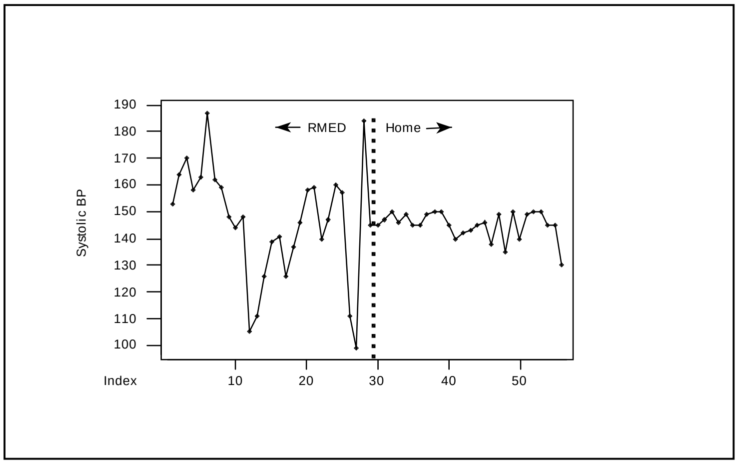

Figure 7: Individual Systolic BP Readings for Patient 3

In Figure 8 we have the individual systolic readings for patient 6. Notice for this patient, not only has the variation changed, but the mean as well. Again, we suspect less than honest reporting on the part of the patients. In this case we conjecture that multiple readings were taken and the lowest was reported. This would explain the values seen in the figure.

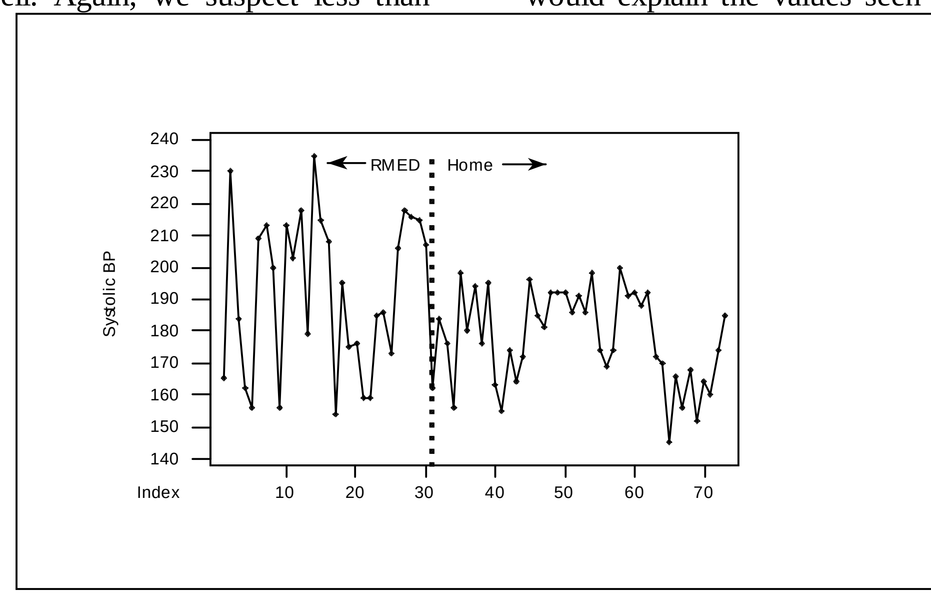

Figure 8: Individual Systolic Readings for Patient 6

In summary, it is clear that there is much work to do before a formal analysis can be performed. Some patient data may have to be thrown out. Still, there appears to be reasonable consistency between the RMED readings and the traditional home readings. If formal analysis bears this out, we may be able to proceed with the implementation of data base and decision support features. In Figure 9 we show a hypothetical exponentially weighted moving average (EWMA) depiction of a patient's progress under care. Ideally, the physician would be able to monitor interventions in the patient's care and have them displayed in a manner similar to Figure 9.

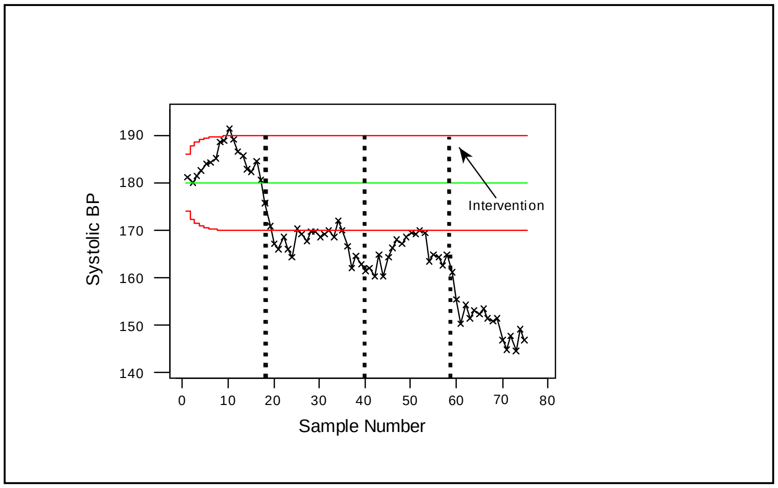

Figure 9: Hypothetical EWMA of a Patient's Systolic BP Under Physician Care

III. FUTURE EFFORT

A working prototype of the RMED hypertension system is complete with the foundation hardware and software firmly in place. Future extensions to the program require attention in two key areas. First, an expanded field study with cost-benefit analysis should be performed. The field study would verify and validate the efficacy of the system. Second, further refinement of the decision support technology is essential. In order to provide the greatest possible benefit to patient care physicians will require state-of-the-art decision aids be available. Refinement of this tool will be augmented as more patient data are gathered. Outlined in this section are the four technologies targeted as meeting the needs for the decision support aspects of this project: case-based reasoning (CBR), fuzzy logic, statistical process control, and classification. A brief description of each technology and its application follows.

Case-Based Reasoning

In simple terms, CBR is a problem-solving paradigm that utilizes specific knowledge from past experience as the basis for the solution to new problems. For our medical application this paradigm is a natural fit. Physicians routinely draw on past experience (cases) to diagnose and treat new patients. In point-of-fact, a leading measure

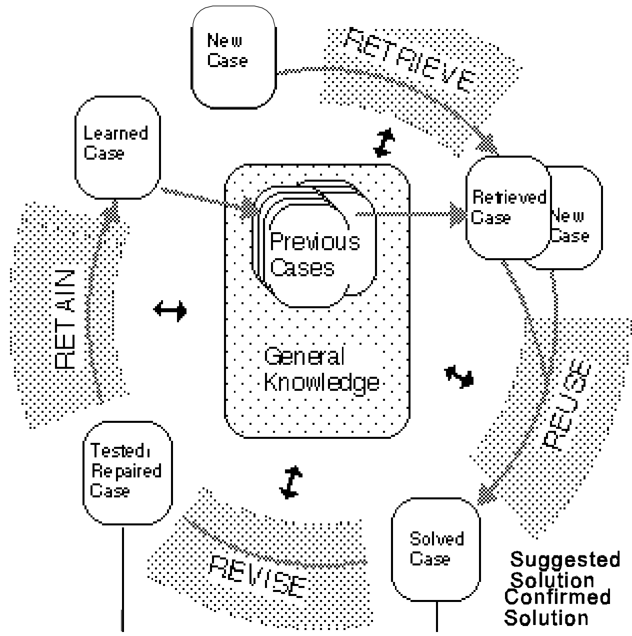

Figure 10: Typical CBR Cycle

for a specialist in the medical field is the number of similar "cases" treated in the past. Depicted is Figure 10 is the typical CBR cycle [9].

For this project an exact determination as to the specificity of representation and the necessary modifications to the CBR cycle will be made after several real data sets are gathered. Envisioned is a frame/object-based CBR with a case history based on patient characteristics, calculated ratios, and blood pressure readings. Important to the CBR selection will be the ability to tailor the retrieval and revision stages to incorporate fuzzy logic.

Fuzzy Logic

Where classical Boolean logic restricts responses to either "true" or "false", fuzzy logic allows for the introduction of partial truths and imprecise concepts [10]. A partial truth is typically quantified by a membership function that returns a membership value, a number between 0 and 1. The concept of "high blood pressure" could be represented by the membership function shown in figure 10. Here a person with a systolic pressure of 138 is assigned a membership value (partial truth) of 0.75. Fuzzy logic allows a greater degree of flexibility in the assignment of degrees of severity versus the classical "crisp" approaches. For medical applications, dealing with imprecise concepts is of utmost importance; physicians routinely deal with shades of gray rather than just black and white; or true and false.

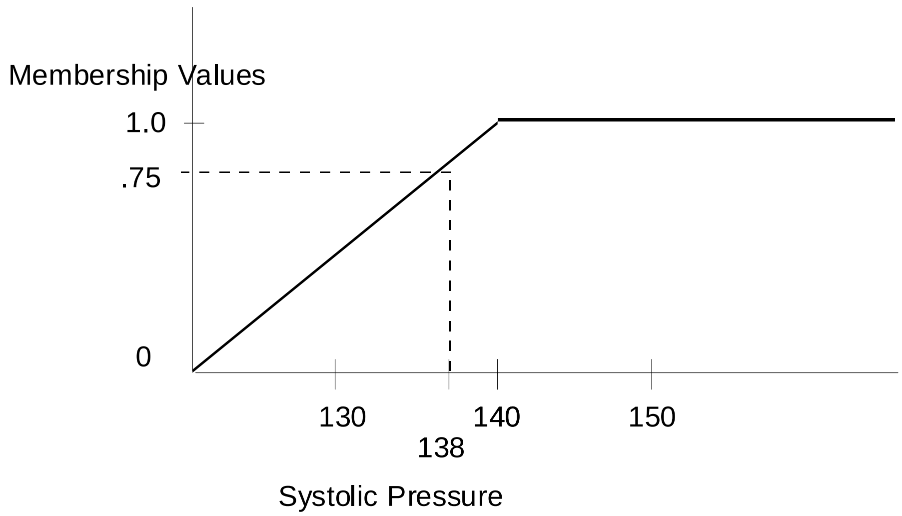

Figure 11: Typical Fuzzy Membership Function

For the hypertension testbed, fuzzy logic will find application in several places. First, fuzzy logic will be used in the "filtering" of blood pressure data. The fuzzy filters will allow "better" determination of when alarm thresholds have been reached. For example, a patient who continually scores a systolic pressure of 178 may never trigger the alarm set at 180 under the classical "crisp" system, but he/she would score a high membership under a fuzzy system.

The second place in which fuzzy logic will play an important role is within the CBR cycle. What is envisioned is the introduction of fuzzy to the retrieval and the revision steps. A fuzzy retrieval system that allows characteristics to be "graded" with the use of membership functions has been developed. The grading allows potential solutions to be rank-ordered. For the revision step, a fuzzy logic approach will be tried to adapt solutions from the given result set.

Statistical Process Control

Statistical process control has its roots in manufacturing and industry but increasingly has been employed in a variety of applications to include service-related tasks. Shewart control charts used in process control may be viewed as decision tools to (1) assist in the identification of unusual process behavior and (2) assist in determining appropriate corrective actions. In the feedback loop terminology of statistical process control, statistical signals support observation and evaluation, diagnosis, decision and implementation. The obvious parallel between the activities related to the feedback loop and a physician's care of a patient motivate the proposal for employing these methods to the process of blood pressure readings taken over time. The statistical signals emitted by this process can be evaluated in an automated manner as a decision-assist for the physician. The advantage gained in monitoring that process with statistical techniques is the recognition of and the accounting for natural variation with the important consequence of quickly recognizing unnatural variation manifested by isolated unusual readings (e.g., stressful circumstances) or process shifts (e.g., effective medication).

Classification

Statistical classification is widely used to separate objects into classes based on their attributes. Cluster analysis is used to establish classes based on statistical measures of "closeness" and discriminant analysis is used to establish models to describe predetermined class assignment in terms of object attributes.
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In the treatment of hypertensive patients, classes might be levels of effectiveness of a dose regimen, adverse reaction categories, or simply the presence or nonpresence of hypertension. Attributes may be any of the common risk factors, along with age, specific treatment regimen, gender, race, etc. Effective discriminant analysis models could provide physicians with alternative courses of action based on the data gathered and maintained in a data base produced by the RMED software. When some predictors are attribute variables, tree-structured methods such as discussed in Brieman et al. (1984) provide an alternative approach to discriminant analysis.

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