Emerging Standards for Medical Logic

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Abstract: Sharing medical logic has traditionally occurred in the form of lectures, conversations, books and journals. As knowledge based computer systems have demonstrated their utility in the health care arena, individuals have pondered the best way to transfer knowledge in a computer based representation (1). A simple representation which allows the knowledge to be shared can be constructed when the knowledge base is modular. Within this representation, units have been named Medical Logic Modules (MLM's) and a syntax has emerged which would allow multiple users to create, criticize, and share those types of medical logic which can be represented in this format. In this paper we talk about why standards exist and why they emerge in some areas and not in others. The appropriateness of using the proposed standards for medical logic modules is then examined against this broader context.

Introduction:

During the last fifteen years, we have seen a major change in the methodology of computer programming in medicine. Programmers had formerly embedded within the program code itself the medical logic for such things as interpreting acid base relationships or flagging abnormal laboratory values. While this approach led to appropriate output and very efficient execution, it was very difficult to maintain, criticize or change the logic in such programs.

The advent of influences of the field of artificial intelligence and difficulties associated with criticizing, changing, and maintaining the hard-coded programs, led to the development of applications in which the knowledge base is separated from the inference engine or logic interpreter. In environments which support knowledge based applications, a medical expert (most often with the aid of a "knowledge engineer") may describe the rules for making decisions or diagnoses and that knowledge can be entered into the knowledge base of the system without the requiring the medical expert to understand programming languages. Some of the knowledge bases became extensive, accurate and useful in the routine care of patients. It also became possible to use the knowledge base for purposes other than those which the original author had anticipated. Constructing extensive, accurate knowledge bases is a time consuming task and it became obvious that such knowledge bases had intrinsic worth similar to other more traditional knowledge bases which are typically found in the library.

To address the issue of sharing these valuable resources, a group of individuals gathered in May, 1989 at the Arden Homestead in Harriman NY (2). At that meeting, it was concluded that the knowledge base in some types of medical logic systems is very difficult to separate from the environment for which it was created, even though the knowledge base is separate from the inference engine. Examples of the problems encountered involve completeness issues of the sort encountered in diagnostic systems or relationships expressed in semantic nets.

It was argued that the best way to share some of these resources may be to install a server on a network and allow multiple users to access the resource as an integrated unit which can stand independently of the clinical information system or other information resources.

However, a subset of medical logic could be written in modular form, (e.g. IF the patient has a

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history of gastritis, THEN consider enteric coated aspirin when treating chronic symptoms of arthritis). The Arden group discussed a format for sharing logic which could be expressed in a modular and independent fashion. Such a logic module must be independent in the sense that a rule could be evaluated and make recommendations even if it were the only rule in the system. We called this unit of medical logic a Medical Logic Module (MLM). We further proposed that such rules be written in a common high level syntax (2,3) which would allow a variety of authors to create, criticize and, by writing a compiler/inference engine that was specific to their particular information system architecture, apply the rule to patient data in the local environment. This proposed standard has now been formally addressed by creating a subcommittee of ASTM (E31.15).

The MLM Arden representation is an ASCII document with slots for management, references, and medical logic. The logic portion of the MLM, although it is the essence, occupies only a fraction of the total content. A major part of the effort is devoted to defining the terms used in the actual logic and in creating links to the local database so that those terms can be properly qualified when they are retrieved from the local database. In systems where the user enters the data, much of the qualification of the data retrieval is performed implicitly by the person who enters the data. For example if the logic needs to know the patient's cholesterol level, the user would implicitly decide whether a level done last week was sufficient, accept a level from a year earlier, or decide to indicate that the cholesterol is unknown. The user of the data entry based system would also not need to know how that information is actually stored in the computer.

However in a system which is interfaced to a clinical database, the compiler that will build the executable instructions needs to know how recent a value for cholesterol must be before it will be accepted in the medical logic and when to conclude that no existing value should be considered. Systems such as HELP (4) and CARE (5) which have been interfaced to clinical databases for some time have addressed these data qualification and retrieval issues and therefore much of the data linkage part of the syntax is modelled after the constructs which have evolved in those systems.

If the 1980's can be regarded as the decade in which the concept of knowledge based systems was accepted and implemented, we postulate that investigators in the next decade will wrestle with solutions to knowledge base management. These issues include quality of the rules, completeness of the rules, redundancy of rules, communication of changes, and ability to disseminate knowledge in computer processable format. It is for all these reasons that the management information section has been expanded. We feel that a standardized format will enhance the dissemination of high quality knowledge based systems and reduce redundant effort on the part of those who must devote many hours to the creation of these sorts of knowledge bases.

Why are standards helpful?

In his insightful book *Information Technology Standards,* (6) Carl F. Cargill defines a standard as the "deliberate acceptance by a group of people having common interests or backgrounds of a quantifiable metric that influences their behavior and activities by permitting a common interchange." He argues persuasively that all standards have economic motivation.

Regulatory standards are used by governments to mandate changes which protect consumers and employees against unfair economic discrimination. However, "well intentioned regulation appears to be waning. Regulation is a poor substitute for market action in either a dynamic society or a dynamic industry: regulation in a dynamic industry in a dynamic society can be positively destructive, for both the regulated and the regulators."

Voluntary standards are also economically motivated and can be used to increase profit, lower costs, and establish directions for future development. Because participation is voluntary, the benefits must be based upon the intrinsic value to the producer or consumer of participating in the definition of and application of the standard

To explore the potential advantages and disadvantages of setting standards for the representation of computer based medical knowledge, we wish to consider an analogy based upon another complex system in which some standards exist and, at the same time, diversity and innovation are encouraged. For our example we have chosen the automobile. Looking at cars from an external superficial perspective, we see that there are many different models and that each model embodies a very complex set of systems. Even a single manufacturer willingly chooses diversity even though such a decision leads to increased production and maintenance costs.

In spite of the outward diversity and real performance and price/performance differences, it is generally possible for an average or below average driver to get out of an expensive sports car and drive an inexpensive sub-compact car. One generally pushes the gas pedal with the right foot, there is a steering wheel, a speedometer, and a gasoline gauge. In other words a consumer can go from the top of the line to the bottom of the line across manufacturers and still drive the car. A driver may need coaching on the use of some of the features of the car such as cruise control, air temperature settings etc, which may not be used properly until the user who desires those features is motivated to experiment or read the users manual. However the basic transportation function is maintained across models, and each model must be compatible with the design of streets and local and federal regulations. The reason for this compatibility is generally acknowledged to be economic.

When a driver needs gas and oil, he or she can go to almost any service station or convenience store and get the required fuel regardless of the model which they may be driving. Here, there are a very small variety of choices, i.e. not only can the driver drive the car, but he or she can get the everyday necessities in standardized products.

As we consider parts that need to be replaced or replenished less frequently than fuel, the diversity of component parts and systems begins to expand. As opposed to three or four types of fuel, there are probably 20 or so tire sizes. Fan belts, batteries, and tires are often manufactured by firms that don't make the cars; but the automobile manufacturers who try to differentiate their products otherwise, have nevertheless limited the variety of these replacement parts so that a customer whose air conditioner compressor or fan belt breaks while driving across a sparsely inhabited desert will not be required to wait an extended period of time for repairs to be made. If there were not standardized replacement items readily available for a particular model of car, a customer could well resolve not to purchase or retain that particular brand or model of automobile. Again the consumer has applied economic pressure for standards, but these standards are not as rigid as those applying to fuel because fan belts, batteries and tires do not wear out as often as we need to refill our gas tanks.

Windshields are another story. A person may typically never need to replace a windshield; it becomes one of the items that goes into the distinctive design of the car and would only be standardized for a particular model of a car.

Based upon this analogy, we hypothesize that certain types of standards evolve in spite of economic desires of the manufacturer to differentiate its product, because the consumer requires daily operation of the system and the logistics required to support diversity pose economic burdens. The "look and feel" of the driver's "cockpit" must also adhere to a set of human interface standards in order to support a variety of users.

Another set of reasons for setting standards may be evident when we analyze the sound system of the automobile. Such systems were obviously not part of the early cars; some of us can remember that radios were once optional when purchasing a car. In contrast today's sound system ordinarily consists of an AM/FM stereo radio and a cassette tape player and, increasingly, a compact disk player. The cassette tape is an independent, modular commodity that can be inserted into a tape player built into the auto. There can be many different manufacturers of tape players and the players may vary in power, fidelity and quality; but the same cassette will play in all of them.

It seems to us that the reason for standards in this instance is not based upon the economic incentives of the tape player manufacturer, but rather upon the fact that no tape player manufacturer can ever be expected to deliver the wide variety of content available within the standard cassette format. The differentiation and variety in cassette tapes occur to a large degree in the content not the format. The customer can pick and choose from hundreds of performing artists or motivational products.

To summarize our analogy, we observe that the car is a very complex system which contains a sound system which can deliver entertainment and knowledge to the occupants at the same time the auto fulfills its basic transportation function. Few would argue for the exclusion of the cassette player because the radio can meet all needs. Individual cassettes have a modular, independent standardized format but different content. The content can cover a wide variety of subject matter and is produced by an equally wide variety of experts.

Some types of medical logic are as modular as the cassette tape. A rule which states that "one should use care in performing intravenous pyelorograms in patients who have evidence of renal failure" could be evaluated in the "logic player" of many different systems. Even if that is the only rule in the system, its output, if correctly evaluated, would still make sense. Other decision modules though modular are less independent. A rule that calculates the likelihood of a particular disease in the absence of comprehensive logic for alternative diseases would be limited because the users would not be able to determine the differential diagnosis list. When one contemplates causal network models or neural network models, the concepts of independence and modularity within knowledge base are more complicated.

While the field of medical informatics has not reached the degree of standardization that exists in the automotive industry, the attempts to build graphical user interfaces begin to address the "driver cockpit" issue and standards like HL-7 and Medix begin to allow us to consider replaceable parts. We realize that there will be many different kinds of "logic players" because of the variety of clinical databases and programming environments. We are seeking to establish a standard representational format for MLM's that will diminish the effort devoted to "playing the cassette" and increase the variety of modules which someone who builds or buys such a "logic player" can access.

One argument against implementing standards in a non-mature area of application is that standards stifle technical progress. One could argue alternatively that standards do create environments which accelerate progress and quality by creating markets that could not logistically exist in the absence of standards which do allow technical improvement in format and execution. Some can remember using the mechanical, wind-up (non-electrical) Gramophone, the electrical versions of 78 rpm record players, a new model which rotated forty-five times per minute, and yet a newer model which had options for 33 rpm in addition to the two already mentioned. Next came reel tapes, then cartridge tapes, then cassette tapes. Now as we look forward to compact digital disks, we already hear about Digital Audio Tapes and worry that we will make the wrong choice.

Producers of "players" have consistently improved the product for economic advantage even though the industry accepted voluntary standards. Master recordings that were first produced for one generation of products have also been transferred to the new format as a testimony that consumers seek the best technical representation of an often enduring artistic content. This migration is possible because form and content are distinct. Changes and improvements in the recording industry have not stifled the parallel improvements in radio broadcast technology.

A second argument against standards is that the standard may be inappropriately applied. QMR (7) and DXplain (8) are two leading examples of valuable knowledge bases. Both of these systems have modular knowledge bases which are processed by a logic evaluator (ad hoc scoring system) which reflects the nature of the format of the knowledge base. The logic in both of these systems could be recast in the Arden syntax, but there is little motivation for the developers to do so since there are no major economic reasons for doing so at the current time. The system representation and scoring algorithm is different in each case. There are also major issues of independence; one would not currently simply mix some of the logic from QMR and DXplain into one format and expect them to co-exist for the purpose of jointly producing a list of differential diagnoses.

Another aspect of voluntary standards is that they must be accepted. If a single manufacturer can set a de facto standard by virtue of market share or proprietary process, a voluntary association of self anointed have-nots is powerless. The question is whether such de facto standards currently exist.

When systems that generate alerts automatically by critiquing data as they are entered into the clinical database are examined, we perceive that a de facto standard is emerging. In these systems, substantial effort must be invested to create the clinical database and capture data from myriad sources within the patient care environment. Such systems cannot be easily changed to conform to a decision-making system that was originally created in a substantially different environment. The proposed Arden standard reflects the conventions of HELP and CARE which are two prominent decision systems which are currently interfaced to clinical databases and have the property of independence as well as modularity.

The groups at LDS Hospital/University of Utah, Columbia University, Erasmus University in Rotterdam, Holland and Linkoping University in Sweden are currently developing different versions of the logic player which will evaluate MLM's which adhere to the Arden syntax, and the Regenstrief group is planning to begin in the near future. Given this critical mass of voluntary cooperation, and the incorporation of the experience from two of the leading systems which have had successful experience in this arena, we think the time is ripe for acceptance of such a standard.

Multiple commercial vendors, encouraged by the initial successes of knowledge based systems which are coupled to a clinical database, are now readying or delivering products which will provide these capabilities. Potential consumers of, and contributors to knowledge based systems can influence the commercial vendors to consider the intellectual as well as the financial economy of accepting a framework so that the logic can be shared. The task of capturing and accessing the clinical data is arduous enough without the added burden of reinventing medical logic which has already been developed, tested and used successfully.

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