Chapter 3.7
Data Driven Interpretation of Laboratory Results in the Context of a Medical Decision Support System

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1 Introduction

In this chapter, we will describe a routinely used and effective computer based system for assisting the clinician in the role of decision maker. We will first discuss the philosophical issues of such systems, then describe in detail how the system functions. We will also discuss the integration of laboratory data for decision-making purposes and describe our experiences with, and evaluations of, the system.

1.1 Philosophical issues in automated decision assistance

The volume and variety of clinical laboratory tests has substantially expanded during the last decades. This increased utilization has caused two types of problems for clinical pathologists: 1. they must assume increased management and production responsibilities, and 2. they must play a more active role in assisting their clinical colleagues to appropriately use, and interpret, the results of laboratory tests.

To manage the increased volume of tests performed in the laboratory, to provide more rapid results reporting, and to insure adequate records for the financial aspects of providing health care, most modern laboratories have turned to computer based laboratory information systems. In such systems, many of the high volume analytic machines have been directly interfaced to the information system. Although these systems have measurably improved the management and production of clinical laboratories, the main impact of these sytems on improved patient care to date has been to improve the rapidity with which test results for the correct patient can be reported and to improve methods of quality control.

It is the goal of a new generation of computer programs to go beyond the management functions which are currently provided by laboratory information systems. These new systems can transfer the expertise (knowledge of laboratory tests) of trained clinical pathologists, as well as test results, to the physicians who are directly involved in patient care. In other words, computer programs have been developed and are continually emerging which can substantially assist the practicing physician to interpret (convert numbers to diagnostic or therapeutic information) the meaning of laboratory test results for individual patients. Examples of the algorithms and mathematical models which have been developed to interpret laboratory test results, and thereby increase the efficacy and clinical impact of laboratory data, are described in the preceding chapters of this book as well as in reviews by Beck, Meier, and Rawnsley (1) and Henry (2). By using traditional programming techniques, these algorithms have been, or could be made, available in currently available commercial laboratory information systems.

In contrast to these traditional "hard-coded" programs in which the algorithmic logic or expertise is embedded directly in the computer instruction codes, another approach to providing expert consultation has emerged during the 70's and 80's. In this latter approach, the interpretive and clinical expertise (knowledge) is stored separately from the computer program which uses this knowledge to interpret clinical data (facts) about a patient. When the clinical expertise is stored in this separate representation, it is known as the "knowledge base" for the system.

There are several advantages to this knowledge-based approach. A single control program (sometimes called the "inference engine") can function across broad areas of medical applications if the appropriate expert rules for multiple subspecialties are contained in the knowledge base. The clinical expertise and interpretive rules in the knowledge base can be reviewed, modified and expanded independently by clinicians who are not required to have programming capabilities. This approach allows the breadth and power of the system to be improved by adding to and modifying the knowledge base in a modular fashion.

When the content of the knowledge base is used to provide consultation and make decisions in specific medical domains, these knowledge-based systems are sometimes called "expert systems". These systems provide the expertise of a specialist in a particular field to users who may not even be aware of their need for an expert consultation. The topic of expert systems is covered in detail in Chapter 3.8 by Trendelenburg.

The difference between these knowledge-based systems and the dedicated, hard coded algorithms found in the traditional computer programs is generally not a matter of functional capability, but approach. "Since there is no one formal definition of [knowledge-based systems] and recent implementations have explored variations on virtually every aspect, their use becomes more an issue of a programming *style* than of anything else. ... Since it is possible to imagine coding any given [computer] in either procedural [i.e. traditional 'hard coded' programming] or [knowledge-based systems] terms ..., in the formal sense their computational power is equivalent. This suggests that, given sufficient effort, they are ultimately capable of solving the same problems. The issues ... are not questions of absolute computational power, but of the impact of a particular methodology on program structure, as well as the relative ease or difficulty with which certain capabilities can be achieved" (3).

The present authors interpret this insightful statement to mean that "there is nothing magic" about knowledge-based systems. In a hard coded program, the programmer must have explicitly foreseen every branching point in an algorithm.

Such deterministic protocols or algorithms can have a positive impact on healthcare. However, traditional programs are most appropriate in noncomplicated, straightforward situations where the logic is well defined. If there are complicated situations, the separate knowledge base approach lets appropriate rules be applied to situations which the knowledge base authors did not explicitly foresee or solve in advance.

Another advantage of having the rules for decision-making in a readable stand alone format is derived from the realization that the decision logic may contain an author's moral or ethical judgements or personal biases. In knowledge based systems, these biases remain exposed for scrutiny and discussion by the clinical, rather than the programming community. This independent representation of medical knowledge may also contribute solutions to the as of yet unanswered dilemmas regarding the responsibility and liability associated with the use of decision-making systems.

In spite of these additional advantages of a knowledge based system, it has generally been recognized that the power which leads to superior performance of a computer system comes from the richness and content of the expert knowledge contained in the program rather than the language or style in which it is programmed.

We are of the opinion that there are additional considerations which must be kept in mind as one contemplates a system for the interpretation of clinical data: 1. the way in which the expert logic is activated will have a profound effect upon it's use and acceptance, and 2. some provision must be made to guard against reliance upon a system which may not have the necessary expertise in the domain about which the user is seeking assistance. We feel that the philosophical approach to these issues is extremely important to the success of a useful, productive program for the clinician. Because some expert systems have been developed in a research environment in which the computer science aspects of the project were of more interest than the ultimate clinical application, these two practical issues have not always been fully addressed.

If these issues are neglected, systems which are intrinsically powerful may prove to be quite sterile in a user's environment for the following reasons. First, in order to receive decision-making assistance from the variety of expert systems which are currently (1988) available, the user may be required to have multiple expert systems or hard coded programs; one for diagnosing diseases in internal medicine, another for assessing strokes, a third for assessing rheumatoid arthritis, a fourth for interpreting abnormal bilirubin results... etc. If the user is well enough qualified in a field to know which of the expert systems or programs s/he should turn to, or even more importantly, to know when to consider the need for additional consultation, there is a good chance that the system will not surpass the user's or the consultant's expertise in a specific area. In other words, there are currently only a limited number of systems which contain sufficient knowledge to make decisions in a wide variety of medical specialties or with the capability to support a variety of types of decisions e. g. diagnoses, alerts, management, etc. None of the currently available systems has a comprehensive medical knowledge base.

A second problem occurs when the user approaches the computer and asks for assistance with a specific problem. This is generally referred to as a *goal driven* mode for activating the expert consultant because the user wants to solve a particular problem (What is the diagnosis? Is it all right to administer this drug to my patient? What does this laboratory test mean?). After entering facts about the patient, the user discovers (perhaps by way of a nonsensical answer) that the system does not have expertise in the area concerning the user's goal. An inappropriate response in one area often destroys the credibility of the system although it may be highly proficient in other areas.

The third problem arises because one goal of computer systems is to assist the physician in domains where his/her performance is ordinarily very good, but in which some infrequent but important errors do occur, for example monitoring drug prescriptions. This goal can be accomplished in the critiquing mode in which the computer constantly monitors the physician's decisions and issues a warning or an alert whenever certain decisions are questionable. If the physicians must constantly ask if it is all right to prescribe a drug when, in fact, their unassisted decisions are correct most of the time, they may ultimately tend to avoid asking for assistance from the computer when the yield is so low, unless it is extremely easy to receive this assistance.

In order to address these issues of practical application, we have designed a system in which three tasks were accomplished: 1. the decision-making system is imbedded within a comprehensive clinical information system, 2. the knowledge base, though separate from the decision-making program, is constructed in a very modular, procedural representation, and 3. the appropriate decision logic is activated whenever data (facts) referenced in the decision criteria are stored in the clinical information system. This mode of activating the expert logic is known as a *data driven* activation strategy. This approach to activating decision logic insures that those decisions for which sufficient rules and facts exist in the computer, will be evaluated whenever the data are stored. With this philosophy, the user receives consultation in the form of likely diagnoses, interpretation of laboratory tests, alerts, or contraindication warnings without asking for assistance. The problems associated with an incomplete knowledge base are only partially solved with this approach; the program gives advice when it is able to speak authoritatively, but remains silent when it does not have any knowledge or facts about the problem.

2 Functional Implementation of the HELP System

For the last decade, we have been using a computer-based system for automated medical decision-making which is interfaced to a commercially developed computerized clinical laboratory system as well as other computerized subsystems of the hospital. The hospital based expert system is known as HELP (Health Evaluation through Logical Processing) (4) and a key feature of the system is the integration of administrative data processing functions as well as collection of clinical data from many sources to form a comprehensive clinical database. The resulting system thus has test ordering, results reporting, and charge capture capabilities as well as automated interpretation of clinical data, alert generation, and diagnostic functions.

There are three major advantages for an approach in which the decision-making system is integrated with an on-line clinical database. As we have discussed, one of the most important is the fact that the decision-making capabilities can be automatically evoked whenever new data are added to the patient record.

A second advantage is that the entire computerized medical record (not just information from the clinical laboratory) can be used to provide clinical facts which are referenced in the decision logic. Thus, a patient with a negative sputum culture might still be identified as having a hospital acquired pneumonia because of radiology findings or information provided by respiratory therapy technicians.

The third advantage is that such a comprehensive collection of clinical data becomes the primary repository which the clinical users use to review patient information. Recognition of the importance of this format for data storage and display insures that all involved personnel have vested interests in keeping the data accurate and up to date.

In the sections which follow, we shall describe the overall functional design of the HELP system, then discuss specific issues relative to the inference capabilities and the data driven logic activation mechanism.

As can be seen in Figure 1, the system essentially consists of three main parts: a comprehensive clinical patient database, a separate knowledge base which contains expert logic, and an interpreter which controls the evaluation of the expert knowledge.

Those elements in the upper half of Figure 1 (data collection programs, the long term patient file, the current clinical patient file, the reporting functions and the link to the financial system) are standard components which may be found in some

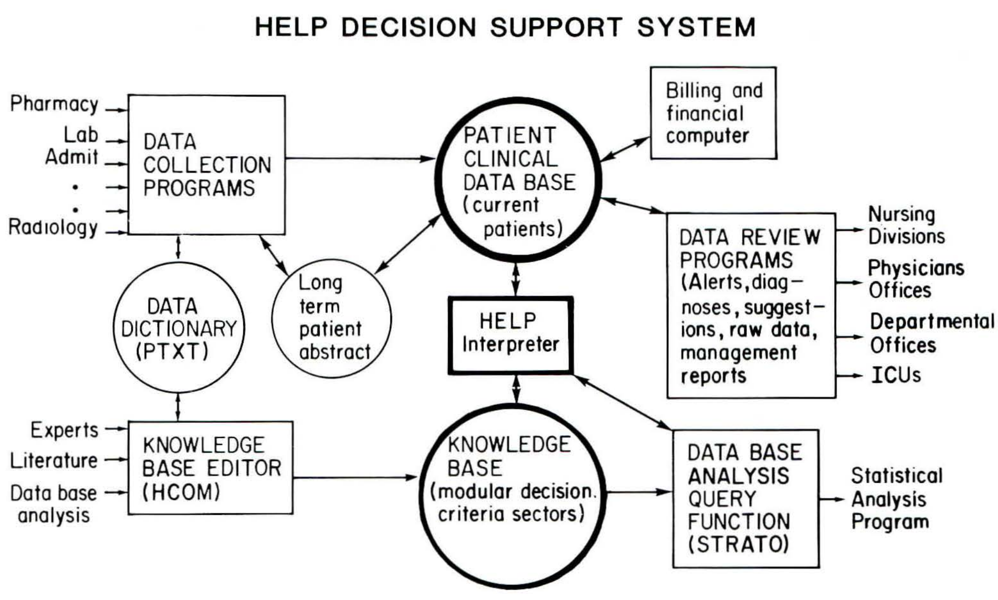

Fig. 1. An overview of the components of the HELP system.

currently available hospital information systems. The central clinical data base integrates data from, and communicates with, computer systems in ancillary departments in order to allow test ordering and results review throughout the hospital.

We have chosen to use the Tandem computer for the central system because it is easily expandable and has built in hardware and software redundancy which help to insure that the system is always operational. In our 520 bed hospital, we presently have 361 terminals and 86 printers attached to a central system which is composed of a cluster of eight computers that function in an integrated mode which allows each computer in the cluster to be backed up by another computer in case of failure by a single unit. Each of these computers in the central cluster has access to all of the system data files. In addition to this central cluster, there are multiple (17 presently) microprocessors attached to the central system which support independent data collection activitiy or act as signal processors.

The long term file contains on-line data for all previously admitted patients and consists of abstracts of clinical and demographic information likely to be useful if a patient is readmitted. The clinical data base contains all data gathered during the current admission. After a patient is released from the hospital, the patient's record is stored in archives which are available for statistical assessment.

In order to facilitate the use of the patient specific information which is contained in the clinical database, it must be stored in some uniquely identifiable form. In our system, clinical data are stored in a coded format which is defined using a data dictionary. The data dictionary is necessary in order to allow those who write programs to acquire patient data, build the logic contained in the expert knowledge base, or construct report formats to accurately reference specific data which may be stored in the patient data base. We have chosen a coded format for the stored data in order to facilitate the rapid retrieval of data which are referenced in the decision-making logic and to allow the use of hierarchical relationships among medical terms. Other developers of knowledge-based systems have used uniquely defined symbols. As long as the user is insulated from the necessity of actually seeing the codes, the distinction between codes and symbols is somewhat artificial. In our case, the codes are retranslated to display the medical terminology to those who review the data.

The elements of the lower half of Figure 1 represent the additional features necessary for a decision support system (knowledge base editor, knowledge base and the HELP interpreter). The expertise contained in the knowledge base can be obtained from opinions of experts, the medical literature, or statistical experience represented in the patient database. The knowledge is stored as compiled "HELP frames" which contain the logic necessary to make a specific decision. The medical knowledge base supports a variety of decision-making models (IF...THEN...rules, patient specific likelihood scores for ranking possible diagnoses, query for "important" missing data, etc.) and allows the medical expert to enter criteria using a high level language contained within the knowledge base editor.

When new results are stored in the patient record or a specific block of the knowledge base is otherwise activated, the compiled logic in the appropriate HELP frames is evaluated by performing the necessary queries to the patient database to see whether the data specified in the logic exist for the patient in question. The frames themselves contain the logic which determines how they are to be evaluated.

Title: Hospital Acquired Pneumonia (16.16.10).

Author: Peter Haug

Message: "Patient may have Hospital Acquired Pneumonia."

Declare Variables:admission^time **as** ADMIT TIME,

late^purulent^sputum as gram^stain^WBCs **or** resp^tx^sputum **where** gram^stain^WBCs is SPUTUM **and** (MODERATE NUMBER OF WBCS or NUMEROUS WBCS) and resp^tx^sputum **is** PURULENT SPUTUM **from** admission^time + 3 days **until NOW,**

purulent^sputum **as** gram^stain^WBCs **or** resp^tx^sputum where gram^stain^WBCs **is** SPUTUM and (MODERATE NUMBER OF WBCS **or** NUMEROUS WBCS) **and** resp^tx^sputum **is** PURULENT SPUTUM

neutropenia **as** white^count **LE** 2.0 where white^count **is** WHITE BLOOD CELL COUNT,

surgery **as** OPERATIVE RECORD,

late^positive^chest^xray **as** PULMONARY INFILTRATE/CONSOLIDATION from admission^time + 3 days until **NOW,**

positive^chest^xray **as** PULMONARY INFILTRATE/CONSOLIDATION

late^positive^sputum^culture **as** SPUTUM and BACTERIA **from** admission^time + 3 days **until NOW,**

positive^sputum^culture **as** SPUTUM and BACTERIA,

previous^admission **as** LAST ADMISSION **from** 30 days ago,

early^negative^chest^xray **as** early^chest^xray **and not** early^positive^chest^xray **where** early^chest^xray **is** CHEST XRAY DATA **from** admission^time **until time of** positive^chest^xray **and** early^positive^chest^xray **is** PULMONARY INFILTRATE/CONSOLIDATION **from** admission^time **until time of** positive^chest^xray.

Logic: If (purulent^sputum or neutropenia) **and** (positive^sputum^culture **or** positive^chest^xray) **and** (previous^admission **or** early^negative^chest^xray) **then conclude,**

Else If (neutropenia or late^purulent^sputum) **and** (late^positive^sputum^culture **or** late^positive^chest^xray) **then conclude,**

Else If surgery **and** positive^chest^xray **and** (**time of** positive^chest^xray - **time of** surgery GE 3 days **and time of** positive^chest^xray - **time of** surgery **LE** 10 days) **then conclude.**

Evoke: If purulent^sputum **or** positive^chest^xray

Fig. 2. A frame which contains the decision logic for identifying certain classes of patients which may have a hospital acquired infection.

An arithmetic statement can be used to perform tasks ranging from Boolean logic to calculation of a discriminant function. Chronologic statements can be used to retrieve the time of a specified event so that time may be used for data limitations or action flags. Existence statements use the presence or absence of a piece of data, rather than the value as the basis for logical manipulations and/or calculations. Data retrieval statements are used to search the clinical database for specific items within specified time limits. These search items may also trigger the evaluation of additonal HELP frame modules or ask for missing but necessary data.

The logic contained in the frame depicted in Figure 2 contains criteria used to recognize patients who may have a nosocomial pneumonia. The bold face terms in the frame are syntactical and structured commands within the HELP language. The top three headings of the frame give the title by which this frame is known in the knowledge base, the author, and the message which will be displayed if the logical criteria contained within the frame are satisfied. The *logical criteria* in this case are a series of IF...THEN... rules. In order to properly qualify the terminology which is used in the logical rules, the terms (variables/symbols) used in the rules are *declared.* These declarations refer back to terms (denoted by capitalized words) which are defined in the data dictionary. A powerful part of these declarations is the use of chronological constraints as well as qualification regarding the value for a variable. The procedural logic is written in a slightly structured, but understandable, language. The data driving triggers are listed under the *evoke* heading. Whenever the laboratory reports a purulent sputum or a radiologist reports a chest radiograph with evidence of infiltrates or consolidation, the frame is evaluated.

When the necessary criteria for a decision are satisfied, a new data string which reflects this result, is stored in the patient record. The storage of one result may activate other decision logic as well as specified reporting mechanisms. This approach is sometimes called the blackboard method; when a new decision is written to the clinical database (blackboard), it may data drive (evoke) other decisions which depend on this new conclusion.

In contrast to the self contained logic frame shown in Figure 2, Figure 3 shows the algorithmic flow chart which is an alternative representation for this decision.

As explained earlier, this logic could be imbedded directly in a hard coded conventional computer program. The differences are that the frame representation can be easily understood by clinical personnel with authorship or review responsibilities, the frame can be independently added to, or subtracted from, the knowledge base, and the data driven evoking mechanisms for the system will automatically access this logic whenever data referenced by either of the evoking criteria are stored for a patient. This concept illustrates how the system can modularly grow in breadth and detail. Of course, for meaningful results to emerge, this logic must be linked to a database in which microbiology results, radiographic findings and respiratory therapy procedures are routinely entered.

There is a wide variety in the types of rules in the knowledge base; for example, to identify a patient with a reportable disease such as Giardia, the decision logic only needs to look for the presence of Giardia in the microbiology test result. Other types of frames are used to calculate probabilistic likelihood scores which are used to rank the most likely diagnoses for a patient. Still other frames ask for data which are missing in order to conclude certain alerts or diagnoses.

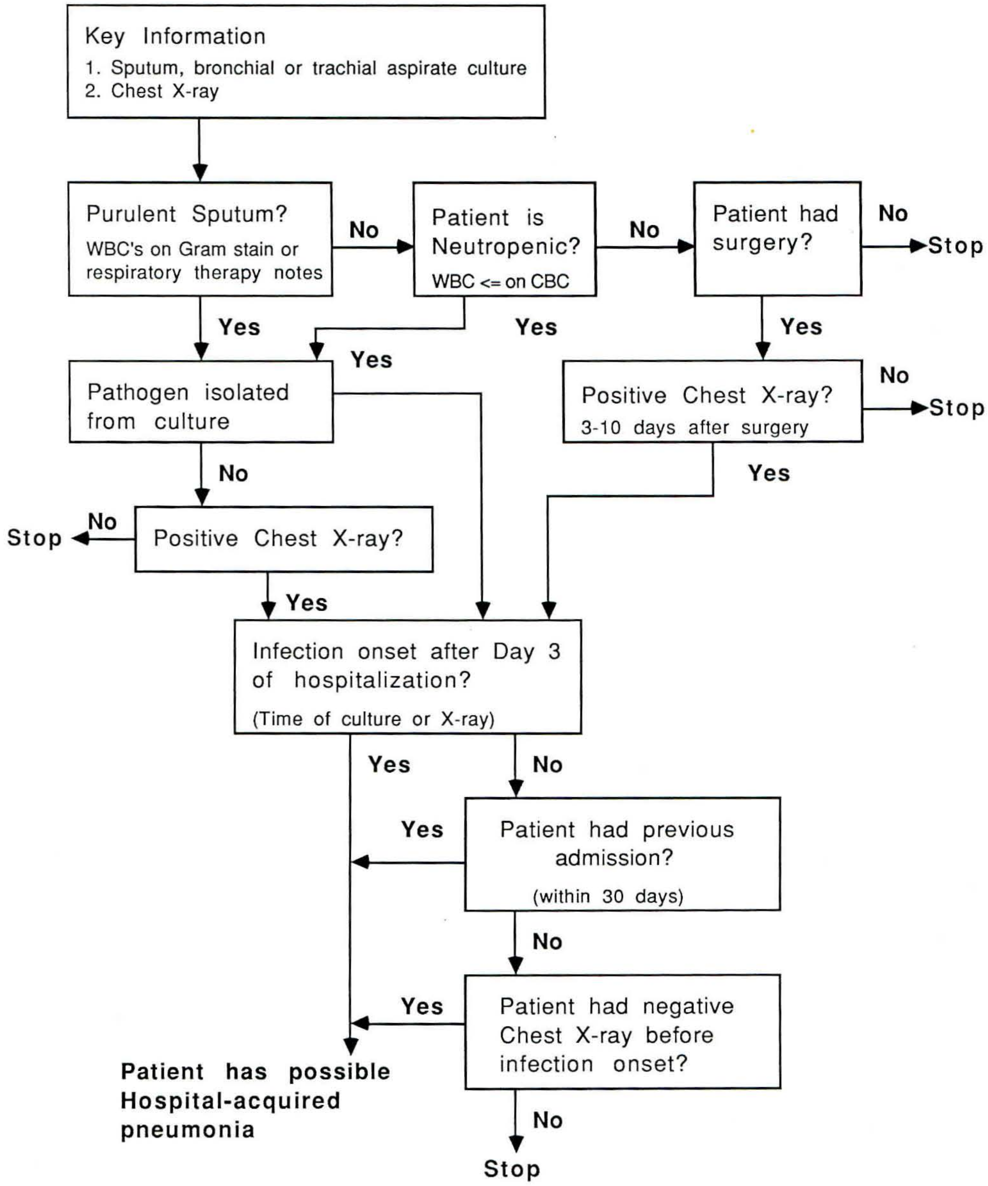

Fig. 3. A conventional algorithmic flow chart representation of the decision logic for recognizing potential nosocomial pneumonias.

2.1 Interface to the clinical laboratory system

Whenever a patient is admitted to the hospital, moved to a new room, or discharged from the hospital, the central computer system notifies the laboratory computer system of these changes. The laboratory system maintains its own database of test results for internal integrity, quality control and operational functions, but results are reported by transferring the data to the central information system and storing the data in the comprehensive clinical data base. When a laboratory test result is sent by the laboratory machine to the central computer, it is temporarily held in a holding file (called a spooler). A translation program then takes the test results, one at a time, and translates them from the laboratory file format into the hierarchical codes used in the central database. Transferring a laboratory result to this central computer activates the charge capture mechanism in the central machine and triggers the appropriate expert logic. The blocks of this expert logic which are activated depend upon the type of test result which has been transferred. Thus, the communication between the systems is two-way; the laboratory system receives information from, and returns its results to, the central hospital system.

2.2 Experience with the decision-making aspects of the system

We currently make decisions in the many areas of medicine. The following list is not meant to be exhaustive, but rather to illustrate the variety of tasks which are addressed by the system:

Diagnosis: Pulmonary disease, anemias, obstetrics, multi-organ failure index, hospital acquired infection, ...

Patient Management: antibiotic usage, diet, obstetrics, ...

Data acquisition: intelligent history, radiology findings, ...

Contraindications/alerts: pharmacy, radiology, clinical laboratory, blood gas, ...

Test result interpretations: Blood gas, hemodynamics, clinical laboratory, ECG, pulmonary function, electron microscopy, ...

Protocol management: Cardiac arrythmias, ...

Departmental management: infectious disease, respiratory therapy ...

Rather than dwell upon all of the specific types of individual decisions that the system is capable of making, we shall describe several of those applications in which laboratory data are used in combination with other sources of clinical data. These types of decisions cannot be easily generated in a stand alone laboratory information system because they rely on the comprehensive nature of the clinical database.

Data driven decision logic is used as the basis for our hospital's infectious disease monitoring program (5). Criteria have been stored in the knowledge base which can be used to identify patients: 1. with hospital acquired infections, 2. not receiving antibiotics to which their pathogens are susceptable, 3. who could be receiving less expensive antibiotics, 4. who receive prophylactic antibiotics longer than appropriate, 5. with infections at normally sterile sites, 6. with reportable diseases, and/or 7. with an antibiotic resistant microorganism. A report containing these alerts is automatically generated every day in the infectious disease department.

Surveillance personnel using computer screening for two months identified more hospital acquired infections than those who used traditional surveillance methods, while requiring only 35% of the personnel time (6). During the same two month period, the computer screening identified 37 patients (in a 520 bed hospital) not receiving appropriate antibiotics and 31 patients who could have received a less expensive, yet equally efficacious, antibiotic. A one month study demonstrated that the computer can automatically identify patients without evidence of infection who are receiving prophylactic antibiotics for an excessive period of time.

The infectious disease knowledge base is also used to generate a respiratory therapy infection monitoring system. This program uses the knowledge base to identify patients who have conditions to which a respiratory therapist should be made aware and also for tracking pneumonias and bacteremias which may have potentially been induced by the respiratory therapy. A daily report identifies patients with positive or pending tuberculosis, mumps, rubella, or hepatitis tests, and/or patients with hospital acquired pneumonias or bacteremias who have also received respiratory therapy. The computer reporting programs also identify which of these patients have a common pathogen and determines whether the same respiratory therapist (technician) worked with two or more of the patients with common organisms during a specific time period.

One of the best received and appreciated applications is the generation of pharmacy-laboratory alerts (7). This application illustrates the strengths of an integrated system with decision-making capability. When drugs are prescribed, the pharmacist enters these prescriptions into the computer. This entry activates decision logic which is based upon a combination of current medications as well as laboratory results. If the prescription is for a diuretic, a group of HELP frames which reference the use of diuretics in their logic are evaluated. One of these frames ascertains whether the prescribed drug is a potassium sparing diuretic and whether the patient's present serum potassium level is within normal limits. If both of these criteria are not met, the computer suggests to the pharmacist that a potassium supplement may be advisable.

If a drug which can potentially impair kidney function (e.g. Gentamicin) is prescribed when the serum creatinine or BUN levels are already high, the pharmacist is alerted that a different drug may be preferrred. If a laboratory test to evaluate kidney function is not requested within 48 hours after the drug is prescribed, the pharmacist is also alerted.

After the pharmacist verifies that the suggested contraindication is valid, the prescribing physician is notified. In approximately 95% of these instances, the physician changes the prescription. In our hospital population we find that 4% of the drugs and 2% of the patients receive pharmacy related alerts. A large fraction of these alerts involve pharmacy-laboratory interactions. A study which estimated the costs associated with stay-extending contraindications showed that the entire pharmacy surveillance expert system was cost effective by a four to one margin. A second study showed that those patients with abnormal laboratory values came back into the normal range significantly faster if the physician or nurse was notified by the HELP system. Based upon these formal evaluations, as well as the broad acceptance of the system which has occurred as physicians have learned how to use the system, we feel confident that expert systems will play an expanding role in the proper utilization of laboratory results.

3 Summary

In domains where the types of data which are to be interpreted are relatively constrained (as in the case of specific laboratory test results), our modular, data driven approach can be very productive and well received by the clinical recipient of the data. The computer rarely surpasses the knowledge of an expert in the field of specialty; most of the alerts to experts come as a result of lack of communication, imperfect memory, oversight or multiple decision-makers caring for the same patient (8). In such cases, most of the alerts are immediately recognized as valid, so the need for elaborate explanations is not a high priority.

On the other hand, a non-specialist is alerted to the need for additional investigation, tests or collaborative support, by the fact that a reminder or diagnosis that s/he had not previously considered, appears. In other words, for the expert, a data driven system provides unceasing oversight in high volume, low yield situations where a small number of mistakes may uncommonly occur for reasons which are not related to the lack of knowledge of the provider. For the non-specialist, the system serves more to alert that the patient may have problems in a domain for which the physician needs additional support. In the present state of the art, we do not think that total reliance on the computer contained knowledge is the ultimate source of this additional support; providing the awareness of the need may be the most important contribution. Once you know that you need help, it's usually obtainable.

In a discussion about how computer systems have failed, Friedman and Gustafson made the following observation. "The great majority of computer applications to medicine, attempted to date, have been excessively modest in scope. Where in other fields the computer has been utilized to perform tasks previously incomprehensive to mankind, in healthcare delivery we have been satisifed to merely duplicate the physician. In mathematics, physics, banking, space exploration, etc., the computer is routinely called upon to perform tasks that all mankind, working 24 hours a day from creation, could not begin to duplicate, but in medicine our measure of success is diagnostic accuracy approaching a skilled clinician, ECG analysis which is substantially correct or historical data acquisition which saves the physician 5 minutes per patient. If our timidity were matched in other fields, it is very unlikely anyone could have justified the expense or the efforts necessary in these successful efforts. The disappointing impact of computer technology on medicine may have been caused by our inability ... to do more than emulate the efforts of an individual physician." (9)

Although some of the unfavorable comparison to the accomplishments which computers made in physics may be explained by the amount of variability in symptoms, progression of disease, individual response to disease and therapy, and to the combinations of problems which sometimes concurrently exist in a patient, the bottom line is that physicians do use logical processes to diagnose disease and manage patients. Data driven knowledge based systems do have the potential of doing something that no human being can logically do: scrutinize every piece of data which is collected for a patient and bring to bear the expertise of specialists regardless of the location of the patient or the time of day at which the data are collected.

As the content of the knowledge base becomes richer and more comprehensive, such systems appear to be capable of tremendously improving the quality, and perhaps the cost, of medical care. Currently, the methods for such accomplishments exist; the need is for more expert physicians to logically examine their thought processes and transmit their expertise to a computer compatible format. Algorithms, rules, and expertise are difficult to elicit and capture for any type of computer based representation. Medicine has traditionally been regarded as an art rather than a science; eliciting the decision-making logic tends to require the transformation of the field into a science. We foresee the day when medical knowledge and expertise will be shared among developers of information and decision-making systems. No single group will be able to adequately capture this knowledge across all subspecialties of medicine for all types (diagnostic and mangement) of decisions.

It is due to the ease of modifying and adding to this vast and currently incomplete medical knowledge base that most current developers feel that the knowledge based systems approach (a separate, easily manageable knowledge base) is superior to the hard coded program approach.

We recognize that the HELP system which we have developed will certainly not be the only system which is capable of providing these services; however, the systems which ultimately successfully emerge must incorporate the two basic principles which have been pivotal in the development and acceptance of our system: 1. integration into a comprehensive clinical database, and 2. data driven strategy for evoking the decision logic. It is still too early to tell whether the successful systems of the future must also have the modular, procedurally oriented frame structure which has characterized the knowledge base of our system. The main advantage of the modular approach is the way in which the system can expand gradually. Because data exist which satisfy the logical requirements for a specific decision, the decision is generally easily validated and believable. Those decisions which are produced are generally specific, valid and timely even though the expert logic may not exist for all possible interpretations or alarms.

In all cases, the ultimate decision-making responsibility remains with the human clinician. Many have wondered about the legal aspects of disagreeing with a computer consultant or placing the blame if the computer gives poor advice which is heeded by a healthcare provider. In our experience, the physician users generally feel that the risks which are avoided by the routine use of such a system substantially outweigh any potential legal disadvantages of such an approach.

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