Translation of Research Models into Clinical Practice

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Abstract

Many innovative techniques have been applied to address problems in medical diagnosis and healthcare delivery. Unfortunately, the vast majority of these do not make the transition into clinical practice for a number of reasons, some technical and others organizational. Technical reasons include inadequate communication between systems developers and medical professionals, limited scope of models, and user interface issues including difficulty of use and unavailability of information required by the software. Organizational issues include lack of buy-in by medical professionals and administrators, requirements for change in workflow, and resistance to technical solutions. In this article, these roadblocks are examined and a system design is presented that can begin to address a number of them.

Key Words: Medical decision support, electronic medical records, medical informatics, intelligent systems

1 Introduction

Over the last two decades, numerous computer-assisted medical decision support systems have been developed and tested experimentally [1,2]. While many have been found to function quite well, in most cases reaching more accurate decisions than human decision makers [3], few of these systems are used in clinical practice. Some specific examples of failure include the electronic medical record (EMR), automated decision support systems, and automated image analysis. In order to address these failures, it is important to understand the reasons for the failure of technology transfer from theory to practice in healthcare applications, and to design new approaches that address these issues. Traditional software engineering approaches involve problem definition with end user input, followed by design of a computer-based approach to meet specifications defined during the problem definition phase. In most engineering applications, the computer solutions are algorithmic in nature, with a resulting set of programs that are designed to specifically solve the given problem. Due to advances in object-oriented programming, the solutions are most often modular, allowing straightforward adaptation to new methodologies as they are developed. This usual paradigm has not worked well in medical applications for a number of reasons, including:

- Communications problems between the technical group and the medical group;
- Complexity of medical applications due to the lack of complete knowledge of the system, resulting in the need for non-algorithmic solutions;
- Limited understanding of the work environment under which the systems will be used.

These difficulties have resulted in the design of systems with one or more of the following shortcomings:

- Solution for a problem that did not need solving;
- Development of a partial or limited solution;
- Design of a system that is impractical to use.

The work described here has two components. In the first part, a systems analysis of the medical environment is done to assess needs and determine which of these needs can be addressed through technology. The second is to present flexible technical solutions to fill these well-defined needs. These components are addressed in the following sections.

2 Needs Assessment

A systems engineering approach to development of medical systems can alleviate some of the shortcomings encountered in earlier systems. As an initial step in the design process for any medical application, a needs assessment should be completed with input from end users. The needs assessment should consider the following:

- Problem definition;
- Definition of user population;
- Practicality of use;
- Convenience of access;
- Time considerations;
- Definition of relevant parameters;
- Incorporation into workflow.

In order to address organizational shortcomings the following are needed:

- Participation by physicians in all phases;
- Buy-in;
- Ease of use;
- Payback;
- Techniques for changing behavior.

3 Technical Solutions

Support of healthcare delivery, including diagnosis, treatment, and patient management, fall into two general categories: computer-assisted decision support and information access. These in fact are not independent in that the decision support system relies directly on information access. The first steps must be determination of the intent of the system and identification of the class of users. The term expert system has in fact been misunderstood in that the knowledge upon which the system is based is obtained from experts, but the system is intended for use by non-experts. In short, clinical decision support must be designed for the intended audience, contain a comprehensive knowledge base, and utilize a sophisticated reasoning structure.

3.1 Decision Support

Decision support systems are either knowledge-based (expert input) or data-based, or a combination of the two. Diagnostic systems can function either as stand-alone systems or as support for human decision-making [4]. Knowledge based systems are designed to mimic human decision making, but the designer must be careful to ensure that they mimic good human decision making. Data-based systems in general use non-cognitive reasoning through the use of neural networks, other learning algorithms or statistically-based systems, or data mining approaches. These systems are ad hoc in the sense that they do not rely on any type of physiological modeling except that they most often contain parameters that do play some physiological role in disease. A third group of decision support systems rely on actual physiological models, but these are usually in very narrow areas such as pharmacodynamics.

3.1.1 Knowledge-Based Approaches

Knowledge-based systems rely on the reasoning paradigm and the knowledge base. Inadequacy in either domain will doom the success of the system. Both components have proven problematic. Early knowledge-based systems used standard conjunctive production rules that no doubt do not truly represent human decision making strategies. The use of consequential reasoning, as described in the next section, extends the reasoning methodology to take into account factors that are important in analysis of decisions, such as consideration of risk and consequences. The use of this framework, however, creates more of a burden for development of the knowledge base, as more information is required.

3.1.2 Data-Based Approaches

Once a good learning paradigm has been established it can be applied directly to any application for which there are sufficient data. In the medical domain, the collection of sufficient, consistent data remains a problem due to a number of factors, including limitations imposed by human subjects committees, non-standardized methods of data collection that precludes combination of data from multiple sources, and the need for long-term follow-up to determined ultimate outcome in many diseases.

3.2 Information Access

Data-based approaches as described above are dependent on information access, including databases. Electronic medical records greatly facilitate the establishment of disease-specific databases that can in turn be used to generate decision aids. Other sources of information include efficient literature searching to keep abreast of new developments. The web provides potential for supplying patients with important medical information, but a means must be found for establishing the validity of the information.

4 Examples

Solutions to some of the problems stated above are illustrated in four specific problems, followed by the technical solution for each.

4.1 Problem: Non-use of systems due to data entry problems
Solution: Widespread use of electronic medical records

Even though the electronic medical record was proposed over thirty years ago, its use is still not widespread, even in large medical centers [5]. This shortcoming directly affects the use of automated tools for both decision support and healthcare management as well as limiting the potential impact of worldwide access to medical records. Fortunately, advances are being made in the implementation of electronic medical records in many countries. In the United States, the Veterans Affairs hospital system has led the way in conversion to the EMR. Standards need to be established for the EMR similar to hardware and software standards to assure consistent interpretations. Figure 1 shows the potential for worldwide integration of the EMR along with other sources of medical information. Note that the physical location of the EMR is not indicated since it is not relevant in this design. It is necessary, however, to have standardized formatting and transmission protocols that protect confidentiality.

4.2 Problem: Naiveté of reasoning paradigm
Solution: Consequential reasoning

The traditional production rule format contains a premise (or antecedent) with one or more parts and a conclusion (or action) also with one or more parts:

Premise $\Rightarrow$ Action

This structure must be augmented to include the potential consequences:

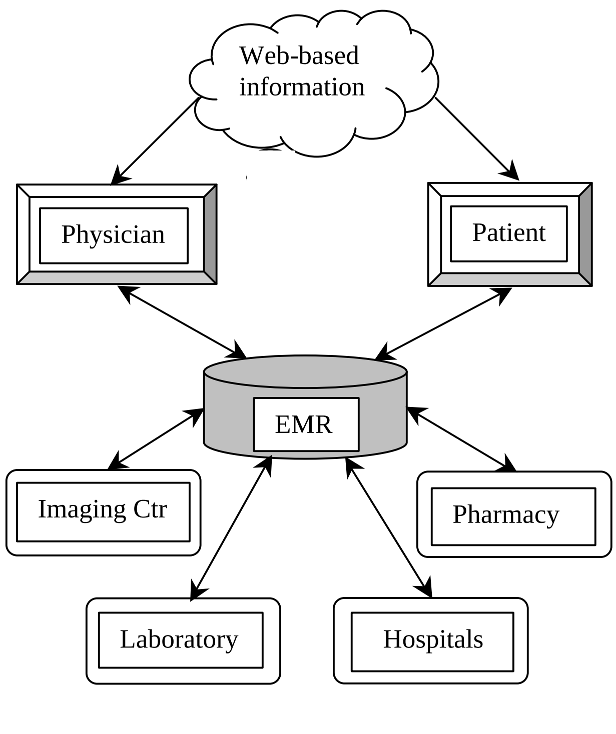

Figure 1: Electronic Information Transfer

Premise $\Rightarrow$ Action $\Rightarrow$ Consequence

Note that an action can result in more than one consequence, and that not all consequences are of equal importance. The new production rule structure is shown in Figure 2. Note that the basic premise-action portion uses approximate reasoning techniques, and is explained in detail in [6]. The certainty of evidence for each premise (a_i) is combined with the importance of the premise (w_i) using

$$V_P(r) = \max[(Q \sum_{i=1}^{n} r_i \wedge w_i) \wedge \min_{i=1,\ldots,n} (a_i^{\,r_i \wedge w_i})] \qquad (1)$$

where ^ indicates minimum, a_i and w_i are the weighting factor and degree of substantiation, respectively, of the i^{th} antecedent, $r_i \in \{0,1\}$, and n is the number of antecedents. The rule is substantiated if $V_P(r) > T$, the threshold for the rule. This structure has been expanded to include analysis of potential consequences. Each action in a rule can have multiple consequences. There are different consequences for taking the action (indicated by +) and not taking the action (indicated by -). Approximate reasoning techniques are applied to quantify the potential consequences, represented by the function G, which are then used in conjunction with the necessity measure n_i (an indication of the need for taking the action given that the premise has been confirmed). If G > S, where S is the consequence threshold, then the action should be taken.

		Certainty	**Weight**
Premise	1	a_1	w_1
	2	a_2	w_2
	⋮		
	n	a_n	w_n
Threshold	T		

		Consequence	**Necessity**
Action	1	c_1	n_1
	2	c_2	n_2
	⋮		
	m	c_m	n_m

		+	**-**	**Weight**
Consequences of action i	1	p_1	q_1	ω_1
	2	p_2	q_2	ω_2
	⋮			
	l	p_l	q_l	ω_l
Consequence Threshold	S			

$$C_j = F[p_k, q_k, \omega_k],\ k=1,l$$

$$A_i = G[c_i, n_i]$$

Figure 2: Structure of Knowledge Base

4.3 Problem: Insufficient data for neural network development

Solution: Hierarchical neural networks

A system of hierarchical neural networks is used to reduce one network with a large number of input nodes to a series of smaller networks. Each sub-network addresses a specific problem for which a smaller data set is sufficient for training. The structure is shown in Figure 3 [7]. Each network is then trained independently. A meta processor uses expert-derived information to determine the level of detail that is required for the current problem. Development of this portion requires consultation with domain experts. The advantage of this approach as compared to traditional knowledge elicitation is that the number of rules and the level of detail are both limited thus reducing the time and effort required to develop the knowledge base. The general structure shown has to be customized for each application. The exact configuration relies on knowledge derived from the domain expert. The meta processor directs the application to the appropriate network or networks in layer i. Output from layer i is combined using the evidence combination rules described below. Using this information, the meta processor determines if another level should be applied and if so which components of it are relevant.

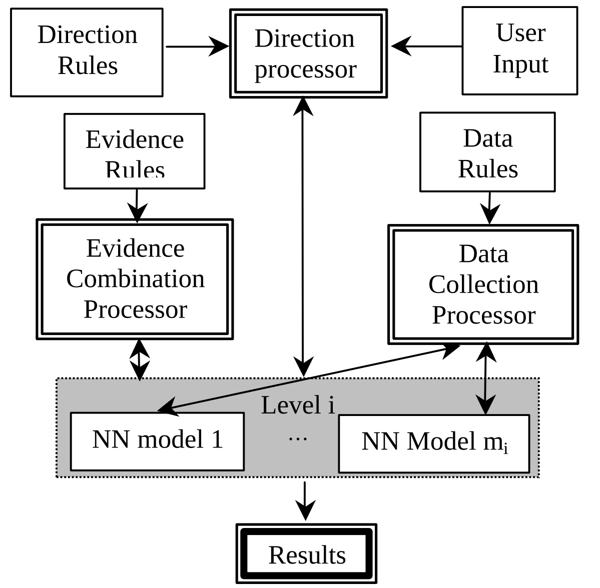

Figure 3: Structure of Hierarchical Neural Network Model

4.4 Problem: Development of comprehensive tools for decision support Solution: Intelligent agents

The above components are combined into a comprehensive system using an intelligent agent approach in which each of the three components listed above work as independent models whose results are combined to give a comprehensive picture of the diagnosis, treatment, or patient management strategy, depending on the current application. The medical professional is also included in the structure as an agent, thus allowing the computer-assisted portion to standalone or act as a supplement to the human decision maker. This method has been applied to a number of applications, including diagnosis, staging, and treatment of Alzheimer's Disease [8], cancer chemotherapy [9], and differential diagnosis in cardiology [10].

5 Discussion

Previous work by the authors in computer decision support has been expanded in two directions. First, the focus on diagnosis has been generalized to include the entire disease process, from diagnosis to treatment and patient management. Second, each component has been expanded to address issues of adequacy of the knowledge base and extension of reasoning methodologies to provide a more sophisticated reasoning structure with a more solid underlying knowledge structure. This new system takes advantage of advances in electronic information, which, while currently still not fully implemented, will in the near future provide crucial information for the delivery of healthcare.

6 Conclusion

The last three decades have produced unprecedented advances in computer technology, both in hardware and software. Coupled with these new means of implementation, theoretical developments have opened the possibility of providing insight into diagnosis and management of disease. Now that the necessary components are in place, the challenge remains to convert theory into practice that will impact healthcare delivery at all stages. In order to accomplish this transfer, technological experts must work closely with medical professionals to define problems and propose solutions that address shortcoming in current practices.

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