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Integration of A Computer-Based Consultant Into the Clinical Setting

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1 Introduction

For approximately ten years our research group has studied the application of artificial intelligence (AI) techniques to decision making tasks in clinical medicine. Our early work on the MYCIN program helped us understand the power of production rules as a scheme for representing judgmental knowledge of experts [7], but a variety of pragmatic constraints prevented us from implementing that program clinically. Thus, in 1979, we decided to adapt our previous experience with MYCIN to a new task domain in which chances for clinical acceptance and smooth system integration were greater than had been the case for the earlier work. The resulting program, ONCOCIN [10], and our experiences achieving its clinical introduction and local acceptance are the subject of this report.

ONCOCIN's design and implementation has occurred in unison with a set of studies and analyses intended to help us better understand the demands of physicians as computer users. Our study of physician attitudes towards computer-based clinical consultation systems [12] emphasized the importance of a system's explanation capabilities and helped convince us of the important role that AI techniques are likely to play in the development of optimal decision aids. We also have proposed a set of sequential "stages" through which an evolving consultant program will pass, and suggested a set of criteria to use in determining whether a proposed clinical application is likely to meet with short-term implementation success [8]. The ONCOCIN task domain in clinical oncology was selected for our recent work largely because it met the specified criteria. We have also tried to emphasize the important practical issues that will account significantly for a consultant program's success or failure [9]; excellent decision making performance is only one element of the total optimal scheme. We were influenced in these analyses by past studies that have indicated that physicians are reluctant to introduce computers into their clinical practice setting [6, 11], and by a perceptive essay that cited some of the major impediments to successful implementation of clinical computing systems [2]: poorly designed user interfaces, systems whose performance does not exceed those of the physician, an inability to prove that the system has a beneficial impact on patient care, and systems with an inflexibility inhibits transferability. We believe that with careful system design, and the ongoing involvement of the intended system users, these impediments can be avoided.

2 ONCOCIN

ONCOCIN is an oncology protocol management system that assists physicians with the management of patients enrolled in cancer chemotherapy protocols. The system has been in limited use at the Stanford Hospital since May of 1981. The potential utility of such a system has been recognized at several major cancer treatment centers, and other groups have been developing systems to assist with similar tasks [4, 1, 13]. Protocols are described in detailed documents often 40 to 60 pages in length, which specify the alternate therapies being compared in the experiment, and the data that need to be collected in order to study the effectiveness and toxicity of the compared treatment plans. Protocols specify drug dosages and modifications, and the intervals at which patients should be seen and laboratory tests and X-rays should be ordered. These specifications are generally complex and no single physician is likely to remember all of the details in even one of the protocol documents, not to mention the 30 to 60 such protocols that may be used in a major cancer center. Although, the documents are usually available in the oncology clinics where patients are being treated, a busy clinic schedule, coupled with a complex protocol description, often leads a physician to rely on memory or advice from colleagues when adjusting drug doses or deciding which laboratory tests to order. Furthermore, the protocols do not spell out solutions to all possible treatment contingencies that can occur. Physicians must therefore often use their own judgment when treating patients, thereby leading to some variability in treatment decisions. Similarly, the data needed for statistical analysis of the protocol results may not be completely or accurately collected. These factors indicate a need for assistance with remembering the details of the protocols and with accurate data collection. Furthermore, oncologists who care for protocol patients generally acknowledge that assistance would be useful.

Since the core of knowledge about oncology protocols is written up in the protocol documents, the cancer chemotherapy domain has the additional advantage of having a readily available source of the core knowledge of the field. The ongoing involvement of oncologists with ONCOCIN, both as research colleagues and as potential systems users, has provided additional expertise and highly motivated collaboration in knowledge-base development. We currently have encoded the protocols for Hodgkin's Disease, non-

Hodgkin's Lymphoma, and oat-cell carcinoma of the lung[2] , and will be adding all of the other treatment protocols employed at Stanford. It should be emphasized that the resulting computer-based protocols include both the specific rules gleaned from the protocol documents and some additional judgmental expertise from out experts who have defined the ways in which the system ought to respond to unusual or aberrant situations.

In order to design a program that could be operational in the short term, our initial design plan was to consciously avoid major theoretical barriers such as management of inexact reasoning and generalized methods for temporal reasoning. We recognize that these issues will ultimately need to be addressed, however, and look forward to the research challenges they will provide us in the future. In the short term, however, by encoding the protocol specification and supplementing it with some additional judgmental knowledge from our experts, we could develop a system which is already proving useful. ONCOCIN was built using artificial intelligence techniques, which have the advantage of making the system flexible and easily modifiable so that additional protocols, inexact reasoning, and temporal trend analysis can be added without major design modifications. Another advantage of AI techniques is that they facilitate the development of code to explain the system's line of reasoning.

2.1 System Design

ONCOCIN's system design is a result of the combined efforts of an interdisciplinary group of computer scientists, clinicians, statisticians and support staff totalling 29 individuals. System design began in July of 1979. From the outset, the logistics of how a consultation system could fit into the busy oncology clinic was a crucial design consideration; one of our first tasks was to study the flow of information within the clinic. We asked the oncology fellows their attitudes about computers and asked them to assess the potential role of such technology in the oncology clinic. A Stanford industrial engineer with human factors experience was consulted during the interface design phase. This phase was an iterative process. Programmers would offer mock demonstrations to those with little or no computer expertise. After getting comments and suggestions on the demonstration, modifications were made, and a new

[2]The oat cell protocol is the most complex protocol at Stanford. It was implemented to verify that our representation scheme would apply to essentially any of the protocols currently in use. However, it has not yet been released for routine use pending its thorough testing.

mock up presented. This process was repeated until all felt satisfied with the interaction. All design decisions of this type were discussed at regular research meetings that involved both physicians and computer scientists.

The design of the reasoning program, which is written in Interlisp and uses AI representation techniques, was affected by our desire to create a system which provides rapid response. The original ONCOCIN prototype used keyboard-oriented interactive programs borrowed from MYCIN. We knew from our earlier work, however, that this type of interaction would be too tedious and time-consuming for a busy clinic physician. A physician using MYCIN often had to wait while questions were generated and rules were tried. The use of this interface, however, enabled us to create the program's knowledge base and to evaluate its therapy recommendations while we were concurrently deciding upon the clinic interface design. The ultimate interface design incorporates a fast interface program that is separate from the AI reasoning program [3]. Thus, ONCOCIN is actually a set of independent programs that run in parallel and communicate consultation data with each other.

A major design goal was to have ONCOCIN used directly by the physician at the time of a patient's visit to the clinic for chemotherapy. One way to encourage their involvement was to make the system easily accessible while providing a variety of hard copy reports that had previously either not existed or had required manual preparation. A computer-generated summary sheet is produced in the morning for each scheduled patient enrolled in one of the protocols handled by the computer. The summary sheet is attached to the patient's chart and serves as a reminder of the patient's diagnosis and stage, expected chemotherapy, and any recent abnormal laboratory values or toxicities. A centrally located video display terminal is used by the oncologist after the patient has been examined. The physician interacts with ONCOCIN's high speed data-acquisition program called the *Interviewer*. The mechanics of this interaction are described in the next section. While the clinician is entering data through the *Interviewer*, it is passing pertinent answers to the reasoning program, (called the *Reasoner*) which uses the current patient data, the past history and the protocol assignment to formulate a treatment plan. By the time data entry is complete, the *Reasoner* has generally completed its plan formulation and has passed the results back to the *Interviewer*, which in turn displays the recommendation for the user. The physician can then agree with or modify the system's treatment recommendation, make adjustments to the laboratory and X-ray tests

suggested for the patient by ONCOCIN, and end the session. Progress notes are printed out for the physician on a printer near the ONCOCIN terminal so they can easily be removed, verified and signed by the physician, and then placed in the hospital chart. After the session the computer also generates an "encounter sheet" which lists the tests to be ordered, when they should be scheduled, and when the patient should return to the clinic for his or her next visit. This information is generated on a second printer located at the front desk where these activities are scheduled.

The system design attempts to prevent the computer system from being perceived as an unwanted intrusion into the clinic. The physician/computer interaction takes the place of a task that the physician would otherwise perform by hand (the manual completion of a patient flowsheet), and requires only 5 to 7 minutes at the terminal. A training session of only 30 minutes has been adequate to achieve independent use of the system by physicians, and the hard copy reports assist the physician with their responsibilities. Because we were eager to make the system as flexible as possible, and to simulate the freedom of choice available to the physicians when they fill out the flowsheets by hand, the program leaves the users largely in control of the interaction. Except for the patient's white cell count, platelet count, and information about recent radiation therapy (key issues in determining appropriate therapy), the physician may enter whatever flowsheet information they feel is pertinent, leaving some fields blank if they wish. An important evaluation issue that we are accordingly investigating, is whether ONCOCIN encourages more complete and accurate recording of the flowsheet data despite the user's continued ability to skip entries if he or she wishes to do so. They may enter data into the flowsheet in whatever order they prefer; they may skip forward or back in the flowsheet and change current or old answers.

2.2 Terminal Interface

The system incorporates a special terminal interface to ensure that a busy clinician can find ONCOCIN fast and easy to use, as well as simple to learn. The physician interacts with a high-speed (9600 baud) video display terminal with multiple windows, simulating the appearance of the conventional paper flowsheet. Simulation of the form makes the interaction more comfortable and familiar.

A customized keyboard was designed for data-entry (Fig. 1). It allows the physician to enter the flow sheet information using a 21-key pad which is located to the

right of a conventional terminal keyboard. We considered light pens and touch screens but felt that they were either too expensive or too unreliable at the present time. Furthermore, a simple keypad was adequate for our needs. The layout of the keypad is simple and self-explanatory. Ten of the keys are a number pad which is laid out the same as the numbers on push-button telephones. Our human factors specialist recommended this decision because we could assume user experience with push-button telephones, but user experience with the calculator-style number pad would likely be more limited. The other keys on the pad are "Yes" and "No" keys, and cursor control keys. The labels on the cursor control keys suggest that the user is filling in the blanks on a paper form, such as "Next Blank", "Clear Blank", "Jump Ahead" etc. Our human factors consultant suggested this terminology instead of terms which include the word "field" (e.g., "next field") which are information processing terminology and not as intuitive for naive computer users. This decision reflects our general effort to avoid computer jargon when talking with the physicians, printing text on the terminal screen, or in communicating with them in memos.

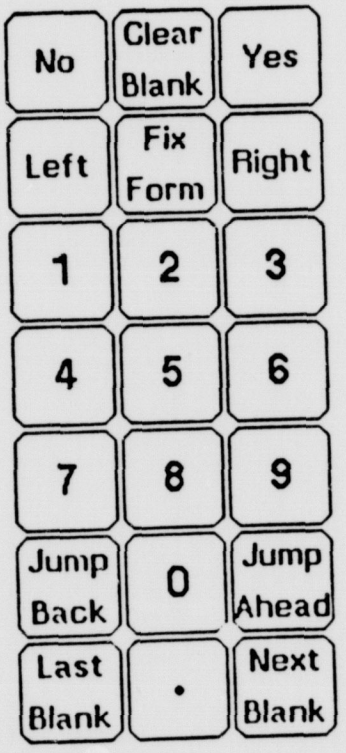


Figure 1: ONCOCIN's 21 Key Pad

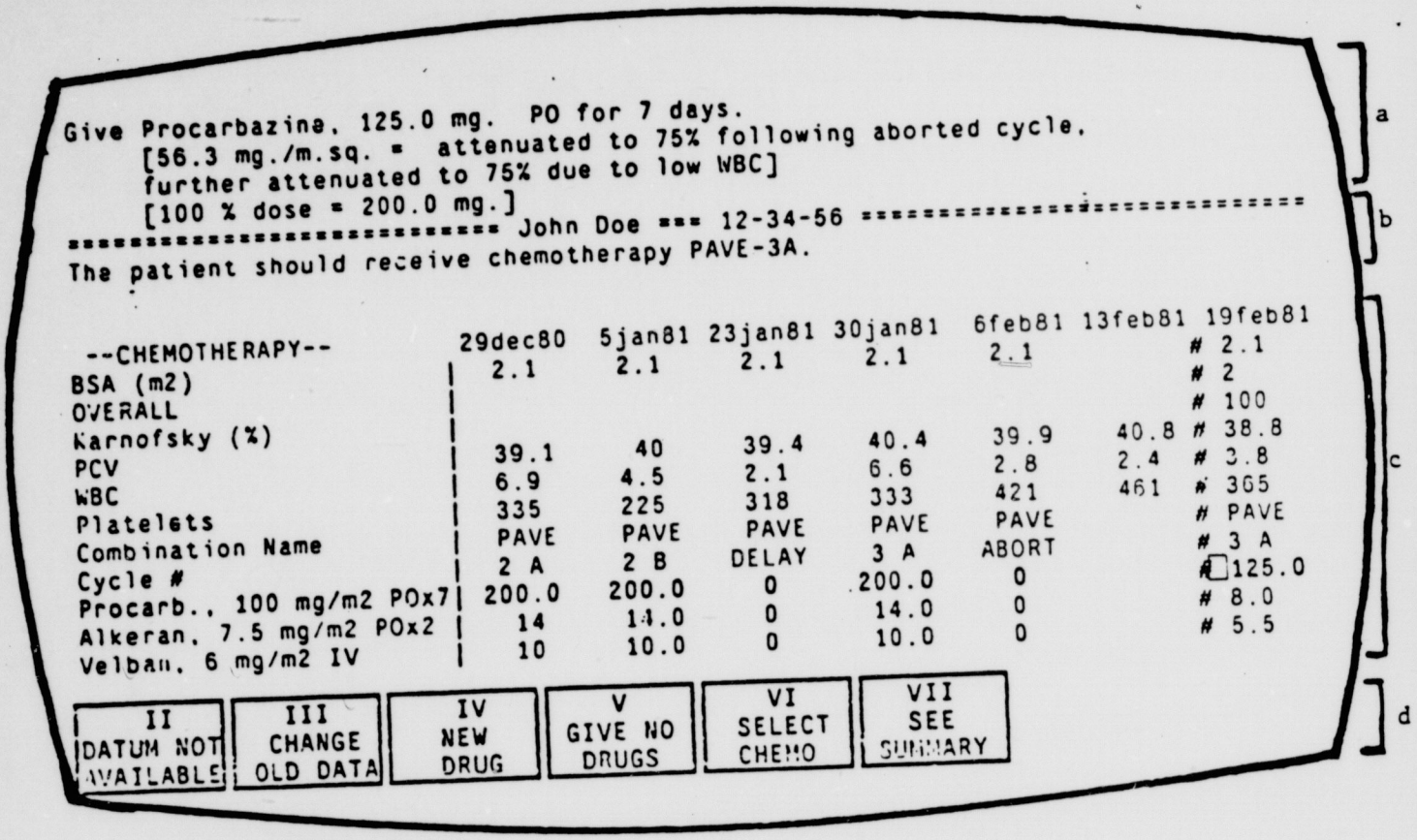
2.3 Display Design

The design of the display is derived from the paper flowsheet used for many years for protocol data gathering and analysis. The main portion of the screen displays one region of the conventional flowsheet (Fig. 2). When the cursor is aligned with an entry on the form, that line appears in bold face and the explanation for that line is shown in the "explanation field" at the top of the screen. When the physician is entering patient data, this explanation field specifies the range of expected entries for the item with which the cursor is aligned. When the system has recommended therapy (see Fig. 2), the explanation field provides a brief justification of the drug dose indicated by the cursor location. On the bottom portion of the screen are labels for special function keys. These are associated through Roman Numerals with colored control keys aligned across the top of the keyboard. At different times during the interaction, these keys perform different functions. The bottom of the screen gives a description of the function each of these keys currently will perform. There is also a special "message" section in the middle of the flowsheet where important information about the patient or the running of the case can be displayed.

2.4 Integration Into the Clinic

To make ONCOCIN's clinic integration as smooth as possible we scheduled clinic meetings led by the oncology members of our research team. One such meeting to announce that the system would soon be available was held. At this meeting we gave a system demonstration and held discussion of our project goals. Individual training sessions were then scheduled to teach each physician how to use the system. These orientation sessions were brief and informative. They stressed that the physician is the ultimate decision-maker about the patient's care, and that the computer consultant is to remind the physician about the complex details of the protocols and to collect patient data. Members of our group meet with oncology faculty and physicians occasionally to give them progress reports on our research effort.

We also enlisted the help of a data manager who is responsible for training sessions, assures that on-line patient records are current and sees that the system runs smoothly. The data manager is available whenever the system is running in the clinic and offers assistance when necessary. This role has proved to be particularly crucial. The data manager is the most visible representative of our group in the clinic (other than the



This diagram shows the layout of a typical display seen by the physician when he uses ONCOCIN. The screen is divided into four sections as indicated.

a: the explanation field, which presents the justification for the recommendation indicated by the user-controlled cursor location (the box in the figure).

b: the message field, which identifies the patient and provides a region for sending pertinent messages from ONCOCIN to the physician.

c: the flow sheet, which displays a region of the conventional hard-copy flow sheet; the display includes columns for past visits and the physician enters data and receives recommendations in the right-hand column.

d: the soft key identifiers, labels that indicate the special functions associated with numbered keys across the top of the terminal keyboard.

Figure 2: Sample ONCOCIN Screen

collaborating oncologists themselves). The person selected for this role therefore needs to be responsible, personable, non-imposing, intelligent, aware of the systems goals and capabilities and able to communicate effectively with the physicians. If the person in this role is unable to satisfy these qualifications he or she can make system usage seem difficult, undesirable and imposing to the physician users.

Integration of the system into the clinic was planned to be a gradual process. When the system was first released, the program handled a small number of patients and protocols. As use of the program became more familiar to the physicians, we added more patients to the system. We are in the process of adding new protocols, which in turn will mean additional patients being handled on the computer. ONCOCIN was initially available only three mornings per week. It is now available whenever there are patients scheduled who are being followed on the computer. This plan for slow integration of the system into the clinic has made ONCOCIN's initial release less disruptive to the clinic routine than if we had attempted to incorporate a comprehensive system which handled all patients and protocols from the onset. This method of integration has also allowed us to fine-tune our system early in its development, based upon responses and suggestions from our physician users.

2.5 Responses and Modifications to the System

After the system's initial release into the clinic, the data manager and the collaborating oncologists collected comments and suggestions from the physicians who used the system. We accordingly made numerous program changes in response to suggestions for modifications and desirable new features. Our group also conducted a number of formal studies to evaluate the impact of the system on a number of different levels.

We soon learned that some of our initial design decisions had failed to anticipate important physician concerns. For example, when the *Reasoner* needed an answer to a special question which is not on the regular flowsheet form, our initial approach was to have the *Interviewer* interrupt data entry. The physicians were annoyed by these interruptions, so we modified the scheme to insert the question less obtrusively on a later section of the flowsheet, and to stop forcing the physician to answer such questions if they were felt not crucial to the recommendation.

Another concern was that ONCOCIN was too stringent about its drug dose

recommendations, thereby requesting justifications from the physician even for minor changes. We needed to take into account, for example, that a different pill size might decrease or increase a dose slightly and yet would be preferable for a patient's convenience. We subsequently obtained from the oncologists on our team, ranges for each chemotherapeutic agent within which any modifications could be considered insignificant. Dose modifications within this range no longer generated requests for justification.[3] We also modified the program to recommend the same dose that the physician prescribed during a prior visit if that dose recommendation is within the acceptable range relative to the dose recommendation calculated by the program.

Some system users also asked whether the program could generate a progress note for the patient's visit. When we developed this feature and installed a small printer to prepare these notes in duplicate, use of the system was immediately made more desirable because this capability saved the physician the time required to dictate a note. This feature also helps to encourage the physician to enter relevant data completely and accurately because the quality of the resulting progress note is dependent on the data entry process.

When the system was first released into the clinic, it was only available the three mornings per week when the majority of lymphoma patients were seen (the computer, a Decsystem 2020, was used at other times by other members of our research community). This was to provide rapid response time through an arrangement for high priority use of the computer. Since lymphoma protocol patients were sometimes seen at other times, however there were continuing problems keeping the computer-based files up to date and establishing ONCOCIN's role as a reliable aid for the management of that subset of patients. In response to this we have made the system available whenever a patient known to the system is seen in the clinic. When the physician initiates a consultation, the program checks to see if the computer response is expected to be slow and prints out a warning to this effect. The physician may then either abort the session or proceed with the anticipation that the interaction will take longer than usual. We have found the the physicians understand and appreciate this feature and will often continue despite the expected delays.

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[3]Current research is also investigating an adaptation of ONCOCIN's recommendation scheme whereby it will critique the physician's own therapy plan and only give advice when specifically requested to do so [5].

The anecdotal system descriptions here are being accompanied by three studies conducted as part of this research: (1) Physician attitudes towards a computer system in the oncology clinic were surveyed before and after ONCOCIN's integration into the clinic, (2) the suitability of ONCOCIN's recommendations compared with the treatment proposed by the physicians prior to computer assistance is being studied, and, (3) the completeness and accuracy of data collection with the computer compared to that prior to the system's introduction is being studied. Formal reports on these investigations are in preparation.

3 Lessons Learned

It is clear that in order for a computer-based consultant to be effective in a clinical setting, the overall system design must take into account both the needs of the intended users and the constraints under which they function. This is the central theme of the lessons that we have learned from the ONCOCIN experience. The program must be designed to satisfy a need for consultation and to provide this assistance in a fast, easy-to-use, and tactful manner. It should ideally avoid an incremental time commitment or an increase in the responsibilities of its users or they will tend to resist its use. We have found that providing extra related information processing services, such as printing the progress note for the physicians significantly heighten the system's appeal.

For ONCOCIN to have an effective role as a physician's assistant, providing both data management functions and consultations on patient treatment, it needs to be part of the daily routine in the clinic. Because of the limited number of patients and protocols currently on the system, ONCOCIN is thus far the exception to the daily routine; this will change as more protocols are encoded and the system is transferred to dedicated hardware. We are planning to move ONCOCIN to a personal workstation (capable of handling large AI programs) so that it will be self-contained. As it becomes the principal record keeping system in the oncology clinic, and the oncologists are able to receive useful advice for essentially all of their patient encounters, ONCOCIN will have become successfully integrated into the clinic setting. The next stage will be to disseminate the system, mounted on single-user workstations, into other practice settings beyond Stanford.

Since our goal is to offer expert consultation, we also need to continue our research into expert systems development so that we are able to encode the less well-specified

aspects of oncology expertise. More active research into temporal reasoning and issues of uncertainty is necessary in order to allow ONCOCIN to handle the most unusual cases in this domain. Oncology protocols often refer the physician to the Protocol Chairman or a faculty member for consultation; an important research goal is to provide ONCOCIN with an ability to handle these special cases where more complex reasoning is required to decide upon patient treatment.

Physician involvement in the design of ONCOCIN has been crucial in all aspects of the system development. The collaborating oncologists provide answers to questions that are unclear from the protocol descriptions, evaluate the program's recommendations to assure they are reasonable, offer useful feedback during the development of the user-interface, and provide advice about how the computer-based consultation system can best fit into the clinic setting. Their collaboration, along with that of the computer scientists, medical personnel and others in our interdisciplinary group, all who have been committed to the creation of a clinically useful consultation tool, has combined to create a system for which limited integration into a clinical setting has been accomplished, and for which we expect that total integration will be feasible in the next few years.

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