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Improvements in Data Collection Through Physician Use of a Computer-Based Chemotherapy Treatment Consultant

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ABSTRACT

Improvements in Data Collection Through Physician Use of a Computer-Based Chemotherapy Treatment Consultant

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The impact of a computer-based data management system on the completeness of clinical trial data was studied before and after the system's introduction in an oncology clinic. Physicians use the system, termed ONCOCIN, to record data during patient visits and to receive advice about treatment and tests required by experimental cancer protocols. Although ONCOCIN does not force the user to enter all data expected by the protocol, after its introduction there was improvement in the recording frequency of such data. The percentage of expected physical findings recorded increased from 74% to 91% ($p<.05$), toxicity history from <1% to 45% ($p<.01$), general chemistry results from 36% to 82% ($p<.01$), x-ray results from 44% to 73% ($p<.01$) and physicians' assessments of overall disease activity and Karnofsky performance status from 73% to 91% ($p<.05$). Analysis of the steps in data collection and their contribution to loss of data suggests that observations or test ordering which are dependent on the physician are most improved by the system. Furthermore, analysis of post-ONCOCIN visits when the system was unavailable suggests that the recording of physician-dependent data (physical findings and assessments of disease activity and performance status) is likely to revert to pre-ONCOCIN levels if the system is not used routinely. The results show that ONCOCIN can greatly enhance recovery of those data expected for chemotherapy protocol patients. The program's interaction with the physician is central to its effectiveness in data collection, especially for data that arise directly from the patient-physician encounter.

INTRODUCTION

Probably no field of medicine has adopted the routine use of clinical trials as actively as medical oncology. Cancer therapy research has resulted in a marked improvement in prognosis for many malignancies. However, as the use of multi-modality treatments has increased, so has the complexity of the clinical trials designed to establish efficacy, to evaluate toxicity, and to assess the superiority of one treatment over another. Computers are now used routinely for oncology protocol data analysis and increasingly for protocol management providing feedback to physicians regarding therapeutic actions [1, 2, 3, 4, 5, 6, 7, 8].

Most computer systems manage relevant patient data after the information has already been collected and transcribed for analysis, thereby avoiding direct interactions with physicians who care for the patients enrolled in the study. However, it is only through direct physician use of such systems that computers can dynamically offer advice and explanations while assessing the integrity of the data being entered. Accordingly, there has been increasing interest in the development of acceptable computer-based tools for direct use by physicians participating in clinical trials.

Elsewhere we described ONCOCIN, a consultation system for use in the management of patients enrolled in cancer chemotherapy protocols [8] and presented data regarding the expert-level advice offered by the system [9]. In those reports, we have discussed our rationale for providing physicians with computer-assisted management advice at the time they make treatment decisions regarding protocol patients. In the current paper we focus on the data collection process, assessing the computer's effect on the completeness of patient data that are captured and made available for statistical analysis. The completeness of the patient database before and after ONCOCIN's introduction into our oncology clinic provides a measure of the system's impact.

Physicians and clinic data managers were recording patient data on structured flowsheets even before the introduction of ONCOCIN. Thus, improvements in data collection were due to the physicians' interactions with the machine rather than simply to use of a structured system for recording data. Our findings also suggest that interactive computer systems designed for direct use by physicians may improve the process of data capture and validation for clinical trials in other settings.

METHODS

The ONCOCIN System:

ONCOCIN is a medical consultation system that draws upon artificial intelligence techniques and has been influenced by a predecessor program known as MYCIN [10]. ONCOCIN uses knowledge about chemotherapy protocols for Hodgkin's and non-Hodgkin's lymphoma to provide advice on drug selection, dosing, test selection and other data aquisition. Technical aspects of the system's operation have been described elsewhere [11]. Because ONCOCIN uses artificial intelligence techniques and judgmental knowledge acquired from expert oncologists to give advice, it is an example of an "expert system" [12]. However, the present study focuses on ONCOCIN's data management capabilities rather than its performance as a consultant. All interactive sessions involve the physicians themselves, with ancillary personnel using the system only for chart review and to enter laboratory data that become available between clinic visits. The clinic physician can choose to use either ONCOCIN or traditional hand-written flow-sheets to record data during a patient visit. During ONCOCIN's development, a data manager has monitored both online and handwritten data, keeping each modality up-to-date for all patients.

In our oncology clinic, the physicians follow protocols that define permissible treatment options and set data-gathering requirements to assure a well-controlled experiment with adequate data for analysis. The physician records clinical data such as patient symptoms, physical findings, laboratory data, and treatment onto a flowsheet (datasheet), which is later transcribed into a patient databank for statistical analysis. Thus, the flowsheet is the critical document tracing the course of any patient undergoing treatment on our protocols. ONCOCIN replaces the paper flowsheet with a consultation system designed to acquire and record the same data that were previously hand-written on the flowsheet. Because protocol-guided management decisions are generally based on flowsheet data, ONCOCIN combines clinical information with protocol guidelines and additional knowledge provided by expert oncologists to provide management advice and to remind the user about data that need to be collected.

All interaction with ONCOCIN takes place at a conventional high speed video display terminal equipped with a 21-key keypad that allows the physician to avoid typing [8]. During data entry, the display screen mimics the structure and entry format of the paper flowsheet. There are messages at the top of the screen indicating acceptable responses for the entry about to be made. The physician directly enters clinical data at the terminal and ONCOCIN verifies their acceptability by range and type checking.

Before ONCOCIN's introduction, data were captured by having the physician write a test result or a standardized numeric code onto the paper flowsheet. This task was voluntary, and the physicians did not always record the full set of data required by the protocol. The computer system also does not force the physician to enter any information, except for the patient's current blood counts and the date of completion of any recent radiation therapy. Thus essentially all entry tasks were highly structured, but voluntary, both before and after the computer's introduction.

ONCOCIN has been used experimentally since May of 1981 to assist with the management of lymphoma protocol patients in the Oncology Day Care Center at Stanford University Medical Center. After furnishing informed consent for a protocol, patients are treated and followed in a lymphoma chemotherapy clinic staffed by post-doctoral oncology fellows under the supervision of senior oncology faculty.

Data Completeness Study:

To assess ONCOCIN's impact on the completeness of data collection, we studied clinic records before (pre-ONCOCIN) and after (post-ONCOCIN) the system's clinical introduction as an assistant in the management of lymphoma patients. The pre-ONCOCIN analysis considers all patients with Hodgkin's disease who were enrolled in protocol chemotherapy at Stanford between July 1, 1980 and May 15, 1981. During this period, all clinical data were manually recorded on paper flowsheets by the physicians who were treating the study patients. Because most data are collected only once at the beginning of each cycle of chemotherapy, we assessed only the first visit of each cycle. There were 20 patients contributing 66 visits, and all data were collected prior to introduction of the system. The post-ONCOCIN analysis considers all patients with Hodgkin's disease treated with assistance from ONCOCIN between March 1 and October 1, 1982. There were 29 patients contributing 114 visits in this group. Sixteen oncology fellows participated in this study, 10 before and 11 after ONCOCIN's introduction, each caring for one to seven patients. Five fellows in the pre-ONCOCIN period also conducted 25 of the post-ONCOCIN visits, but no patients were seen during both periods.

ONCOCIN runs on a research computer (Digital Equipment Corporation 2020) provided by SUMEX-AIM, a shared national resource for investigations of artificial intelligence techniques and their application to biomedicine. This machine has been made available for experimental use of ONCOCIN on the three weekday mornings when most Stanford lymphoma outpatients are treated. When post-ONCOCIN study patients were seen at other times, or when the computer was unavailable due to hardware failures or scheduled use by other research projects, the physicians in our clinic were unable to use ONCOCIN and were forced to revert to manual data recording on the paper flowsheet. Of the 114 post-ONCOCIN visits, there were 56 when the doctor used ONCOCIN and 58 when the doctor could not use ONCOCIN.

For each visit we collected the following general information: patient identifier, treating physician, calendar month, months of physician experience as an oncology fellow at the time of the visit, and the protocol for that patient. These items include the most important and measurable sources of potential confounding factors when comparing pre-ONCOCIN to post-

ONCOCIN data collection. The clinical and laboratory data required at each visit were defined by the protocol documents and summarized on flowsheets in the clinic chart. These included toxicity history, physical examination findings, assessments by the physician of overall disease activity and Karnofsky performance status, nurses' data, and radiographic and laboratory results (Table 1). We have found it is useful to distinguish these items by three possible paths of information flow from patient to flowsheet (also see Table 1):

- The patient's history, physical examination, and assessments by the physician (data items that are initiated, collected and recorded by the physician). Both before and after the introduction of ONCOCIN, the presence of the patient was the only reminder for the physician to collect these data.

- The patient's weight, measured routinely at each visit by nursing staff, and the results of radiologic examinations ordered by the physician at previous visits (data items that are gathered or performed by others but ordered and recorded by the physician). Prior to ONCOCIN the physician had to remember which radiologic studies to order, whereas ONCOCIN later provided reminders for this task.

- Laboratory data, such as general chemistries and serum copper, (data items that are ordered by the physician but recorded by the clinic's data managers). After ONCOCIN's introduction the computer reminded the physician to order such tests, but the results continued to be entered into the computer by a data manager.

For the purposes of this study, "expected" data items were defined as those items required by the protocol on the first day of each cycle. An item was considered "recorded" when it was entered in the proper place on the flowsheet, either by hand or by using ONCOCIN.

Laboratory and radiologic data were considered "done but not recorded" if a result could be found in the hospital record or in the progress note but no entry appeared on the flowsheet. Items were considered "ordered but not done" if they appeared in the oncology clinic's summary log of each day's test ordering but no test results could be found. Data not on the log were considered "expected but not ordered." For toxicity history, nursing data, physical examination, and physician assessments of disease and functional states, there is no time during data collection when a test is "ordered". These items were therefore classified as either "expected but not done" (when no evidence of collection of this information could be found after detailed chart review) or "done but not recorded" (if the chart review showed evidence of collection of the required information but the information was not transcribed onto the final flowsheet).

For our analysis we compared three groups: pre-ONCOCIN visits, post-ONCOCIN visits when the doctors used ONCOCIN, and post-ONCOCIN visits when the system was unavailable for use. Protocols were categorized into those that were simple or complex, the latter having alternating drug regimens or chemotherapy alternating with radiotherapy. Visits also were distinguished according to the number of half-years (one to four) of the fellow's experience in oncology. Differences in the proportion of items completed were computed for each of the levels of these factors, standardized, and combined by weighting inversely by the variance. This resulted in a standard normal variate (Z-score) from which two-tailed p-values could be calculated. The data also were analyzed uncorrected for the two factors (protocol complexity and physician experience) to assess whether or not they were associated with outcome. The standard normal variate is a conservative statistic since any subset (cell) with no observations requires discarding all cases in the comparison cell prior to obtaining the weighted Z-score. As a consequence, four or more subdivisions of our data caused loss of statistical power to detect less than 20% differences in recording.

RESULTS

ONCOCIN improved physician data recording for 28 of 30 items for which data were expected by the Hodgkin's disease protocols. The range of responses depended on the type of data expected (Figs. 1 and 2). In the case of blood counts, which are essential to proper dosing of chemotherapy, recording was nearly perfect even before the use of ONCOCIN (Fig. 1). At the other extreme, all 19 toxicity items were essentially never recorded on the flowsheet in the pre-ONCOCIN period (Fig. 1). When ONCOCIN was available, however, about half of the expected toxicity information for each of the 19 items was recorded. Recording of physical findings (lymph node and spleen) and physician assessments of disease acitvity and performance status showed modest improvements with ONCOCIN. Radiology and nursing data recording showed larger improvements from a generally lower pre-ONCOCIN level. Pre-ONCOCIN recording of general chemistry and serum copper was low, but was significantly improved after ONCOCIN was introduced (See Figure 2).

Analysis of data recording for post-ONCOCIN visits when the consultation system was not available further demonstrated the impact of the computer system. A comparison of physician data recording with ONCOCIN to data recording when ONCOCIN was unavailable showed deterioration of data recording to pre-ONCOCIN levels for 27 of 30 data items. Items whose rate of recording remained at high levels were those that were either essential for patient management (blood counts) or dependent on entry by a data manager (chemistries and copper). Recording of items requiring physician assessment (nodes, overall disease activity, Karnofsky performance status, and spleen status) deteriorated to levels worse than in the pre-ONCOCIN period.

When confounding factors were analyzed, post-ONCOCIN fellows had an average of six months more experience in oncology than did the pre-ONCOCIN fellows. When this factor was controlled, the statistical significance of the observed increases in recording persisted for all items except measures of disease activity (physical examination, overall disease status and radiographs). For physical exam items and overall disease activity, the loss of significance was due to loss of power to detect a 20% difference in recording completeness. For radiographs, there was a trend toward more complete recording by experienced physicians. Many more complex protocols were in effect after ONCOCIN was introduced, but statistical analysis revealed no confounding influences attributable to this factor. All post-ONCOCIN comparisons between visits when the doctors used ONCOCIN and visits when ONCOCIN was unavailable (Figs. 1 and 2) were statistically significant, even after controlling for half-years of physician experience and protocol complexity.

As described above, we categorized the sources of data loss according to the last completed step in the data acquisition process: "Expected," "Ordered," "Done" and "Recorded" (Fig. 3). The type of data represented by each item (Table 1) influenced how well the information was preserved. Loss of information from the physical examination and physician assessments was largely due to omissions of recording (Fig. 3), which was a physician responsibility both pre- and post-ONCOCIN. In contrast, loss of general chemistry information was largely due to failure to order tests (a physician responsibility pre-ONCOCIN, but assisted by reminders post-ONCOCIN). Radiographs showed an intermediate pattern with about 30% of the information loss due to failure to order an expected study while the remainder represented omissions of recording (both were physician responsibilities pre-ONCOCIN). There was little loss of data in the execution phase of information gathering, between "ordered" and "done" (always the responsibility of clinic or hospital support staff).

DISCUSSION

Use of the ONCOCIN system significantly improved data recording, ranging from modest 15% improvements for some items to a marked increase in toxicity data recording. This improvement was apparent from both historical and concurrent comparisons and remained statistically significant for most items after controlling for physician experience and protocol complexity. This improvement occurred in a clinical setting that already used a well-structured data collection system with a comprehensive flowsheet backed up by clinic data managers. We believe that the improvements in data collection accomplished by ONCOCIN are attributable to its use by physicians at the time of their encounter with the patient.

The central importance of the treating physician as the originator or the recorder of data is suggested by parallels between the results summarized in Figures 2 and 3 and the three paths of information flow outlined in Table 1.

- Although items totally within the physician's domain (e.g., physical examination) are expected by protocols, the physician is reminded to make these observations simply by the presence of the patient. The only time that the physician is otherwise reminded about such parameters is when completing the flowsheet, either on the computer or by hand. When ONCOCIN was unavailable, recording of these items deteriorated to levels worse than those in the pre-ONCOCIN period (Fig. 2). Review of patient charts indicated that this loss of physician-dependent data was entirely a recording problem (Fig. 3).

- For data items performed by others but recorded by the physician (radiologic tests and patient weight), ONCOCIN improved the frequency of recording. For radiologic procedures, the system contributed to data collection on an ongoing basis by reminding the physician to order the pertinent studies. However, recording returned to pre-ONCOCIN levels when the system was unavailable (Fig. 2).

- The persistence of good recording levels for clinical laboratory items (Fig. 2), even when the computer was unavailable, is attributable to a conscientious data manager who later transcribed these data into the system. Physicians entered data only on the day of the patient's visit.

There are two likely explanations for the improvement in recording by physicians when using ONCOCIN. The first relates to ONCOCIN's data entry process. The system requires that physicians actively move the terminal's screen pointer (cursor) past an empty space if they wish to omit entry of a piece of data [8]. This seems to provide a strong incentive to enter the expected information. The second point relates to the process of test ordering. ONCOCIN reminds the physician about expected tests, but this prompting disappears when the system is not available. Thus ONCOCIN offers formal reminders about test ordering and serves as a functional reminder for data entry by consistently presenting options for recording data whenever physicians use the program to obtain treatment advice. Our findings also corroborate those of others, showing that the beneficial effects of computer-generated reminders for physicians may not carry over into subsequent periods when the systems are removed or rendered temporarily inoperative [13, 14]. This contrast between preservation of complete data recording by the data manager and the deterioration attributable to physicians unaided by ONCOCIN underscores the importance of high reliability and availability for this type of interactive data management and consultation tool.

Our findings for recording of toxicity history are of particular interest to those concerned with complete data for analysis of a clinical chemotherapy trial. The computer's prompts to enter each of 18 treatment toxicity items clearly improved recording of the presence or absence of toxicity. Similarly, in studies of protocol chemotherapy for children treated near their homes with computer-generated advice sheets and data collection forms, toxicity recording was completed much more frequently than was true in the affiliated regional oncology center [15]. Since 97% of post-ONCOCIN recorded toxicity items indicated absent or minor toxicity, the pre-ONCOCIN absence of recording probably represented corresponding absence of significant toxicity. However, one cannot be sure that rare toxicities were truly not overlooked. Also, the research protocol specifies recording of all toxic side-effects, even those that are common, while clinicians quickly become accepting of chemotherapy side effects and may thereby stop perceiving mild toxicities as worthy of note. Thus the manually-recorded research database for toxicity loses value for milder toxicities and has uncertain value for analysis of major toxicities.

Although many oncology protocol management systems have been described [2, 4, 5, 6, 7, 16, 17, 18], evaluations of their impact on the quality of data collection are scarce or unpublished. However, the evaluation reports known to us [19, 20] lend support to our conclusions regarding the central role of the physician in data collection. Friedman and coworkers found that data recording compliance was worst for "subjective tests that required physician judgment" [19]. Our findings also parallel those of a randomized trial evaluating a computer-based oncology information system [20]. That study showed perfect compliance with protocol data collection requirements when physicians used computer-generated advice and recording forms at each patient visit.

The significance of ONCOCIN's impact on data collection may be contrasted with studies of other efforts to use computers for medical information management. Several large information systems have been described (e.g., TMR [21], HELP [22], and the Regenstrief system [23]). Most have been evaluated on the basis of user satisfaction, rapidity of access to information, and declining dollar costs. Similarly, comprehensive ambulatory record-keeping systems, such as COSTAR [24], STOR [25, 26] and DUCHESS [27], have been described and evaluated for cost, user satisfaction and ease of implementation. Such systems facilitate quality control activities such as the issuance of reminders to physicians about necessary procedures [13, 14] or the retrieval of all patients taking a drug newly suspected of adverse effects [28, 29]. All of these systems depend on personnel other than the physician for entry of primary data into the computer.

A common theme for all these efforts is efficient delivery of information services to providers in diverse general medical settings. Cancer therapy trials have the additional goal of complete capture of comprehensive clinical and laboratory data about treatment, disease response and potential as well as known toxicities. The evaluation of ONCOCIN discussed in this report emphasizes the system's impact on this aspect of data management for clinical trials. ONCOCIN is unique in facilitating physician-machine interaction during a patient's clinic visit, both for data collection and for giving protocol advice [8, 9]. Clinical researchers running randomized trials in other fields have begun to move from centralized data management to distributed data collection support at each participating site [30]. Our results suggest that delivery of the computer one step further, to the primary providers themselves, will capture data that otherwise may be lost prior to transcription onto a flowsheet or into a delayed data retrieval system.

This report does not address three additional important elements in the evaluation of a medical information support system: system acceptance, quality of advice, and impact on patient outcomes. The methods and results of an attitude and acceptance study regarding ONCOCIN are in preparation and will be the subject of a subsequent report. Our assessment of the quality of ONCOCIN's chemotherapy advice has been reported elsewhere [9]. Both these studies required methodologies different from those described in this report. Patients managed using ONCOCIN have not been followed long enough to report a meaningful outcome study at this time. Furthermore, confounding variables related to other changes in cancer treatment over time make it unlikely that a valid outcome study of this type can be realistically undertaken.

Due to recent advances in computer hardware, there appear to be few obstacles to ONCOCIN's eventual implementation on office computer systems of moderate cost. We expect that this development will allow ONCOCIN to evolve from its current use as a research tool to a role as a treatment advisor and protocol data manager for community oncology trials. Thus, community physicians and their patients will find it easier to participate in chemotherapy trials that have previously been difficult to perform outside university centers. Our evaluation of ONCOCIN's costs and benefits awaits completion of a small computer version of the program and its implementation in a community oncology setting.

In the future, the most effective clinical consultation and data management systems will be designed to interact with physicians throughout the process of patient care. After all, clinicians must collect and interpret accurate data in order to provide optimal clinical care. This study and others have shown that items of information gathered and recorded by the physician tend to show the most improvement with the use of computer-based systems, and are the hardest to preserve without computer assistance. Physicians who inherently are overloaded in their information management tasks can thus derive great benefit from automated data management systems (see also [31]). Although we have studied complex chemotherapy protocol environments, others have argued for similar benefits of computer systems for clinical data management in primary care settings [28, 32].

Our evaluation has shown that routine use of ONCOCIN in a university clinical research setting can have a major beneficial impact on the collection and recording of clinical trial data. As computer systems such as ONCOCIN become available in communities remote from tertiary care centers, barriers to enrollment of additional patients in cancer chemotherapy trials may largely be overcome. We have shown that a consultation system can provide expert-level treatment advice in this domain [9], and the current study suggests that an integrated data management tool can also help assure the integrity and completeness of the patient information being collected for analysis. It must be emphasized, however, that the results of studies such as the one reported here may not generalize to new environments away from the university setting. Only by continued and thorough evaluation of such systems as they are transferred elsewhere can we identify and eliminate shortcomings that may arise. The effort is worthwhile, however, in light of the potential advantages provided patients and physicians by effective clinical data management and by decision support tools.

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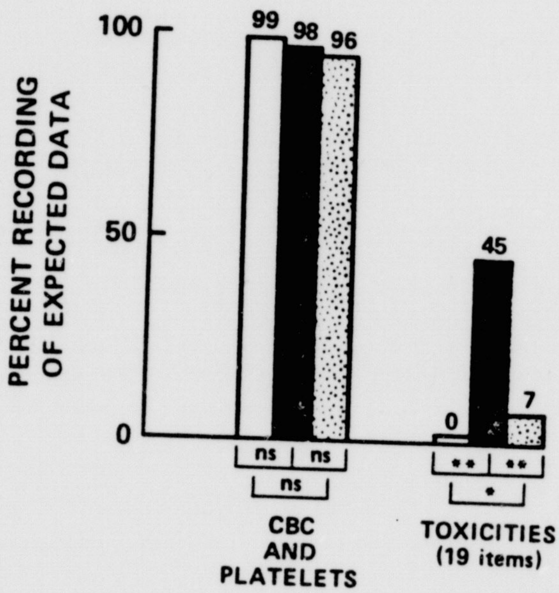
Legends to Figures

Figure 1: Comparison of recording percentages with and without ONCOCIN for blood count and toxicity data expected by Hodgkin's Disease protocols. All 19 items of toxicity showed the same recording frequencies, so they are combined for display. In Figs. 1 and 2, open bars correspond to data for physicians before the introduction of ONCOCIN (n=66), black bars are data for post-ONCOCIN physicians who actually used ONCOCIN (n=56), and shaded bars are data for post-ONCOCIN physicians who were unable to use ONCOCIN (n=58). Statistical significance: **=$p<0.01$, *=<0.05, "ns"=$p>0.05$. See text for discussion of the extreme cases shown here.

Figure 2: Comparison of recording percentages with and without ONCOCIN for data expected by Hodgkin's disease protocols. Legend as in Fig. 1.

Figure 3: Preservation of information expected by Hodgkin's Disease protocols for pre-ONCOCIN visits and post-ONCOCIN visits when doctors used the program. The four steps are **E**: item Expected by protocol, **O**: item was Ordered, **D**: collection of item was Done, and **R**: item's value was Recorded on clinic flowsheet. With the exception of the blood count and toxicity data previously noted to be extreme cases (Fig. 1), the three graphs provide mean values for the three types of data defined in Table 1. Percentages on the ordinate are the fraction of expected data that could be found at each step in the flow of information from the patient to the flowsheet. For details, see text.


100
50
0
PERCENT RECORDING
OF EXPECTED DATA
99
98
96
45
0
7
ns
ns
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*
CBC
AND
PLATELETS
TOXICITIES
(19 items)

FIGURE 1

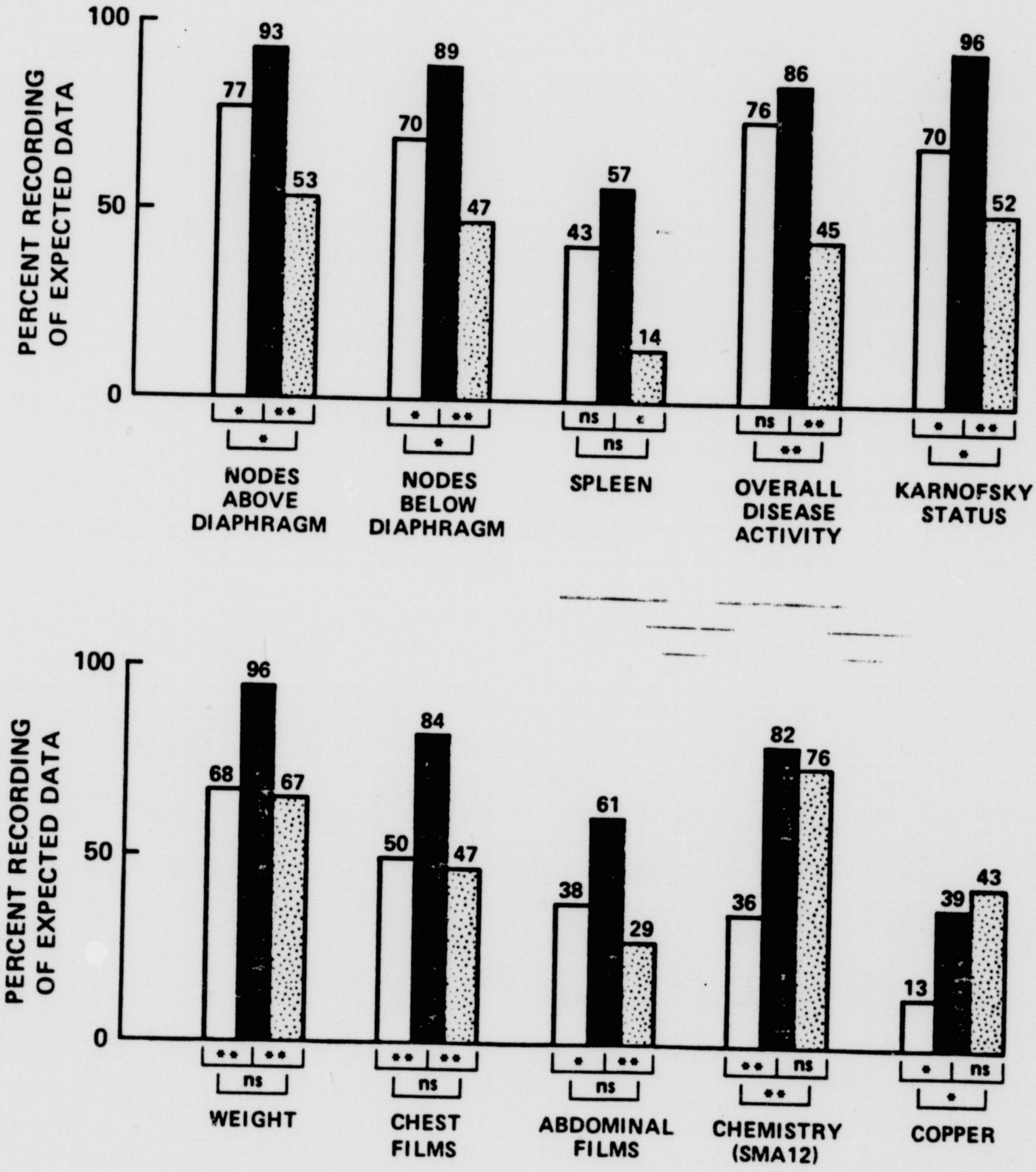
PERCENT RECORDING OF EXPECTED DATA
100
50
0
77
93
53
70
89
47
43
57
14
76
86
45
70
96
52
NODES ABOVE DIAPHRAGM
NODES BELOW DIAPHRAGM
SPLEEN
OVERALL DISEASE ACTIVITY
KARNOFSKY STATUS
68
96
67
50
84
47
38
61
29
36
82
76
13
39
43
WEIGHT
CHEST FILMS
ABDOMINAL FILMS
CHEMISTRY (SMA12)
COPPER

FIGURE 2

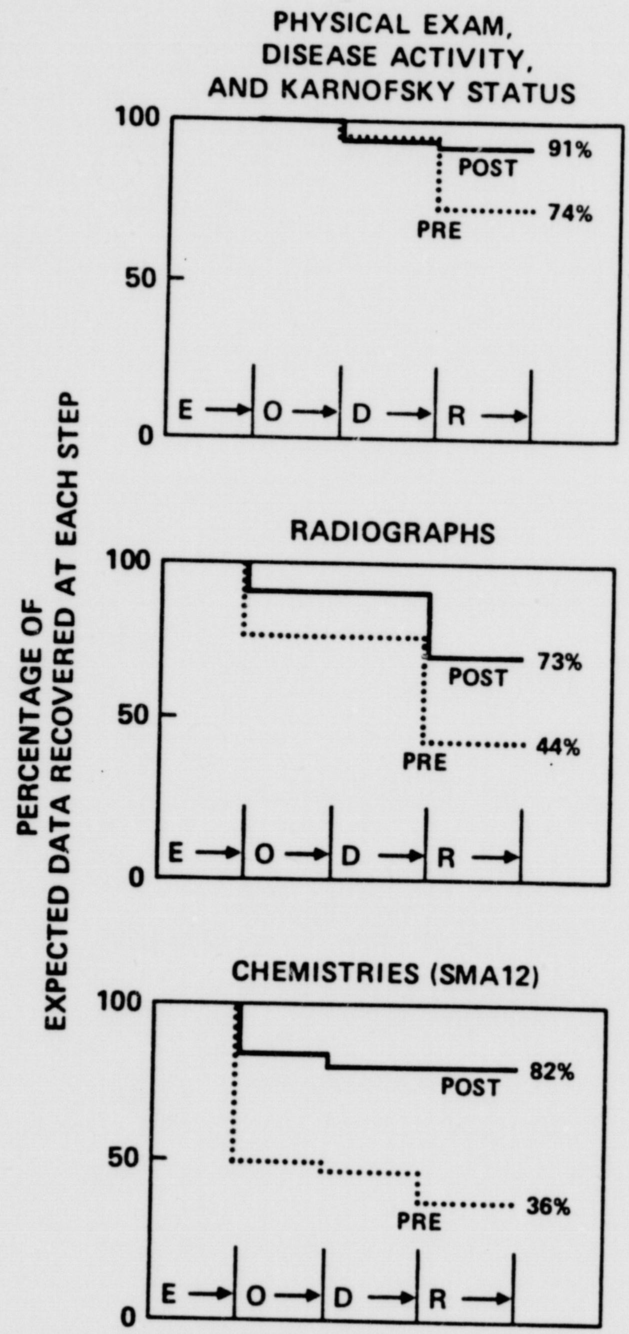
PHYSICAL EXAM, DISEASE ACTIVITY, AND KARNOFSKY STATUS
100
50
0
91%
POST
74%
PRE
E
O
D
R
RADIOGRAPHS
100
50
0
73%
POST
44%
PRE
E
O
D
R
CHEMISTRIES (SMA12)
100
50
0
82%
POST
36%
PRE
E
O
D
R
PERCENTAGE OF EXPECTED DATA RECOVERED AT EACH STEP

FIGURE 3

Table 1: Characteristics of Three Types of Patient Data Expected on Protocol Flowsheets

Data Types	Items Expected by Protocol	Reminding Mechanism	Data Recorder
Toxicity History	19 items	presence of patient	M.D.
Physical Examination	lymph nodes above & below diaphragm	presence of patient	M.D.
	spleen status*	presence of patient	M.D.
	other evidence of disease	presence of patient	M.D.
Other Physician Assessments	Karnofsky Status	presence of patient	M.D.
	Overall Disease Activity	presence of patient	M.D.
Nursing	weight	done by nurse at each visit	M.D.
Radiology	Chest film	ordered at prior visit	M.D.
	Abdominal film	ordered at prior visit	M.D.
Laboratory	CBC (WBC, Hgb, and Hct)	ordered at prior visit	Data manager
	Platelet Count	ordered at prior visit	Data manager
	General Chemistry (SMA12)	ordered at prior visit	Data manager
	Serum Copper	ordered at prior visit	Data manager

*Due to physician confusion about proper coding of the left upper quadrant after splenectomy, we analyzed recording of spleen status only prior to splenectomy.

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