AN EVALUATION OF THE CLINFO DATA MANAGEMENT AND ANALYSIS SYSTEM

PREPARED FOR THE NATIONAL INSTITUTES OF HEALTH

M. D. HOPWOOD, G. F. GRONER, N. A. PALLEY, W. L. SIBLEY,
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PREFACE

This report describes the evaluation of a prototype data management and analysis system designed for use by clinical investigators in clinical research centers. This evaluation was carried out as part of the CLINFO project, a scientific inquiry sponsored by the Division of Research Resources (DRR) of the National Institutes of Health (NIH). During its first phase, the project characterized the information processing activities in clinical research. In its current phase, it is developing and evaluating methods for facilitating those activities.

The CLINFO project is being conducted by clinical investigators and their system managers—H. K. Thompson, Jr., and J. C. Mabry at the Baylor College of Medicine; T. G. Christopher and R. O. Ling at the University of Washington; and W. W. Lacy and J. L. O'Connor at Vanderbilt University; by information scientists G. F. Groner, M. D. Hopwood, N. A. Palley, and W. L. Sibley at The Rand Corporation; and by staff members of the DRR. A clinical investigator at the University of Oklahoma also participated previously. The project has thus far

- Broadly characterized the information-related activities of the clinical research process.
- Identified research data management and analysis as major problems in clinical research.
- Carried out an extensive survey among clinical investigators which indicated that these problems are widespread.
- Examined a number of existing systems aimed at alleviating these problems.
- Prepared an initial functional description of a prototype data management and analysis system.
- Implemented this prototype using standard minicomputer hardware, an operating system supplied by the manufacturer, and specialized computer programs written in the Basic language.
- Installed, operated, and evaluated copies of the prototype in three clinical research centers.
- Developed and tested operating procedures and specifications for support personnel.
- Developed specifications for an improved version of the prototype system to be installed in other clinical research centers.

Project results to date are described in a number of articles and in the following Rand reports:

N. A. Palley and G. F. Groner, *A Survey of Clinical Investigators and Their Information Processing Activities*, R-1539-NIH, July 1974.

G. F. Groner, M. D. Hopwood, N. A. Palley, N. Z. Shapiro, and W. L. Sibley, *A Plan for the Development and Evaluation of a Data Management and Analysis System for Clinical Investigators*, R-1542-NIH, August 1974.

W. L. Sibley, M. D. Hopwood, G. F. Groner, and N. A. Palley, *A Prototype Data Management and Analysis System for Clinical Investigators: An Initial Functional Description*, R-1621-NIH, August 1974.

G. F. Groner, N. A. Palley, and N. Z. Shapiro, *A Structural Characterization of Clinical Research Participants and Their Activities*, R-1540-NIH, January 1975.

G. F. Groner, W. R. Baker, Jr., T. G. Christopher, M. D. Hopwood, N. A. Palley, W. L. Sibley, and H. K. Thompson, Jr., *The Design and Evaluation of a Prototype Data Management and Analysis System for Clinical Investigators*, P-5746, November 1976.

G. F. Groner, N. A. Palley, M. D. Hopwood, W. L. Sibley, and B. Fishman, *CLINFO User's Guide: Release Three*, R-1543-3-NIH, September 1977.

G. F. Groner, M. D. Hopwood, N. A. Palley, and W. L. Sibley, *An Introduction to the CLINFO Prototype Data Management and Analysis System*, R-1541-NIH, December 1977.

This report should be of interest to members of the NIH staff, to information scientists interested in the information processing needs of clinical investigators and in prototype evaluation techniques, and to developers and evaluators of future CLINFO systems. It should also be of interest to individuals considering or preparing for installation of CLINFO systems in their research centers.

SUMMARY

In 1972 the National Institutes of Health initiated a project called CLINFO (for CLINical INFOrmation) to determine

- The information processing activities and needs of clinical researchers who investigate diagnostic and therapeutic techniques in clinical research centers (CRCs) supported by the NIH General Clinical Research Centers (GCRC) Program, and
- What, if any, computer technology can meet the major needs of a variety of investigators at scattered geographic locations while being fiscally and otherwise acceptable to their institutions.

The project has been conducted by a national consortium which includes clinical investigators, information scientists, and NIH staff members. After interviewing a representative group of investigators to determine their information processing needs, the CLINFO project designed and developed a prototype computer system for interactively managing and analyzing clinical research data. To evaluate the utility of this system and to develop specifications for future hardware, software, personnel, and operating procedures, prototype systems were installed and put into operation at the Baylor College of Medicine starting in January 1976, the University of Washington School of Medicine starting in September 1976, and the Vanderbilt University School of Medicine starting in February 1977.

The CLINFO prototype is an interactive minicomputer-based system that enables the clinical research investigator to personally explore and analyze his research data and, as a consequence of these explorations, to acquire more information. The system does not require extensive training or computer programming; the investigator may describe his data interactively in his own terms, enter data values while having them checked for validity, store time-oriented patient data in a carefully controlled on-line data base, retrieve data by patient, variable, and time, create subsets of patients with common characteristics, perform statistical analyses, and produce tables and graphs. The system, implemented as a collection of approximately 110 modules written in the Basic programming language, runs on a Data General Eclipse S/200 minicomputer. The hardware configuration costs approximately $100,000, plus an additional $20,000 for four alphanumeric display terminals with attached printers.

An on-site system manager and a clinical investigator are responsible for each system. The system manager is a specially trained individual who oversees the day-to-day operation of the system. His duties include providing guidance and support for user activities, being responsible for on-site hardware and software maintenance, and collecting and organizing much of the evaluation data.

The goals of the CLINFO evaluation were to assess the prototype's acceptability, to determine the benefits that resulted from its use, and to enumerate the improvements that should be incorporated into future systems. The evaluation was carried out in the context of four plans. One plan was designed to evaluate the functional characteristics of the system hardware and software. It was particularly directed toward investigating the utility of the system capabilities and user inter-

face, the potential need for additional features, and the system capacity in terms of both the amount of data and the number of simultaneous users it can accommodate. The second evaluation plan examined operational and organizational implications of a system in the CRC environment. This included evaluating the roles of the personnel who assist in the use of the system, the accessibility and availability of the system, and operating procedures for maintaining the hardware and software and for safeguarding investigator and patient data. A third plan attempted to estimate the benefits and costs of the prototype system. This plan looked for user-perceived benefits (such as investigators' time saved for other activities and minimization of invalid data analyses) and for costs (such as system operating costs and support-personnel salaries). A fourth plan attempted to determine what needs relating to research data management and analysis were left unmet. This plan looked at issues such as which research data were not processed with the system and why, and what other computational aids were used by investigators. Data collection activities under all four plans were begun before the first system was installed in January 1976 and were terminated in November 1977.

The functional capabilities of the system have evolved over the last two years so that the mix satisfies the most common data management and analysis needs of the intended user community. Also, these capabilities can be readily augmented as needed with special-purpose computer programs written in the Basic language. The system design parameters have been adequate to accommodate the data bases of most potential system users associated with the CRC. Allowing more patients to be entered (1000 instead of 392) and larger data matrices, or worksheets, to be built (5000 elements instead of 2000) would satisfy nearly all the remaining potential users we encountered, including those doing research not usually associated with CRCs. Capabilities for copying the contents of a display terminal screen to paper and producing a plot with points connected by line segments are important but are not used sufficiently to justify providing them at every terminal. Users have expressed dissatisfaction with responsiveness when the system is fully loaded, i.e., when four people are using the system simultaneously. Responsiveness could readily be improved in a future CLINFO system. However, user dissatisfaction may be a consequence of rising expectations, so it may be difficult to continue to satisfy users by improving responsiveness and enhancing functional capabilities without sacrificing ease of use.

Historically, computerized medical information systems have rarely been used outside the particular group or institution for which they were designed. Our belief that a system could be built to serve users doing clinical research on many different topics and at different institutions is supported by the utilization data. System use (including use of CLINFO, a text editor, and Basic) over the three sites averages 350 terminal hours per four-week period, with some fluctuation between periods. At that level of use, the systems may be reaching saturation. There are periods during the day when the maximum number of simultaneous users (four) are using the system, and responsiveness is noticeably degraded at that level of system load. CLINFO use by investigative staff (faculty-level clinical investigators, fellows, residents, and Ph.D.-level professional staff) has been high at Baylor and Vanderbilt (150 to 200 hours per period) and somewhat lower at Washington (50 to 100 hours per period). This indicates a high degree of acceptance, because these users are investing their most valuable resource, their own time, in using the system. CLIN-

FO use by the system managers is low, usually less than 25 hours per period; use by support staff (research aides, medical students, laboratory technicians, secretaries, data clerks, and nurses) has been low at Baylor and Vanderbilt and considerably higher at Washington. Recent increases in support staff use at Baylor and the continued high level at Washington indicate that as investigative users become more familiar with the system and its capabilities, they turn routine procedures over to support personnel.

Use of the systems has been dominated by investigators in internal medicine. This is to be expected because (1) the CLINFO systems are treated as CRC resources, (2) investigators in internal medicine are the most frequent users of the CRCs, and (3) the CLINFO systems are available to nonusers of the CRCs only if there is excess system capacity after CRC users' needs are met. Nonetheless, a wide variety of medical specialties and allied disciplines are represented among CLINFO users. These include immunology, pediatrics, psychiatry, surgery, pharmacology, and biomedical engineering, as well as subspecialties within internal medicine. This indicates that the CLINFO system is applicable to a variety of research methodologies and topics. Because the areas represented include some not generally associated with CRC users (e.g., psychiatry and biomedical engineering), the CLINFO system appears likely to be applicable outside the CRC environment in other clinical and biomedical research contexts.

The results of our examination of operational and organizational implications indicate that the CLINFO system and support personnel are well accepted and heavily used in the CRC environment. The systems are available more than 96 percent of the hours scheduled during the normal work day, and when they are unavailable for long periods, the cause is usually either a hardware or environmental problem (e.g., air-conditioning malfunction or power failure). A full-time system manager has been necessary at each site because of the experimental nature of the project. However, a system manager is expensive ($18,000 is an average annual salary), and it may be hard to find and retain qualified people. Because the evaluation has ended and because users are becoming more sophisticated, full-time system managers will probably not be necessary in the future. Full-time coverage shared by several individuals who also have other responsibilities would be desirable. This would work particularly well if, as occurred with the prototypes, individuals from various research groups take over much of the new user training for their groups. Centralized support for site staff and user training, software maintenance, and troubleshooting hardware and software problems has been provided by the system designers/implementers. A provider of future CLINFO systems should supply similar kinds of support.

CLINFO system users claimed to have benefited in the following ways:

- Studies require less elapsed time, and nonproductive time is decreased.
- The system affords greater and earlier insight into the meaning of research data.
- More data can be examined and more questions can be answered from a single data base.
- Fewer data manipulation errors occur.
- More publishable results emerge from CLINFO-assisted studies.

They also found that the CLINFO system made it easier to

- Organize and store data.
- Retrieve, reduce, and analyze data.
- Write research reports to sponsors.
- Publish research papers.

Costs for the prototype system include computer purchase, hardware maintenance, supplies, insurance, site preparation, and space rental. If the computer equipment is depreciated over five years, the average cost for these items, a full-time system manager, and other personnel is $77,000 per year ($42,000 for equipment and $35,000 for personnel), including both direct charges and overhead. At the utilization rate of 350 terminal hours per four-week period, the distributed operating cost for the prototype is about $17 per terminal hour. Utilization has been as high as 450 terminal hours per period, and at that rate the cost per terminal hour is $13.

Approximately 1100 suggestions for system improvements were recorded in two years, and most of these suggestions have been implemented. A few were discarded because they were outside the scope of the CLINFO system. The 150 that remain unimplemented include increasing the maximum allowable number of patients and size of worksheets, adding new statistical capabilities, adding new modes in data entry and retrieval, and making greater use of defaults throughout the system.

Although most of the research data management and analysis needs of clinical investigators are met by the CLINFO prototype, other computer systems continue to be used for dealing with analog data (such as electrocardiograms) and for specialized and complex statistical and modeling capabilities.

A follow-on CLINFO system designed for widespread distribution rather than evaluation of concepts should have the same functions and mode of operation as the prototype. However, responsiveness should be improved, and suggestions for more patients, larger worksheets, new modes of data entry and retrieval, and greater use of defaults should be incorporated if they do not impact responsiveness. Hardware to support these capabilities should be similar to that of the prototype but should include at least 50 million characters of disk storage and should be less sensitive to environmental conditions. Each system should be under the administrative control of a CRC, should have full-time system manager coverage provided by one or more individuals, and should be readily accessible to potential users.

ACKNOWLEDGMENTS

The evaluation described in this report could not have been accomplished without the cooperation and diligence of a number of people. The clinical investigators at the Baylor College of Medicine, the University of Washington School of Medicine, and the Vanderbilt University School of Medicine who spent many hours answering our questions deserve our special thanks. Not only did they agree to frequently repeated interviews, they remained cooperative and hospitable throughout.

Reduction of an incredible amount of data was carried out at Rand by Judy A. Stein and Maureen F. Carney. Their persistence in the face of numerous problems was a major factor in our ability to report quantitative results. Diana K. Dickerson at Rand also contributed to this effort during the later stages of the project.

The research reported in this document is the culmination of five years of work. We want to thank our project officers, Dr. William R. Baker, Jr., and Dr. William R. DeCesare, for their continued support and guidance. We also wish to thank the advisers to the NIH for the CLINFO project for their guidance, encouragement, and participation. Those who were involved for all or most of the five-year period and deserve special recognition include Dr. Shannon Brunjes of the Georgia Institute of Technology, Dr. Jerome R. Cox, Jr., of Washington University, Dr. Keith Glick of the Charles S. Draper Laboratory, Dr. Ralph S. Goldsmith of the University of Texas in San Antonio, and Dr. W. Gordon Walker of The Johns Hopkins University.

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I. INTRODUCTION

BACKGROUND

The CLINFO project, under the sponsorship of the Division of Research Resources of the National Institutes of Health (NIH), was undertaken to identify the information processing activities and needs that are critical to clinical investigation (medical research involving human subjects) and to recommend ways to satisfy those needs. The first phase of the project identified the information processing activities and needs of clinical investigation and then focused on one problem area, clinical research data management and analysis. The second phase of the project involved the design and development of an interactive minicomputer-based prototype data management and analysis system and the installation, operation, and evaluation of the system in three clinical research centers (CRCs) of the 83-center General Clinical Research Center (GCRC) Program. As a result of user acceptance and satisfaction, the NIH has decided to acquire up to thirty systems based on the CLINFO prototype and to install them in other CRCs. This report presents the evaluation questions and answers that support the NIH decision and that provide the basis for the specification of an improved version of the prototype for wider dissemination.

During the year-and-a-half first phase of the CLINFO project, we observed and informally interviewed more than 100 clinical research personnel at over a dozen clinical investigation sites. These initial sessions led to the identification and description of a number of problems, such as staff and patient scheduling, research data storage, retrieval, and analysis, and clinical research protocol generation. We then developed some tentative problem solutions, and of these, it appeared that the use of computer technology to provide a data management and analysis capability would have the greatest immediate impact.

To explore this further and to begin developing initial requirements for a computer-based clinical research data management and analysis system, we formally interviewed 89 clinical investigators at 23 CRCs and examined the computational facilities available at their institutions [1,2]. The clinical investigators indicated that the problems of organization, storage, retrieval, and analysis of research data present major impediments to their research. Although most (85 percent) of the investigators interviewed have access to computing facilities, 72 percent of those who have such facilities rarely or almost never use them. The investigators who did not use computers to alleviate their data management and analysis problems indicated that they did not appreciate the value of computers, did not understand how to use them, or did not have the assistance they needed to use them. On the other hand, they stated that if they had a readily accessible computer system designed to meet their needs and if specially trained personnel were available to assist them, their productivity would be improved, both in time saved and results produced.

Other information obtained from these interviews helped complete a characterization of clinical research studies in the CRC environment. This characterization included information about the size and duration of clinical research studies and

the number of studies likely to be in progress simultaneously at a center. This first phase of the CLINFO project culminated in a plan for the development, installation, and evaluation of a prototype data management and analysis system for clinical investigators [3], a set of requirements, and an initial functional specification [4].

The goal for the three-year second phase of the CLINFO project was to develop and evaluate a CRC-based computer system compatible with the needs, level of activity, and budget of a single CRC. The system was to be designed to satisfy the primary clinical research data management and analysis needs of individual investigators and to be used by investigators and members of their staffs who may have had no previous experience with computers. In addition, the system was to be accompanied by specially trained personnel who would be locally responsible for system hardware and software maintenance.

We used an iterative approach to design, implement, and evaluate the prototype system. Although the initial system design was completed before the implementation began, parts of the system were redesigned in response to evaluation findings. Implementation was done in stages as planned and as a result of redesign. The initial plan was to implement and install two copies of a prototype system, investigate their use, repeatedly modify them as appropriate based on evaluation results, and develop maintenance procedures, privacy and security guidelines, and requirements for support personnel. The prototype was to be evaluated at a third site, where personnel had no prior involvement with the project, if an appropriate site with a different environment and different types of potential users could be found and if the prototype appeared to be successful at the first two sites. As a result of these activities, we expected to produce

- Tested, practical prototype systems that can continue to operate at the participating CRCs.
- Specifications for the required hardware, software, personnel, and operating procedures.
- Estimated costs and benefits of the system.
- Statements about the clinical research information processing needs that are left unmet by the system and how they may be satisfied.
- If desirable, plans for promoting the dissemination of the system into other CRCs.

Prototype systems were installed and became operational at the Baylor College of Medicine in January 1976, at the University of Washington School of Medicine in September 1976, and at the Vanderbilt University School of Medicine in February 1977. Clinical investigators at Baylor and the University of Washington have been participants throughout the CLINFO project; personnel at Vanderbilt had no involvement prior to the installation of their prototype system.

THE CLINICAL RESEARCH CENTER ENVIRONMENT [5]

The goals of the GCRC program are to provide a controlled, patient-centered research environment in which physicians and scientists can study human disease problems and to train physicians, scientists, and paramedical personnel in clinical research techniques and disciplines. The program provides financial support to 83

CRCs for beds, laboratories, dietary facilities, computational facilities, and CRC staff. CRCs are generally discrete geographical units located within a medical center complex and usually affiliated with a medical school. The day-to-day operations of each CRC are supervised by a program director, who is a knowledgeable, experienced investigator and clinician and who is responsible for the quality and integrity of the research program.

The investigators using the CRCs are physicians representing many different medical specialties and subspecialties who are carrying out research studies to determine the best treatment for a given disease or to answer questions about the functioning of the human organism. These investigators may also be conducting similar studies on animals outside the CRCs. A typical investigator [1] has little or no formal or informal training in the use of computers, has approximately $80,000 in annual research funds, has four to five ongoing research studies in different states of completion, and works with two senior staff people, two fellows, and three technicians. Senior staff people are usually physicians, but they may also be physiologists, biochemists, statisticians, and engineers who are directly responsible to the investigator. Fellows (and sometimes residents) are physicians who work with the investigator while acquiring research training. Technicians may refine or operate laboratory equipment, and they often perform data reduction and analysis. Along with nurses, research aides, secretaries, and data clerks, technicians are part of the support staff.

The CLINFO system is treated as a CRC resource; approval to use the system is granted in much the same way and by the same committees as is approval to use other CRC resources. Although the initial CLINFO project plans called for the system, the user terminals, and the system manager's office to be located on or near the CRC, these plans were carried out completely at only one site.

THE CLINFO PROTOTYPE DATA MANAGEMENT AND ANALYSIS SYSTEM

The CLINFO prototype is an interactive, minicomputer-based data management and analysis system intended to be used directly by clinical investigators and their investigative and support staffs. It is organized as an integrated set of activities which permit an investigator to design his own data base, to enter data into it, to perform different types of data retrieval, and to apply simple statistical and display procedures to his data. The functional capabilities of the system are described in detail in a user's guide [6].

The system has ten major activities, most of which have directly accessible subactivities:

- *Describe* allows the user to specify, by building a *schema,* the characteristics and the structure of the data he wishes to collect. The user can build and edit the schema interactively.
- *Enter* provides the mechanism for entering and reviewing data to be incorporated into a user data base (called a *Study Data File).* Data are time-oriented in that every data item or group of items (called a *panel)* is identified by a specific date and time of day. The entry process makes use

of the schema to ensure that all data entered conform to the specified characteristics (e.g., have values within an acceptable range).

- *Examine* allows the user to display, modify, and delete the values of data items previously stored in the data base.
- *Retrieve* provides multiple options by which a user can organize previously entered data for purposes of review, display, and analysis. Data can be retrieved either one panel at a time or as rectangular, tabular representations called *worksheets.*
- *Worksheet* provides for creating, discarding, labeling, displaying, printing, entering data into, and sorting the contents of worksheets. The worksheet, whether generated automatically by means of a retrieval or created directly by these worksheet subactivities, is the principal form in which a user examines his data.
- *Calculate* permits the user to perform arithmetic and logical operations, as well as elapsed-time, statistical, and other special calculations, on rows and columns of worksheets.
- *Analyze* provides the user with capabilities for carrying out simple parametric and nonparametric statistical procedures on specified rows or columns of worksheets. These procedures include descriptive statistics, t-test, sign and rank tests, linear regression, analysis of variance, chi-square, cross-tabulation, and life-table analysis. Other subactivities enable the user to display scatter plots and histograms.
- *Subset* permits the user to group patients into sets based on the values of items for those patients that satisfy certain conditions.
- *Response files* provides a mechanism for creating, using, modifying, and deleting files of CLINFO commands. This enables the user to deal more easily with repetitive tasks.
- *Files* lists all user files (data-base files, worksheets, subsets, and so forth) and their attributes.

The system is implemented as a collection of approximately 110 Basic modules on a Data General Eclipse S/200 minicomputer. Up to four users may use the system simultaneously via alphanumeric display terminals with attached printers. The hardware configuration for each prototype, exclusive of terminals, costs approximately $100,000.

CLINFO PERSONNEL AT THE CLINICAL RESEARCH CENTER

The system manager is a specially trained individual responsible for the day-to-day operation of the CLINFO system. His duties include providing guidance and support for user activities, being responsible for on-site hardware and software maintenance, and collecting and organizing much of the evaluation data.

There is also an on-site CLINFO project director, who has experience as a clinical investigator. He provides guidance and support for user activities as well.

System representatives are members of the system design/implementation team. During the evaluation phase, they visited the sites regularly to familiarize site staff and users with new system features. They also helped users solve problems and recorded suggestions for system improvements.

EVALUATION GOALS AND PLANS

The goals of the CLINFO evaluation were to assess the prototype's acceptability, to determine the benefits that resulted from prototype use, and to enumerate the improvements to the prototype that should be incorporated into future systems. As part of the assessment of acceptability, information provided by the evaluation was used to drive the ongoing evolution of the system. Because the system would evolve as information became available, the evaluation process had to be viewed as a natural experiment. We expected the constraints resulting from the lack of stability in the experimental environment to preclude, in general, the possibilities of statistically significant conclusions.

Prior to completion of the initial functional description, four general evaluation plans were developed by the information scientists and clinical investigators collaborating on the CLINFO project. The plans and their goals are described in some detail in Ref. 3. These initial plans were intended to help us pose questions, the answers to which would enable us to determine whether or not the CLINFO system was fulfilling the needs for which it was designed. Additional plan details, including data collection, management, analysis, and reporting, were developed by the information scientists as the project progressed. All four plans were carried out between January 1976 and November 1977.

The first evaluation plan was designed to evaluate the functional characteristics of the system hardware and software. It was particularly directed toward investigating the utility of the system capabilities and user interface, the potential need for additional features, and the system capacity in terms of both the amount of data and the number of simultaneous users the system can support.

The goal of the second plan was to examine the operational and organizational implications of a system in the CRC environment. This included evaluating the roles of the personnel who assisted in the use of the system, the accessibility and availability of the system, and operating procedures for maintaining the hardware and software and for safeguarding investigator and patient data.

The third plan attempted to estimate the benefits and costs of the prototype system. A precise assessment of benefits, particularly regarding the impact of the system on clinical research, would require both more data and a longer time span than was possible in a three-year project. Thus, this plan looked for user-perceived benefits such as investigators' time saved for other activities. It also attempted to determine system operating costs.

The fourth plan was to determine what needs relating to research data management and analysis were left unmet. This plan looked at issues such as which research data were not being processed by the system and why, and what other computational aids were being used by investigators. As unmet needs were identified, capabilities that could satisfy those needs were discussed and, if feasible, were added to the CLINFO system.

Section II of this report discusses functional characteristics of the CLINFO system and the user needs that remain unmet. Section III discusses operational and organizational implications of the CLINFO system. Section IV discusses system benefits and costs. Section V recommends appropriate software, hardware, personnel, and operating procedures for a possible future CLINFO system, discusses possible reasons for the project's success, and lists issues that are yet to be resolved.

Appendix A contains supplemental information about benefits, and Appendix B discusses the collection and management of the data used to carry out the evaluation plans. The CLINFO terminology used and the functions mentioned in the following sections are explained in greater detail in Ref. 7.

II. FUNCTIONAL CHARACTERISTICS OF THE CLINFO SYSTEM

LEVEL OF ACCEPTABILITY AND BREADTH OF APPLICABILITY

Questions and Data Sources

Historically, computerized medical information systems have rarely been used outside the particular group or institution for which they were designed [8,9,10]. We were aware of that situation when we began the CLINFO project and consequently planned to have extensive contact with clinical investigators from different institutions and medical specialties who used different terminology, approaches, and methods in their research. Our interactions with these investigators convinced us that, in the context of research data management and analysis, they had much in common. Further, we believed that if investigators would accept a standard way of describing their terminology, we could develop a system that would accommodate the various requirements of different disciplines. Finally, we knew that a major measure of acceptability that the NIH would apply was the extent to which investigators who were also faculty members used the system. For evaluation purposes, we formulated five questions about the acceptability and applicability of the planned CLINFO prototype system:

1. Will faculty-level investigators use or become familiar with the CLINFO system?
2. Will junior investigators and professional and support staff personnel use the system?
3. Will a high level of acceptability, as reflected in sustained use over the evaluation period, be achieved?
4. Will investigators from a variety of medical specialties and allied disciplines find the system applicable to their research?
5. Will the result apply to CRCs at scattered geographic locations?

During the course of the evaluation, data that would provide answers to these questions about the extent of utilization came from the *transaction log*, a comprehensive recording of user/system interactions that was collected automatically on magnetic tape as the system was used. Each log entry contains an encoded user identification, the date and time of interaction, the system port number, the entry type, and an optional text field. The user identification uniquely identifies the user, his category (e.g., faculty investigator, fellow, or technician), and his study. Entries were made in the log for every sign-on and sign-off, user input line, entry into a CLINFO module, error message, and occurrence of a special condition being monitored. A log entry was made by executing a system call from a CLINFO module. The system managers provided the additional information necessary to relate studies to medical specialties.

Answers to Questions

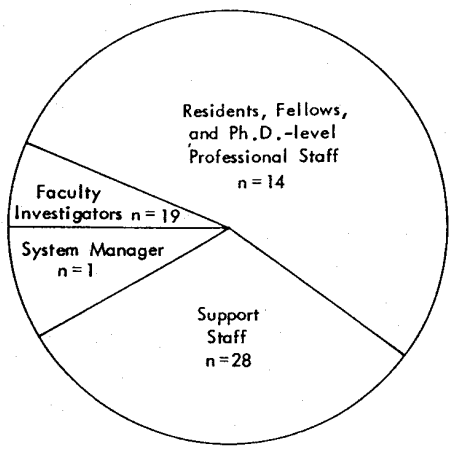
As the specifications for the CLINFO prototype system were being developed, care was taken to make the resultant system directly applicable to both investigative and support personnel in the clinical research community. An indication of the level of acceptability of the system is the extent to which various categories of users actually spend time using it. Figure 1 shows the relative amounts of time spent on the system by users in various categories at the Baylor College of Medicine, the University of Washington, and Vanderbilt University. The faculty investigator category includes assistant, associate, and full professors. Other investigative staff includes residents, fellows, and Ph.D.-level professional staff. The support staff category includes research aides, medical students, laboratory technicians, secretaries, data clerks, and nurses. The data used to generate these figures cover the last 16 weeks during which such data were collected and include all CLINFO use at the sites (use of the text editor Clem and the programming language Basic and all remote use by Rand and NIH personnel are excluded) and all studies including those done for demonstration and administrative purposes.

The Baylor system had been in operation for 60 weeks, the Washington system for 28 weeks, and the Vanderbilt system for four weeks prior to collection of the data shown in Fig. 1. There were some similarities among the sites in several categories. Of particular interest is the fact that at two sites, more than 60 percent of the system use was by faculty investigators and fellows, residents, and professional staff (who are likely to be supervised by faculty investigators).

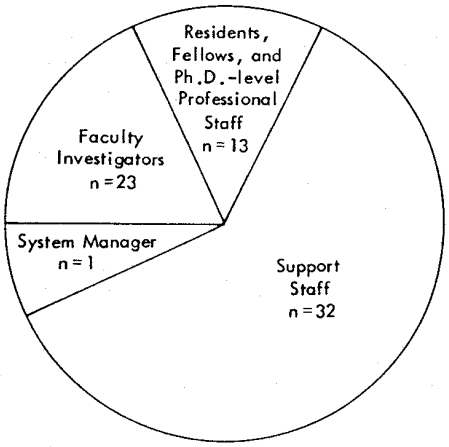
Figure 2 shows the use of the CLINFO system over time at each site by faculty investigators, other investigative staff, support staff, and the system manager. Although use in most categories varied from period to period, there are indications that the level of use may be stabilizing. Use by investigative staff appears likely to stabilize at 150 to 200 hours per period at Baylor and Vanderbilt and 50 to 100 hours at Washington. Use by the system managers has been low, usually less than 20 hours per period at each site. Support staff use has been low at Baylor and Vanderbilt and considerably higher at Washington. Recent increases in support staff use at Baylor and Vanderbilt, the continued high level at Washington, and direct observations indicate that as investigative users become more familiar with the system and its capabilities, they turn routine procedures over to support personnel.

Part (a) of Fig. 3 compares CLINFO use over time at all the sites, and part (b) compares total system use (including use of CLINFO, the text editor Clem, and Basic). Points with the same reporting period number show comparable times in the history of the sites. Each site (after the first) took less time than the previous operational site(s) to reach approximately 250 hours of use per period. CLINFO personnel and users from Washington had access to the CLINFO system at Rand for a year before their own system was installed, so it is not surprising that their level of use rose rapidly. However, the system manager and the clinician/project director at Vanderbilt had no previous involvement with the CLINFO project and they had access to a CLINFO system for only about two months before their system was installed.

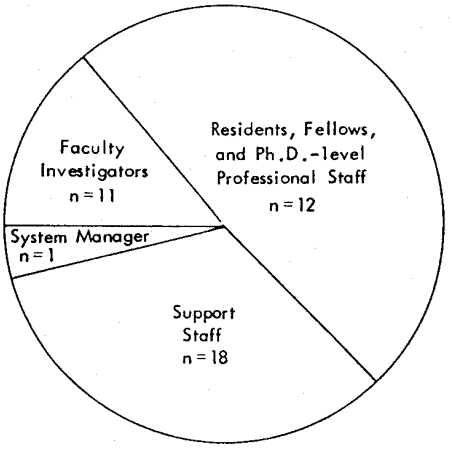
Determining whether and, if so, at what level system use stabilizes is a matter of continuing interest. The total system use at Baylor has continued to increase, and it is likely that a level of between 350 and 400 hours of use per period could be



Baylor College of Medicine



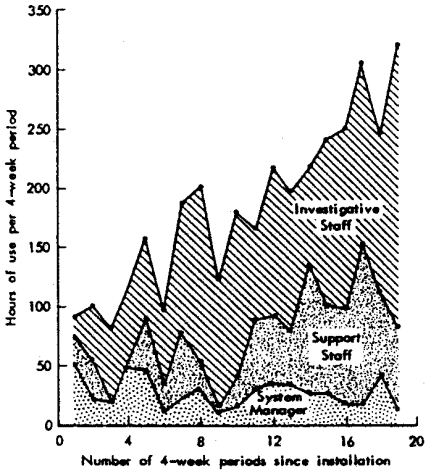
University of Washington School of Medicine



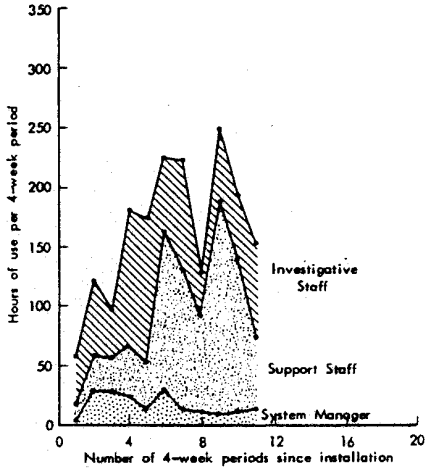
Vanderbilt University School of Medicine

n = number of individuals in category

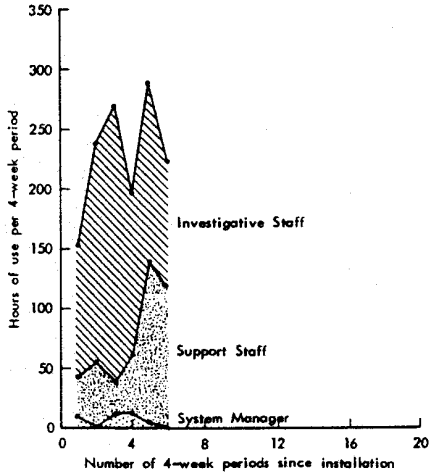
Fig. 1—CLINFO use by user category



Baylor College of Medicine

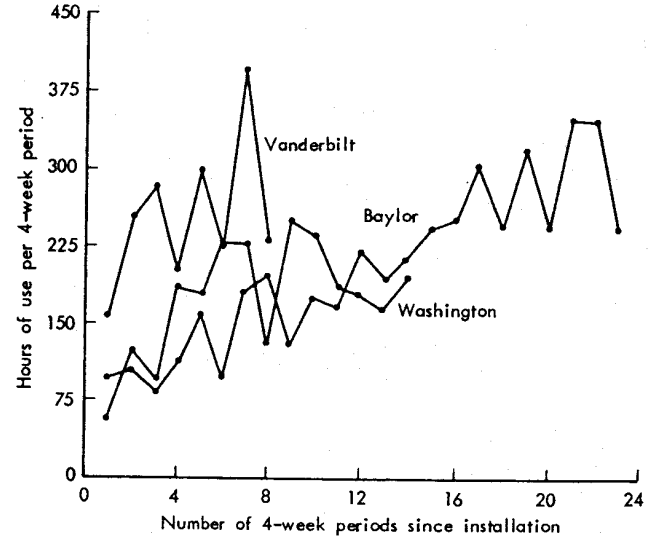


University of Washington School of Medicine

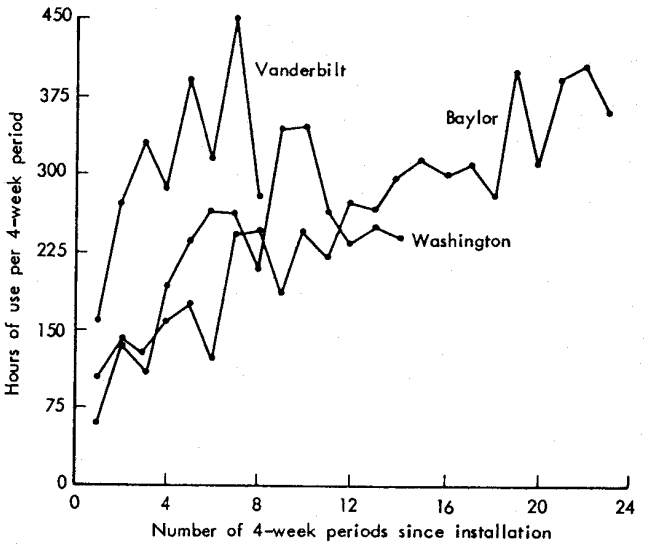


Vanderbilt University School of Medicine

Fig. 2—CLINFO use since installation



(a) CLINFO use



(b) Total system use

Fig. 3—Comparison of use at the three clinical sites

sustained over time. Use at Washington may be stabilizing at about 250 hours per period. There is no clear trend at Vanderbilt. The fluctuation in use between periods at Vanderbilt during the evaluation phase often resulted from changes in the use of the system by a single research group. For example, one group's use for three consecutive periods was 65, 236, and 27 hours. For other periods, fluctuations cannot be identified so clearly with individual research groups. Despite this fluctuation, a sustained level of use equal to or higher than that at Baylor seems likely.

As illustrated in Fig. 4, the data collected at the clinical sites indicate that the CLINFO system is useful to investigators in a number of medical specialties and allied disciplines. It should be noted that the specialties represented are, at least in part, a function of the careful way in which the initial users at each site were introduced to the CLINFO system. The predominance of use by investigators in internal medicine is to be expected, since these investigators are the heaviest users of CRC facilities and have been given priority in access to the CLINFO system. Nonetheless, the wide variety of medical specialties and allied disciplines represented among CLINFO users indicates that the CLINFO system is applicable to a variety of research methodologies and topics. Because the areas represented include some not generally associated with CRC users (e.g., psychiatry and biomedical engineering), it appears likely that the CLINFO system is applicable outside the CRC environment in other clinical and biomedical research contexts.

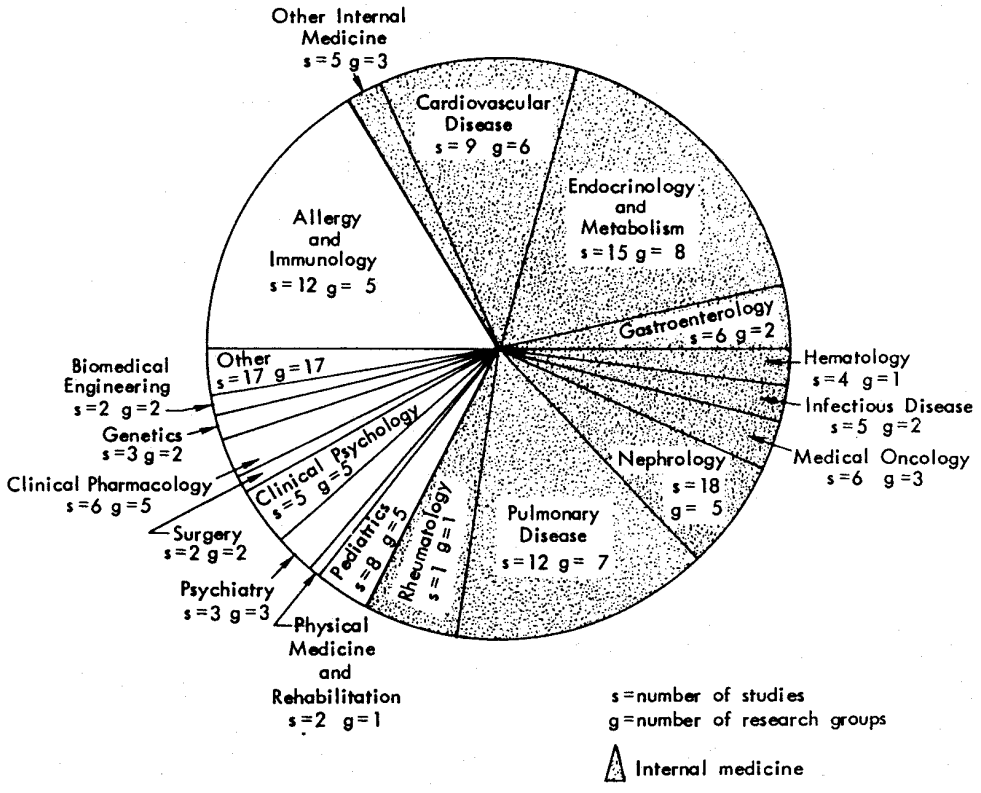


Fig. 4—CLINFO use by medical specialties and allied disciplines

We believe that the level of system use (as summarized in Figs. 1, 2, and 3) is sufficiently high to answer our first three questions affirmatively; and the diversity of investigators as illustrated in Fig. 4 is sufficient to answer our fourth question affirmatively. With regard to usability at scattered geographic locations, we do not believe that geography has anything to do with acceptability. The question we cannot answer is whether a large number of GCRC-supported CRCs will find the CLINFO system desirable. Our results cannot be generalized because we dealt with only three sites, and the clinician/project directors from two of the three CLINFO sites had been members of the project team since its inception. Nonetheless, it is encouraging to note that at Vanderbilt, where there was no previous project involvement, system use rates were equivalent to or higher than those at the other sites at comparable times in their histories.

CHARACTERISTICS OF USER DATA BASES

Questions and Data Sources

One of the CLINFO design goals was to provide a system that would be compatible with the data volumes of 80 percent of the potential users. We used the results from the survey of clinical investigators as a starting point. In the survey, the 50th percentile number of patients on a study was 25 and the 80th percentile was 75. In order to be conservative and allow for error in the survey, and because of certain implementation considerations, we chose 392 as the upper limit for the number of patients on a study. For other data-base parameters, survey data did not provide information directly. Rather, to determine initial parameter values, we used information about the number of active investigators at a typical CRC, the number and duration of their studies, and the amount of data that could be collected per bed day in an active CRC.

Our questions about the characteristics of user data bases were:

1. Will the numbers of patients anticipated and the numbers for whom data are actually entered on CLINFO studies be comparable with the numbers obtained in the 1973 survey of investigators?
2. Will the system design parameters accommodate the potential users' data bases?

The system managers provided most of the data used to answer these questions. They provided computer-generated listings of data-base descriptors and numbers of patients for many of the investigators' studies. The information scientists then extracted data volumes from these listings. Other supporting information came from discussions with users.

Answers to Questions

Figure 5 illustrates percentiles of the number of patients entered on CLINFO studies and of the number of patients who were anticipated and for whom space was allocated. The 50th percentile number of patients entered was 41, and the 80th percentile was 100. The 50th percentile number of patients anticipated was 90, and the 80th percentile was 275.

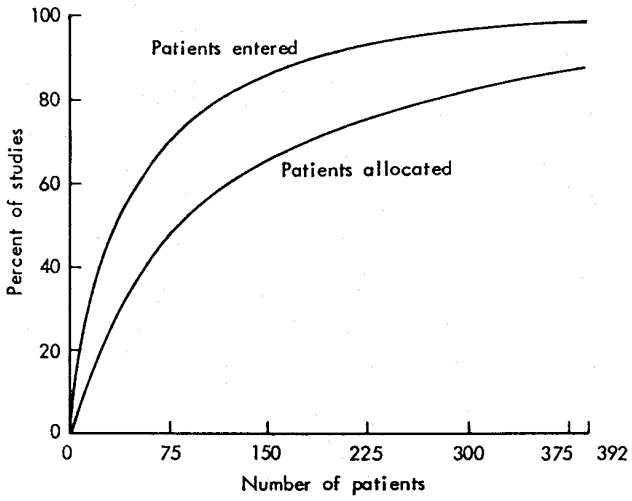


Fig. 5—Percentiles of the number of patients anticipated and the number of patients entered on CLINFO studies

Few studies had numbers of patients near the prototype system limit of 392. We do not know how many potential users were deterred by this limit, but we do know that a few studies involving more than 392 patients were dealt with by setting up separate CLINFO studies, each of which stored data for a portion of the patients. This indicates that at least some users and potential users find the 392-patient maximum a limiting factor.

Figure 6 summarizes the characteristics of user-defined data bases at the three sites. In addition to data on patients anticipated and entered, it also provides information about the kinds of information users collected. For each study, a user defines a *schema,* which names and describes individual items of information. Related *items* (i.e., variables) can be grouped into numeric or textual *panels* (i.e., groups of variables with a common time of measurement). Textual panels contain text items which can have up to 70 characters of commentary as values. Numeric panels contain numeric, character, date, and time items. Character items may take on as many as thirty distinct 8-character (or less) values that are encoded as sequential numeric values.

In general, the maximum values for schema parameters established in the prototype do not appear to pose any serious problems for users. A maximum of 56 panels is possible in a schema, and this has not been a limiting factor in the prototype system. A maximum of 392 items may be defined in a schema, and this also has not been a limiting factor in the prototype system. Character-coded items and all other numeric items are defined with about the same frequency. Text items and date and time items are defined infrequently.

Although character items may have as many as 30 distinct codes, users have remarked that more codes are sometimes required. The limit may have caused some users to make one item which would normally have more than 30 codes into several items, each with 30 or fewer codes.

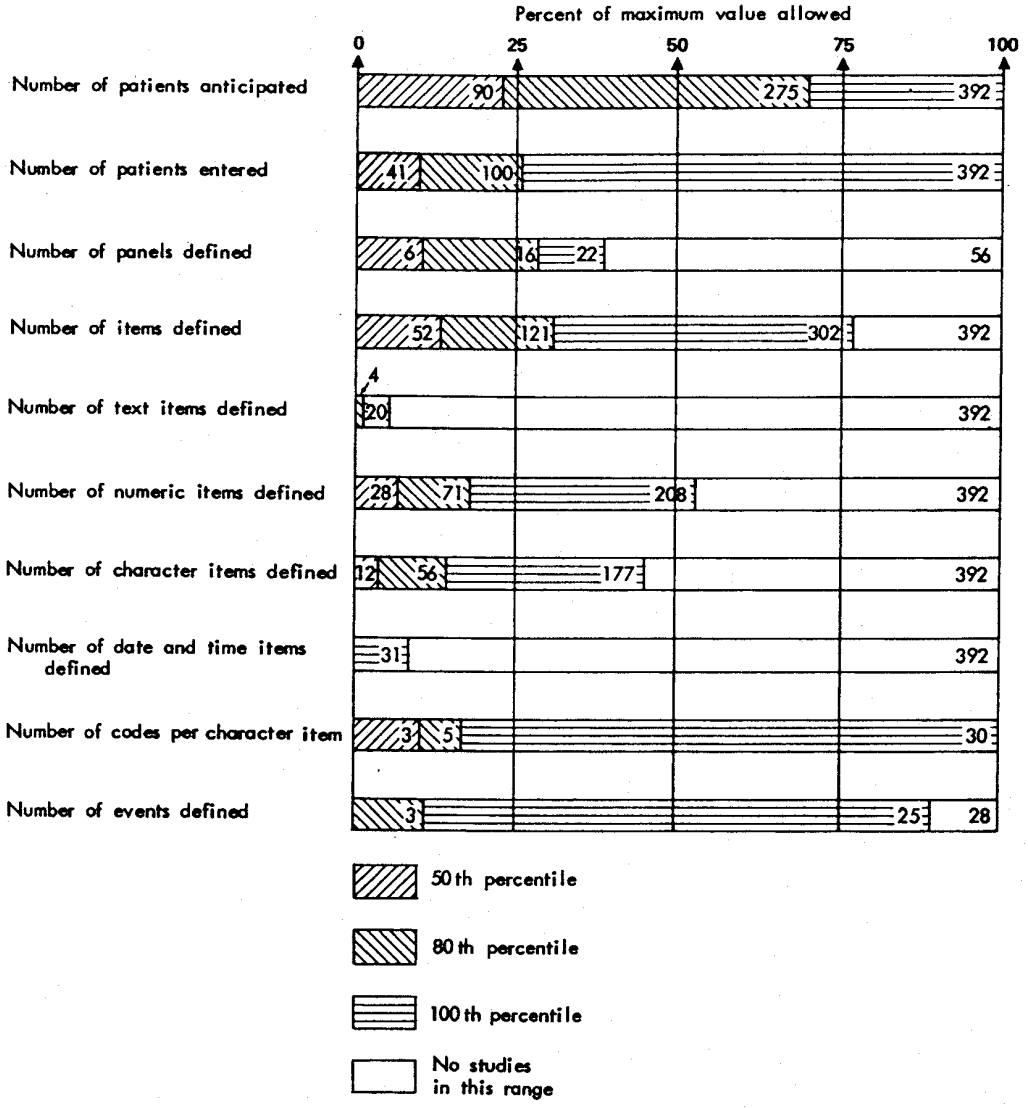


Fig. 6—Characteristics of user data bases

Events (i.e., relative time markers) are defined infrequently. There have been some indications that users may not understand how to use events and that events may be difficult to use. If the use of events is clarified, the number of events possible in a schema may become a limiting factor.

Based on discussions with users, we believe that the major parameter limitation in developing a schema—and it has not been a serious problem—is the number of lines definable in a schema. The limit of 500 schema lines is likely to be reached before the limit of 392 items, since all but the simplest item descriptions extend beyond a single line. It should not be a difficult change to increase the maximum number of schema lines in a future version of the system.

We have no statistical information on the size of user worksheets. Users have indicated that they often want to build worksheets with five or six data values for each patient. Typically, the items in such a worksheet include two items on which to sort, one item that identifies the patient, and two or three items on which to do some analysis. Thus a reasonable upper limit on the number of elements in a worksheet is five or six times the maximum number of patients permissible. In the prototype, a worksheet can contain no more than four values per patient if the maximum of 392 patients is used.

In summary, most of the prototype parameters are acceptable. The possible exceptions are the maximum numbers of patients, codes per character item, events, and schema lines, and the maximum worksheet size. It should not be difficult to increase these limits in a new implementation; in fact, some could be increased in the prototype. In a similar implementation, increasing worksheet size would have the most severe impact, because it would increase the main memory required for computer programs which are already near the address-space limitations of the underlying computer hardware/software system.

SPACE REQUIREMENTS FOR USER STUDIES

Questions and Data Sources

To determine the amount of disk storage needed for the prototype system, we used data similar to those used to determine data-base parameters. Typical CRCs had approximately five active investigators with 25 ongoing studies. Because we were trying to evaluate system use, we wanted enough disk space to be certain that we could support many users. Thus we chose to attach a 25-million-character disk to each of the prototype systems. As a separate issue, we were also interested in exploring the disk storage requirements for a single-user CLINFO system. This might be a system with full CLINFO capabilities or it might be a worksheet-only system, i.e., a system stripped of central data-base construction and retrieval capabilities. Based on these concerns and interests, we formulated two questions:

1. What are the physical disk space requirements for users' studies, and is a 25-million-character disk adequate?
2. What are the physical disk space requirements for an 80th percentile study?

Data to answer these questions came from a program run by the system managers. The program surveyed the disk and calculated the amount of space used by each study in each of several categories.

Answers to Questions

The 25-million-character disk on each of the prototype systems contains clinical study data, Basic and operating system software, Basic programs, CLINFO modules, and perhaps a few administrative studies. Figure 7 shows percentiles of the amount of disk space taken by the clinical studies using CLINFO and by the worksheets from those studies. The total amount of space taken by a study includes

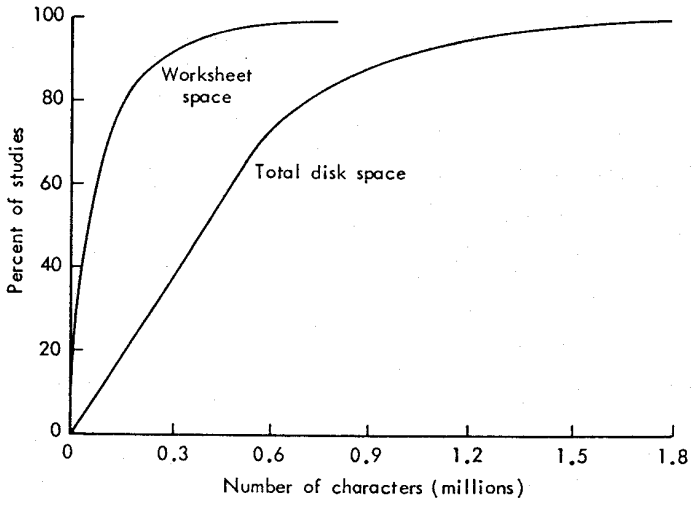


Fig. 7—Percentiles of the total disk space and the worksheet disk space taken for CLINFO studies

space for a Study Data File (i.e., the primary data base), patient and schema files, worksheets, subsets, response files, and various utility files. The study with the most data used 1.8 million characters of disk space; 80 percent of the studies used .7 million or fewer characters; and 50 percent used .4 million or fewer characters. If 80 percent of disk capacity (20 million characters) were available for user studies, there would be sufficient capacity to support simultaneously approximately 10 maximum-size studies, 27 or 28 studies at the 80th percentile, 50 studies at the 50th percentile, or 42 or 43 studies with the data volume distribution illustrated in Fig. 7.

A 25-million-character disk was adequate for evaluating the prototype systems. We initially assumed a faster accumulation rate than actually occurred. However, we neglected to consider the impact of users who had already accumulated several years of data and wanted to enter all of them immediately. The counterbalancing effect of these two factors prevented any serious deficiencies, although some studies were archived to magnetic tape sooner than we anticipated.

A 50-million character disk should provide adequate capacity for a widely disseminated multiuser CLINFO system, particularly if unused studies are removed from the system and archived at regular intervals. Furthermore, minicomputer manufacturers now supply disk drives in the 50- to 100-million-character range. Disk technology and marketing practices are such that purchasing a large, new-technology drive is cheaper than purchasing either a smaller drive based on older technology or multiple drives. With a 50-million-character disk that has 80 percent of its capacity (40 million characters) available for user studies, the system would have sufficient storage capacity to support simultaneously approximately 20 maximum-size studies, 55 studies at the 80th percentile, 100 studies at the 50th percentile, or 85 studies with the data volume distribution illustrated in Fig. 7.

For a single-user system, a 1-million-character disk would have adequate capacity to support any one of 87 percent of the studies. A 5-million-character disk with

80 percent (4 million characters) available for user studies would have sufficient storage capacity to simultaneously support approximately 2 maximum-size studies, 5 or 6 studies at the 80th percentile, 10 studies at the 50th percentile, or 8 or 9 studies with the illustrated size distribution. With regard to worksheet space only, the largest amount of space required for a study was .8 million characters; 80 percent of the studies used .14 million characters or less; and 50 percent used .06 million characters or less. Single-density diskettes (i.e., floppy disks) are widely available and have a capacity of about .25 million characters. Dual-density, dual-sided (or quad-density) diskettes with 1-million-character capacity are available and are likely to be integrated into more computer systems in the near future. These would make it possible to store all the worksheets for an 80th-percentile-size study on one single-density diskette, and to store the worksheets for the largest current study on one dual-density, dual-sided diskette. Whether or not diskettes are sufficiently fast to satisfy user requirements for responsiveness is another issue that must be explored.

USE OF PRINTING AND LINE-DRAWING CAPABILITIES

Questions and Data Sources

The investigators surveyed said that they prefer to have their data, in original, intermediate, and final forms, recorded on paper and kept in their own files so that they can access and make use of them at their own convenience. Research data in their original form are almost always recorded in laboratory notebooks. These data are then generally transcribed onto other data collection forms which sometimes also incorporate intermediate data and final analysis results. Also, investigators make extensive use of graphic representations of their data.

Two special capabilities were incorporated into the CLINFO prototype system to enable users to maintain on paper the same kind of records that they had kept previously. The first of these is the capability to transfer the contents of an alphanumeric display on the terminal screen to an attached printer by pressing a PRINT key on the terminal keyboard. The second capability permits users to display a point plot on the terminal screen and obtain a printed copy with the points connected. (Line drawings cannot be displayed on the terminal screen.) Both of these capabilities use a printer attached to the display terminal. CLINFO also has other capabilities for producing hard copy, e.g., the capability to generate formatted worksheet listings *(worksheet* subactivity 10) and schema listings *(describe* subactivity 2) on the central system printer.

We were interested in answering several questions about printing and line-drawing capabilities:

1. Is it necessary or desirable to be able to copy the contents of a display screen on an attached printer?
2. Is it necessary or desirable to generate line drawings on a printer attached to the display terminal?
3. Would some other arrangement be preferable?

To determine the demand for the printing and line-drawing capabilities, we recorded on the transaction log all uses of the PRINT key and all requests for line drawings. We also talked with users and noted their comments and suggestions about the capabilities being provided.

Answers to Questions

When the first CLINFO system was installed at Baylor, two of the display terminals had attached printers and two did not. The user preference (both stated and observed) for the two terminals with attached printers was so overwhelming that printers were added to the other display terminals.

The data about use of printing and line-drawing capabilities do not completely explain the users' preferences, however. We found that the PRINT key was used in only about 30 percent of the sessions, and the line-drawing capability was used in only 5 to 10 percent of the sessions. These utilization rates make the inclusion of an expensive line-drawing printer with each user terminal questionable. Also, users often generated formatted worksheet and schema listings on the central system printer even when they were using a terminal with an attached printer. Thus, one central graphics printer for the system, with optional alphanumeric printers attached to display terminals, might be an acceptable and more economical arrangement.

Before rejecting the inclusion of a line-drawing printer with each terminal, however, we must carefully consider the fact that certain kinds of clinical research data cannot be distinguished graphically unless lines are drawn connecting the data points. The graphs in Fig. 8 illustrate the problem. These graphs were generated using the printer attached to a CLINFO display terminal. Part (a) of Fig. 8 is a copy of the terminal-screen display, and part (b) shows the points positioned with greater accuracy by the printer and connected by lines. Users with those kinds of data may find a limited graphics display terminal or a standard terminal with an attached line-drawing printer very important.

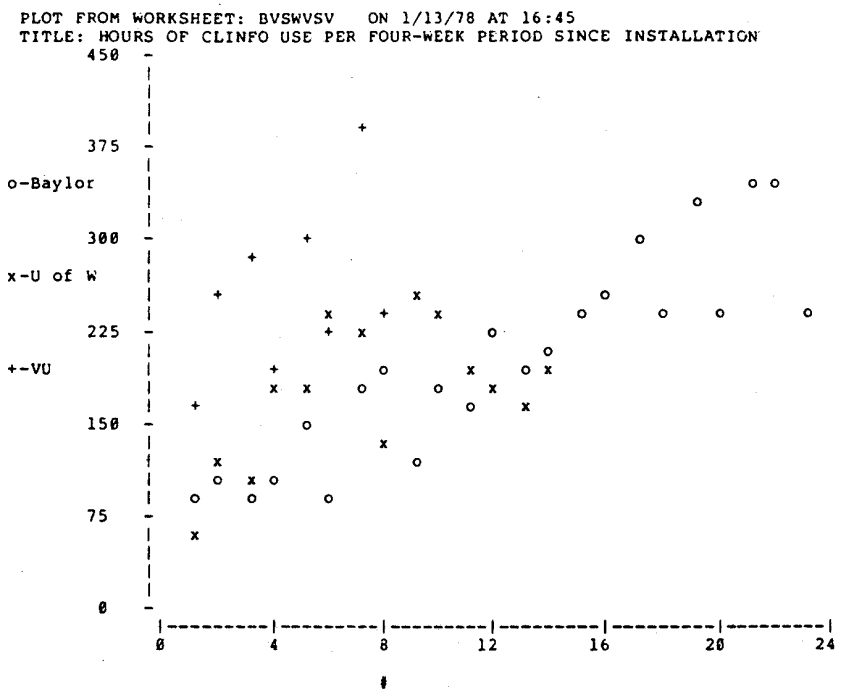
SYSTEM RESPONSIVENESS

Questions and Data Sources

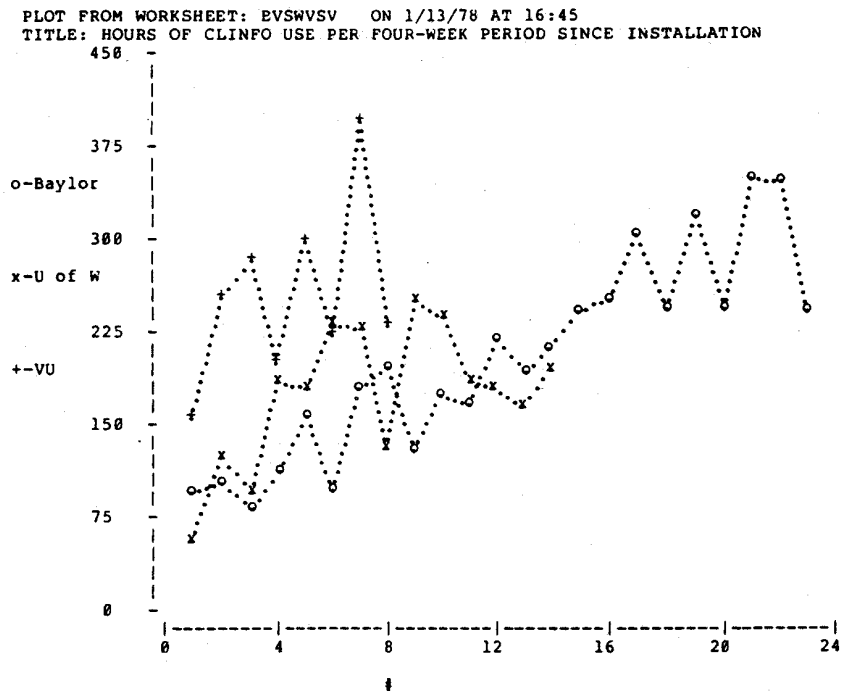
Our goal with regard to responsiveness was to produce a system that would be sufficiently responsive that people would use it and thus provide us with information for evaluation. We wanted a system sufficiently responsive to be acceptable to investigators, research fellows, and others when retrieving, analyzing, and examining their data; and to technicians, nurses, secretaries, and others when entering data. We were also interested in determining if system responsiveness as designed satisfied users or if it should be improved for a widely disseminated version of the system. Thus, we formulated the following questions:

1. Is the system responsive enough for evaluation purposes?
2. Is the responsiveness adequate for a more widely disseminated version?

System-use data derived from the transaction log provided a direct answer to the first question without the necessity of considering responsiveness in detail.



(a) Scatter plot



(b) Scatter plot with lines connecting data points

Fig. 8—Comparison of the same graph shown with and without lines connecting data points

Other data to answer these questions came from discussions with users regarding their impressions of system responsiveness and were imprecise at best. Two experiments were also performed by the information scientists to identify how system response changed as larger amounts of data were processed.

Answers to Questions

It is clear from the system-use data that the prototype systems were responsive enough to attract users and provide a basis for evaluation.

The initial users of the CLINFO system expressed some dissatisfaction with the speed at which information was displayed on the terminal screen. Terminals were then running at 1200 baud (i.e., a display speed of approximately 120 characters per second). We made the necessary hardware modifications at the two sites then in operation to allow four terminals to run at 4800 baud, or four times the original speed. Thereafter we received no further complaints about display speed.

At about the same time as the baud-rate change was made, system utilization began increasing rapidly. Users of the CLINFO prototype system began to report that they were satisfied with its responsiveness when there were no other users on the system, but that tl.ey were often dissatisfied when there were three other simultaneous users (the maximum allowable). Also, data merging, printing when there was an operating system error that prevented spooling, and a few non-CLINFO functions (e.g., reading paper tape) can effectively lock out other users for (usually) short periods of time. We have not been able to determine that any particular CLINFO activities operate too slowly to satisfy users. Rather, the load created by four users actively dealing with their data is sufficient to cause users to be dissatisfied. Responsiveness could readily be improved in a future CLINFO system. However, users' dissatisfaction may stem more from the variability in response that they encounter from session to session than from the actual response times. Also, as users become more adept at data management and analysis, they expect the system to perform increasingly complex tasks in the same manner in which it now performs simple tasks. These factors may make it difficult to continue to satisfy users by improving responsiveness and enhancing functional capabilities without sacrificing ease of use.

We were also interested in exploring the limitations of the system with regard to the amounts of data that could be processed in reasonable times. We performed two experiments to determine system responsiveness with a single user on the system. These experiments were run on the Data General NOVA 840 at The Rand Corporation. We would expect the times to be somewhat faster if the tests had been run on the Data General Eclipse S/200 systems at the clinical sites.

The first experiment explored the change in response time for computing descriptive statistics as the amount of data increases. Descriptive statistics is a commonly used function which is representative of the system's data analysis functions. All tests were run using a worksheet with one column. Measurements were made for 10, 100, 500, and 799 (the maximum in the prototype) rows of data both with and without the median computation. The results are shown in Fig. 9. With a maximum-size worksheet, descriptive statistics without the median takes less than 20 seconds. The time required to compute a median is data-dependent. For this experiment, pseudorandom data were used, and for a maximum worksheet the computation took 4.5 minutes. The changes in time are linear with respect to the

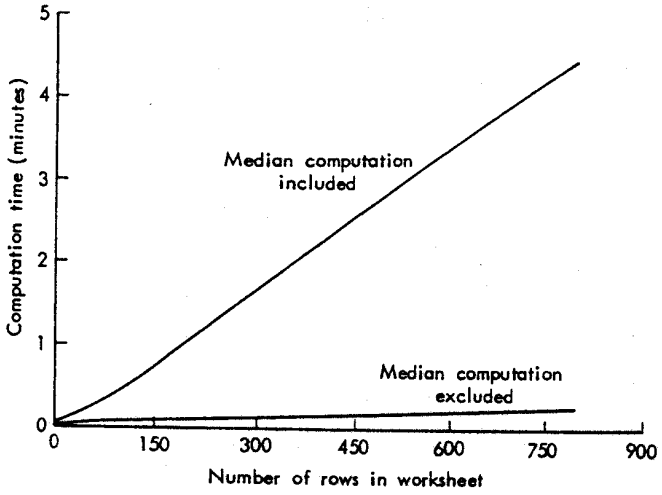


Fig. 9—Computation time for descriptive statistics as the amount of data increases

amount of data analyzed. These results should be considered in specifying a maximum size for worksheets, and in deciding whether or not to implement a computationally more efficient system.

The second experiment explored the change in response time for retrieval from a Study Data File as file size increases. Data retrieval from the Study Data File accounts for about 10 percent of system use and is a time-consuming operation. The Study Data File for this experiment was constructed to have 100 instances (repetitions) of one type of panel for each patient. The experiment was run with patient sets containing 1, 20, 50, 100, 200, and 392 patients. For each patient set, the retrieval was repeated for five different numbers of panels.

The retrieval was structured so that 1, 10, 20, 50, or 100 panels were read to do the retrieval. The survey results and subsequent observations indicate that 10 to 20 panels of data per patient are typical for time-oriented studies. For the worst case, 392 patients and 100 panels read per patient, a 4.2-million-character Study Data File was completely read. This Study Data File is larger, by a factor of 3, than any of those that have been constructed to date at the CRCs.

Figures 10 and 11 show the results of this experiment. Figure 10 shows the change in retrieval time for a fixed number of panels retrieved per patient as the number of patients increases. The changes in retrieval time as patients or panels retrieved increases are linear. In the worst case, 392 patients and 100 panels per patient, reading 4.2 million characters took 64 minutes. Figure 11 shows an enlarged section of Fig. 10 marked with the 50th and 80th percentiles of patients entered by users. For the 80th percentile of patients entered (100 patients), retrieval time for 1 panel per patient is .9 minute; for 10 panels per patient, 2.2 minutes; for 20 panels, 3.8 minutes; for 50 panels, 8.3 minutes; and for 100 panels, 15.9 minutes. For the 50th percentile of patients entered (41 patients), retrieval time for 1 panel per patient is .3 minute; for 10 panels, 1 minute; for 20 panels, 1.7 minutes; for 50 panels, 7.1 minutes; and for 100 panels, 13.6 minutes. It should be noted that

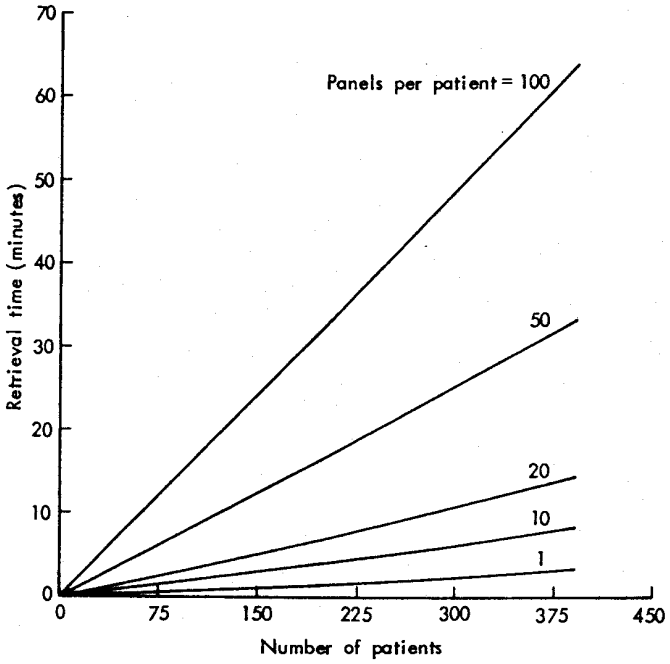


Fig. 10—Retrieval time for a fixed number of panels per patient as the number of patients increases

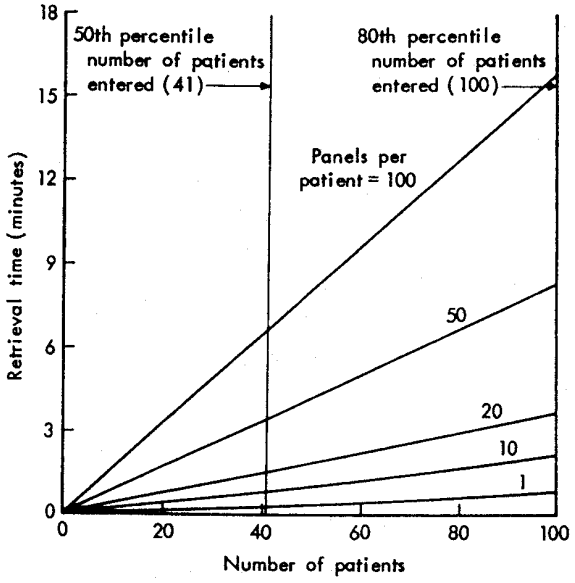


Fig. 11—Retrieval time for a fixed number of panels per patient as the number of patients increases: 50th and 80th percentile of patients entered indicated

these are probably not typical retrievals, in that they involve scanning very large amounts of data. A more common retrieval would deal with data for a single patient or limited amounts of data for a set of patients. In any case, because retrieval time can become long, care should be taken in extending the current limits on patients entered and items in a schema unless changes are also made to improve these times. Such changes might include using a different implementation language and using different data structures.

USE OF CLINFO FUNCTIONAL CAPABILITIES AND UNMET NEEDS

Questions and Data Sources

As part of the iterative approach to system development, the CLINFO system capabilities have been refined as new needs arose and users with different problems were encountered. During the evaluation, we were continually asking and trying to answer the following questions:

1. Does the CLINFO system satisfy the most common data management and analysis needs of clinical researchers?
2. What data management and analysis needs are unmet?
3. Is satisfying a particular need consistent with the goals of the CLINFO project?
4. Can that need be satisfied within the context of the CLINFO prototype?

Data to answer these questions came from transaction logs, discussions with users, suggestions for changes documented by system representatives, and the experience of the system designers/implementers.

Answers to Questions

The CLINFO prototype system includes approximately 80 subactivities (i.e., major functions) and activities (i.e., functional groups). Many of these were present in the first release of the CLINFO software or were planned for subsequent releases. One planned subactivity was not implemented because its function could be easily accomplished by other means. Of the remaining planned functions, only some analysis-of-variance and linear-regression options were not implemented, because users said that these options were unnecessary and other functions would be more useful. Almost all of the subactivities were changed in some way. Displays were reorganized and prompts were clarified, new capabilities were added and old ones improved (particularly in retrieval), subactivities were made into activities (e.g., the *calculate* activity was originally an *analyze* subactivity) to make them easier to use, and other organizational changes were made. Many more small changes could have been made, but we felt it necessary to minimize the impact of changes on the existing user communities.

Many unplanned subactivities were added as the system evolved. The most significant of these enables the user to take data already entered into a worksheet and have them (or data derived from them) screened and copied into his primary data base. This subactivity is important because it enables the user to enter and

review data in a format with which he is familiar, and it facilitates the entry of derived data into the user's data base. The other new subactivities are primarily additions to the analytic and calculation activities. These are not conceptually different from what was originally planned; rather, they evolved as we developed a better understanding of the capabilities that would facilitate research data management and analysis for clinical investigators.

To facilitate access to activities and subactivities, function keys were added to the terminal keyboard. These keys reduced the number of keystrokes usually required to go from one subactivity to another from eight to four.

Figure 12 lists the activities and subactivities whose use is summarized in this section. Subactivities that were not originally planned are identified with an asterisk (*). One subactivity that was not originally planned as a user-accessible function is identified with a plus sign (+). Figure 13 shows the portion of *uses* accounted for by each activity and, for the *enter, retrieve, worksheet, analyze,* and *calculate* activities, the portion of *uses* accounted for by each subactivity. Figure 14 shows the portion of *elapsed time* accounted for by each of the same activities and subactivities. The data used to generate these figures cover the last 16 weeks during which such data were collected and include all CLINFO use at the three clinical sites. Life-table analysis and radioimmunoassay were not available until the last few weeks of that period, and thus the figures show no significant use of these subactivities. The information in Figs. 13 and 14 should be helpful in deciding which functions should be included in a future CLINFO system, which subactivities are candidates for aggregation or disaggregation, and what future implementation priorities should be.

Activity uses and elapsed time do not by themselves give a clear picture of how the CLINFO system is used. Another, perhaps more meaningful way, to look at system use is to examine major functional capabilities in relation to what a user might do manually without the system. A clinical investigator might categorize his manual data management and analysis tasks into four areas:

- Data entry: entering data into laboratory notebooks and reviewing them for accuracy and completeness.
- Data organization and retrieval: recopying data to various tabular arrangements, sorting data, and identifying interesting subsets.
- Data analysis: transforming data and applying analytic procedures to them.
- Instructing assistants: explaining these often repetitive tasks to assistants so that they can perform them.

If we replace manual activities by CLINFO activities, the four task areas become:

- Data entry: using the *enter* and *examine* activities and *worksheet* data entry subactivities (4, 5, and 6).
- Data organization and retrieval: using the *describe, files, retrieve, subset,* and *worksheet* (except data entry) activities.
- Data analysis: using the *analyze* and *calculate* activities.
- Instructing assistants: using the *message* and *response file* activities.

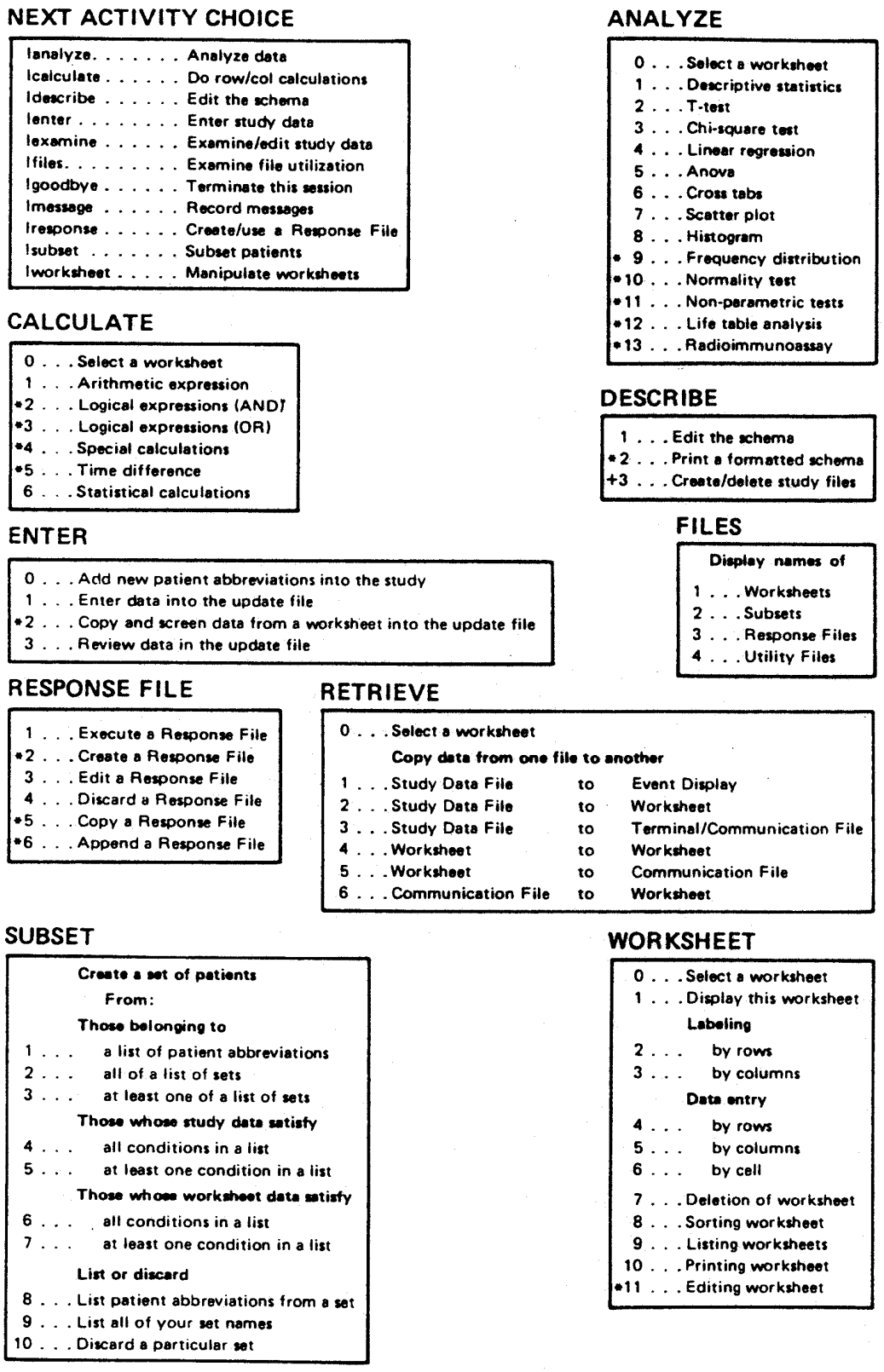


Fig. 12—CLINFO activities and subactivities

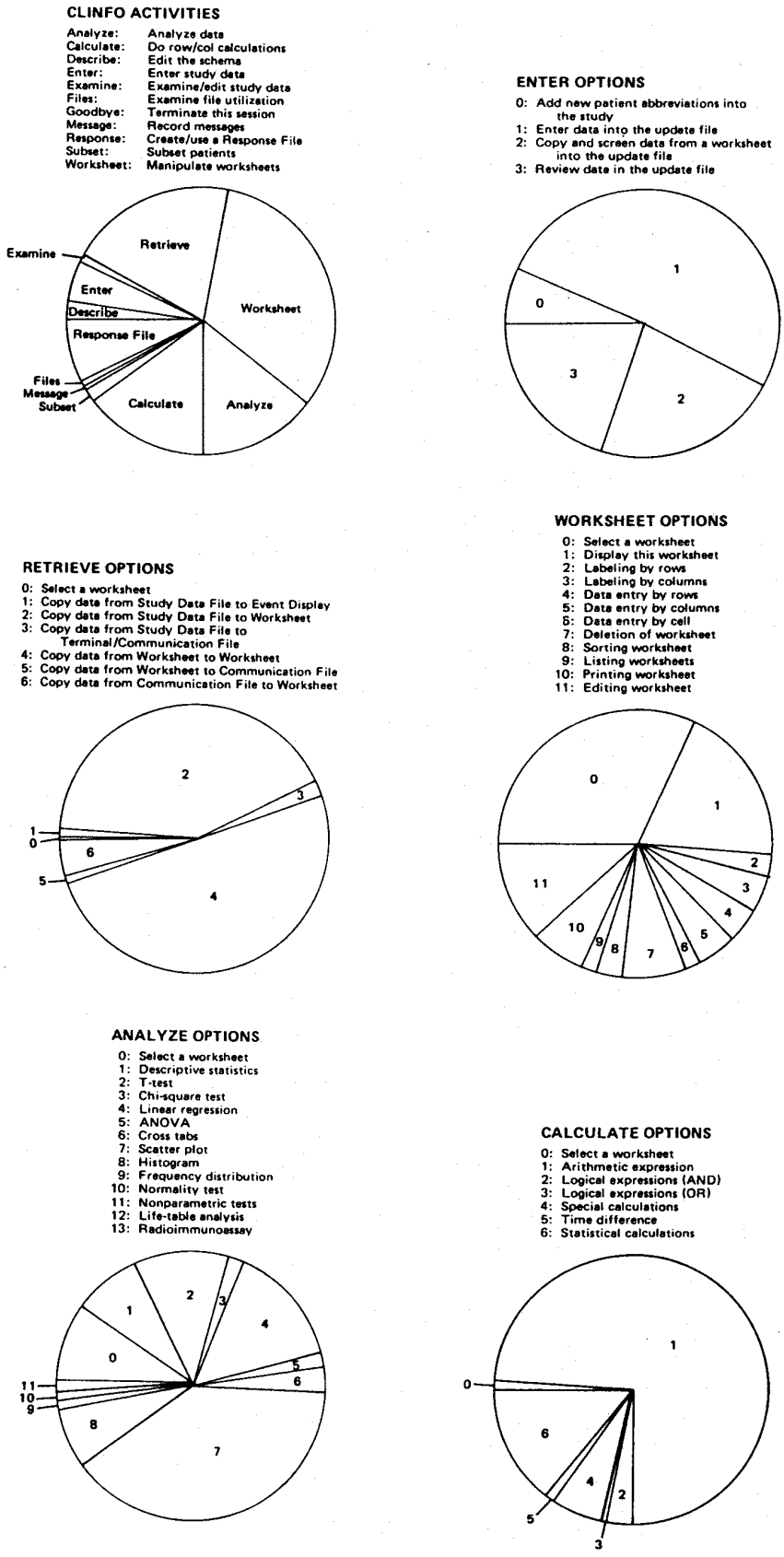
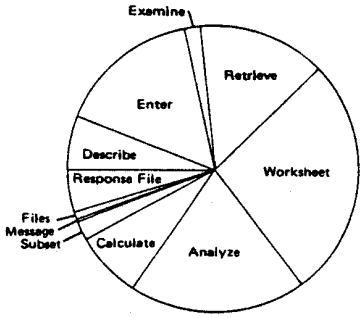


Fig. 13—Relative numbers of uses of CLINFO activities

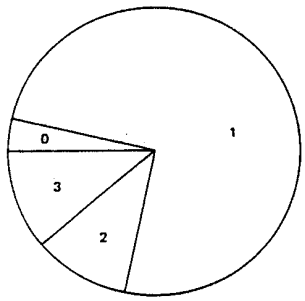
CLINFO ACTIVITIES

Analyze:	Analyze data
Calculate:	Do row/col calculations
Describe:	Edit the schema
Enter:	Enter study data
Examine:	Examine/edit study data
Files:	Examine file utilization
Goodbye:	Terminate this session
Message:	Record messages
Response:	Create/use a Response File
Subset:	Subset patients
Worksheet:	Manipulate worksheets



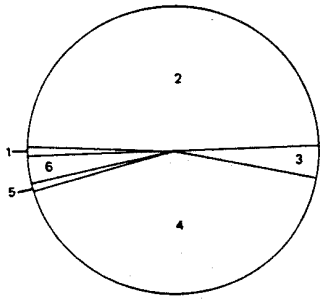
ENTER OPTIONS

0: Add new patient abbreviations into the study
1: Enter data into the update file
2: Copy and screen data from a worksheet into the update file
3: Review data in the update file



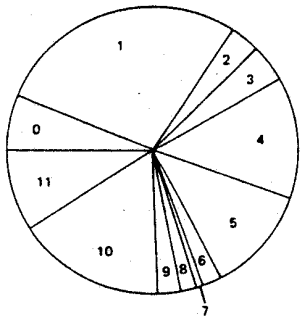
RETRIEVE OPTIONS

0: Select a worksheet
1: Copy data from Study Data File to Event Display
2: Copy data from Study Data File to Worksheet
3: Copy data from Study Data File to Terminal/Communication File
4: Copy data from Worksheet to Worksheet
5: Copy data from Worksheet to Communication File
6: Copy data from Communication File to Worksheet



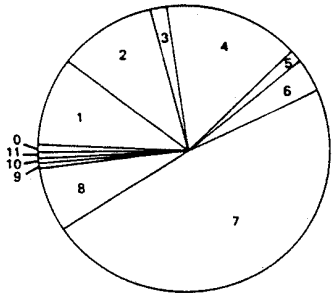
WORKSHEET OPTIONS

0: Select a worksheet
1: Display this worksheet
2: Labeling by rows
3: Labeling by columns
4: Data entry by rows
5: Data entry by columns
6: Data entry by cell
7: Deletion of worksheet
8: Sorting worksheet
9: Listing worksheets
10: Printing worksheet
11: Editing worksheet



ANALYZE OPTIONS

0: Select a worksheet
1: Descriptive statistics
2: T-test
3: Chi-square test
4: Linear regression
5: ANOVA
6: Cross tabs
7: Scatter plot
8: Histogram
9: Frequency distribution
10: Normality test
11: Nonparametric tests
12: Life-table analysis
13: Radioimmunoassay



CALCULATE OPTIONS

0: Select a worksheet
1: Arithmetic expression
2: Logical expressions (AND)
3: Logical expressions (OR)
4: Special calculations
5: Time difference
6: Statistical calculations

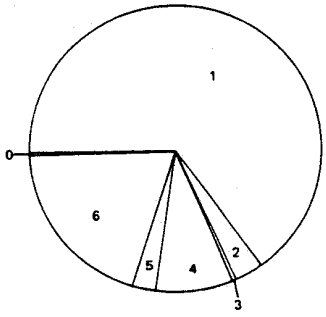
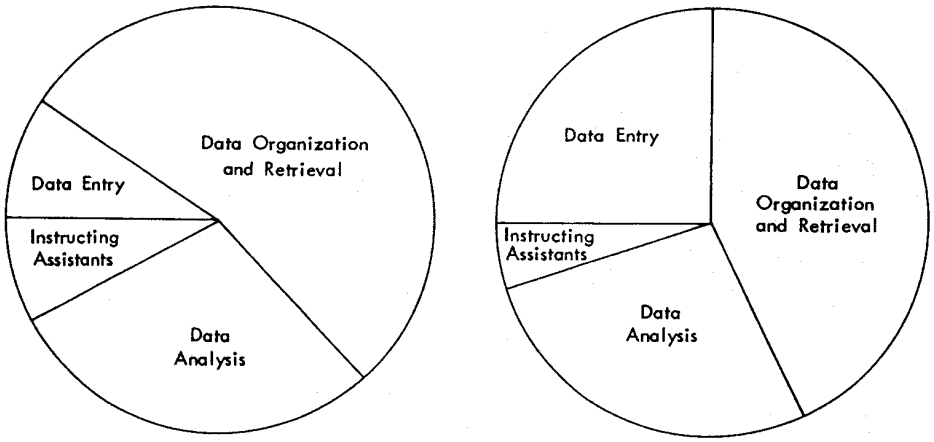


Fig. 14—Relative amounts of elapsed time in CLINFO activities

Figure 15 shows CLINFO system use in these four areas. Part (a) of Fig. 15 is based on uses of activities, and part (b) is based on elapsed time in activities. From these figures we can see that CLINFO users perform more data organization and retrieval than any other task. These data are consistent with the view of CLINFO as a data management and analysis system. The emphasis on data organization (or management) and the apparent ease with which users can perform that task distinguish the CLINFO system from desk calculators and from nearly all other computer-based systems for biomedical research.



(a) Uses of activities

(b) Time spent in activities

Fig. 15—CLINFO system use in major task areas

Since CLINFO software first became available to users in August 1975, we have been collecting suggestions for changes. Rand staff members have documented over 1000 suggestions that resulted either from interviews and discussions with users and potential users or from their own experience with the prototype. In addition, system managers and users at the participating clinical research sites have written over 100 change requests. From these suggestions and from additional discussions, we have found both technical and nontechnical explanations of how and why the CLINFO system does not meet the complete research data management and analysis needs of users and potential users.

Potential users who have not used the CLINFO system for nontechnical reasons generally fall into the following categories:

- Individuals who have already made a large personal investment in building and analyzing a data base on another computer system.
- Fellows and other investigators who never bothered to learn how to use the system because they would soon be leaving the area.
- Individuals who wanted to use CLINFO but were pressured not to by others in their institution.

- Technicians and other support staff who found the system threatening and the investigators who were discouraged by them.
- Individuals who could not see how to use the system effectively for their purposes or who were too committed to their current mode of operation to try.
- Users who were not provided good access because they were not users of the local CRC and the demand for the system from CRC users was high.
- Individuals who did not know that the CLINFO system was available.

We do not know how many people are represented by this categorization. We do know that investigators who have begun to use the system continue to use it as needed unless pressured not to do so. Finally, although users have been assisted in moving their data from other systems to the CLINFO system, decisions about who has access to and makes use of the CLINFO system are made locally at the individual sites.

The technical reasons for not using the system have not usually kept users away but have prevented CLINFO use for particular studies or analyses. Situations in which CLINFO use has been rejected include those in which

- The number of patients the user wants to follow in a single study exceeds the system capacity.
- Conversion of analog data, such as electrocardiograms, to digital data is required before those data can be entered into the CLINFO system.
- More complex statistical analyses than those provided (e.g., factor and cluster analysis) are required by the user.
- Necessary modeling capabilities are not provided.
- There is a large backlog of data that would be costly to enter.

The CLINFO system is designed for small clinical research studies and it was not intended to handle large clinical trials or epidemiological studies. Nonetheless, several users have found that CLINFO is useful for dealing with selected subsets of large studies, and in some cases large studies can be effectively managed and analyzed as several separate smaller studies.

The lack of specific capabilities has been handled in several ways. The CLINFO system has been designed to allow data to be read in from paper or magnetic tape and to be written on magnetic tape. Thus, capabilities provided on other computer systems can be used, and CLINFO can be used either to provide inputs or to process results. System managers and users can also write Basic programs (several programs have been written) to process data from a CLINFO study or another source, and the results can be passed back to a CLINFO study. Finally, a number of capabilities, such as nonparametric tests, life-table analysis, and radioimmunoassay, have been added to the system at the request of users.

The data entry backlog at several sites resulted primarily because the CLINFO system had not previously been available and potential users had not found a satisfactory alternative for their research data management and analysis needs. If users had already entered data into another computer system or if their data were generated on tape, e.g., by a laboratory instrument, Basic programs were written to eliminate the need for manual reentry. If data had not been entered at all, data entry assistance was provided on a limited basis. As users begin new studies, they

are encouraged to enter their research data as these data are acquired. However, the problem persists because the user population is highly mobile and new users previously affiliated with other institutions often arrive with a large amount of data to enter.

User suggestions have been a major influence on the design of the prototype and are responsible for many of the accommodations just described. In fact, nearly all of the changes made during the last fourteen months of development have resulted from such suggestions. When the current software development was concluded, only about 150 of the suggested changes that were consistent with the system's objectives remained unimplemented. Many of these would substantially improve the prototype, but they have not been implemented because of the difficulty associated with making particular changes to the prototype software, because they would change the prototype's behavior in a way that would inconvenience many users who have already learned to expect certain behavior, or because there was insufficient time remaining in that phase of the project. These user-suggested improvements include

- Allowing more patients and larger worksheets.
- Adding new statistical and analytic capabilities and options on existing capabilities, e.g., cluster and factor analysis.
- Providing additional capabilities or modes in data entry and retrieval.
- Making greater use of defaults throughout the system.
- Clarifying prompts throughout the system.
- Expanding response file capabilities.

It should be noted that there is some disagreement about whether all these improvements *should* be made. One suggested improvement, for example, is the inclusion of enhanced capabilities for dealing with stored text. The CLINFO system has few such capabilities now, and while this may account for the infrequent use of text, there has been little demand for improvements in this area. Also, many investigators believe that encoding textual information encourages greater rigor and thus are opposed to enhancing text manipulation capabilities. Other suggested improvements, such as cluster and factor analysis, have been rejected (by the clinician/project directors as a group) as capabilities to be included in a future CLINFO implementation.

III. OPERATIONAL AND ORGANIZATIONAL IMPLICATIONS

SYSTEM AVAILABILITY AND ACCESSIBILITY

Questions and Data Sources

From the beginning of the CLINFO project, we felt that in order for the system to be acceptable to clinical investigators, it would have to be available and accessible on demand. Many of the investigators we interviewed carried out research data management and analysis activities only when their patient care, teaching, and administrative responsibilities permitted. This meant that research data management and analysis received attention for only brief periods during the day and for longer periods at odd hours, on weekends, or just before a paper submission deadline. On the other hand, we expected professional and support staff to make heavier use of the system during the day than at other times. Thus we believed that the system would have to be available seven days a week, 24 hours a day, with time out only for maintenance and system backup. Further, the system had to be accessible; that is, terminals had to be conveniently located and available on demand. Based on these concerns, we formulated the following questions:

1. Can the system be available 95 percent of the time scheduled?
2. Can the terminals be sufficiently accessible to satisfy users?
3. Are four to six terminals at each site adequate?

Information on system availability came from the system managers' records and transaction logs. Other written records, e.g., failure reports and a log kept at the system console, provided supplemental information. Accessibility was somewhat more difficult to determine. At two sites there were more terminals available than could be simultaneously used; this situation was created at all three sites whenever a remote user with his own terminal signed on. We could determine if a user attempted to sign on to the system when no more simultaneous users were permitted, and we recorded that information in the transaction log. However, if all the terminals (or all the conveniently located ones) were in use, the system was also inaccessible to an additional user, but we knew this only if he reported it or if the information was elicited in an interview.

Answers to Questions

In general, the CLINFO system and the supporting personnel have been well accepted by investigators in the CRC environment. The extensive direct use made of CLINFO by clinical investigators from a number of medical specialties and allied disciplines indicates that the system and the supporting personnel satisfy at least part of their data management and analysis requirements. Users have indicated their desire to have the system remain available by inquiring about budgeting funds for CLINFO use in their grant proposals. In addition, leaders of some of the

larger active research groups have inquired about the possibility of obtaining a separate CLINFO system.

We define availability as the percentage of the scheduled time that the system is operational for CLINFO use. The prototype systems are scheduled to be available 22.5 hours per day on Mondays, 23 hours per day on Tuesdays through Fridays, and 24 hours per day on Saturdays and Sundays. These three systems have had high availability during scheduled prime-time hours (7 A.M. to 7 P.M., Monday through Friday) and somewhat lower availability at non-prime times. The percentages of system availability during all scheduled times and during prime times for the three clinical sites are summarized in Table 1. Greater than 100 percent availability indicates that scheduled downtime, e.g., for system backup and preventive maintenance, was not fully used and thus the system was available to users for more time than was scheduled.

Table 1

PERCENTAGE OF SYSTEM AVAILABILITY OVER ALL PERIODS SINCE INSTALLATION
(Available hours/scheduled hours)

	All Scheduled Hours				Prime-Time Scheduled Hours			
Site	Min.	Mean	Median	Max.	Min.	Mean	Median	Max.
Baylor	68.9	89.3	92.1	101.3	83.4	96.7	99.8	105.3
Washington	80.6	97.0	99.7	102.0	86.1	99.8	103.3	105.9
Vanderbilt	84.0	93.4	95.2	100.6	90.4	98.3	98.1	104.5

Figure 16 shows the causes of all significant system unavailability that occurred during nearly two years of operation at the Baylor College of Medicine. In general, software problems have not caused any of the systems to be unavailable for long periods. If a system fails, it usually can be restarted within a few minutes. If a user encounters a software problem in a particular CLINFO activity or subactivity, his use of the rest of the CLINFO system capabilities is usually not affected. Low system availability at all three sites is generally the result of either computer hardware problems or environmental problems. A large part of the downtime associated with hardware problems is spent running diagnostic programs in attempts to isolate the cause of the trouble. A simpler hardware configuration than that used in the prototype systems should lead to reduced downtime due to hardware problems. Environmental problems are sometimes beyond human control; for example, heavy rain and flooding in the Houston area caused electrical power to the Baylor CLINFO system to be out for several days. More frequently, inadequate air conditioning and (sometimes unannounced) electrical power shutdowns are the causes of system unavailability. Because these kinds of problems have persisted over time at all three sites despite attempts to remedy them, we believe that the environmental conditions in CRCs must be considered hostile to computer operations. The designers of future CLINFO systems should be sensitive to these problems and should address issues such as minimizing air-conditioning requirements and reducing sensitivity to power fluctuations. In general, they should attempt to

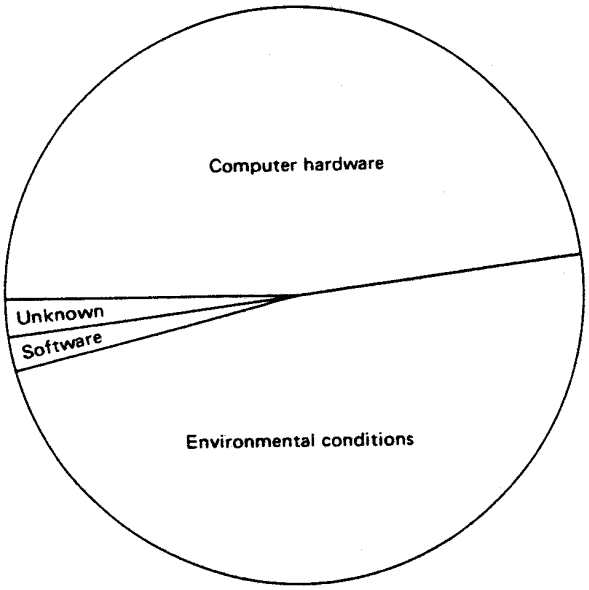


Fig. 16—Causes of system unavailability at the Baylor College of Medicine

produce a system more tolerant of the environment in which it is likely to be installed.

System accessibility changed as more investigators began to make use of the system. When the CLINFO prototype systems were first installed, certain terminals were almost always available. As time passed, we began to hear comments from users about having to work at night or on weekends in order to get access to the system or to get reasonable response time. Data for the most recent few months indicate that four terminals (i.e., all that can be used concurrently) are in simultaneous use for about 13 hours of each 28-day period at Baylor, 4 hours per period at the University of Washington, and 5 hours per period at Vanderbilt. Although the number of hours during which all four terminals are in use is low, there are other factors that make it appear to a user that no terminal is available; for example,

- Some terminals are located in investigators' offices or laboratories and are thus private terminals.
- Users appear to prefer to work in the computer room or close to the system manager, even if terminals are available closer to their own work areas.
- One group of users is located sufficiently far from the CLINFO computer system that they must use the system over a telephone line. They have access to only one terminal at their location.

Thus, the system is or appears to be inaccessible to potential users for some portion of the time.

The system managers now have data and report-generation programs that enable them to monitor the use of facilities. These reports should help them to allocate resources more effectively. For example, terminals that are rarely used

could be relocated and the most frequently used terminals could be assigned the higher-speed (4800-baud versus 1200-baud) terminal ports. After the system managers experiment with terminal placement, they should be able to specify the number of terminals appropriate for their sites. For now, the current four to six terminals per site seems sufficient.

CLINFO SUPPORT PERSONNEL

Questions and Data Sources

We believed that at least a full-time (eight hours or more per day, five days per week) system manager would be necessary for each of the prototype systems. In addition to performing duties that would normally be associated with maintaining operational computer systems, the system managers were expected to spend part of their time on the CLINFO evaluation and to help smooth out problems inherent in dealing with prototype systems. The system managers were not generally expected to be available at odd hours or on weekends, even though we expected the systems to be available and used at those times. We also believed that central support for the individual sites was necessary because the system software was evolving and because solving some problems might require skills or experience the system managers did not have.

Based on our initial plans for support personnel and our concern for the adequacy of the amount of support proposed, we formulated the following questions:

1. What functions do CLINFO support personnel perform?
2. Is a full-time system manager at each site sufficient during the prototype evaluation phase?
3. What level of system-manager support will be necessary after the evaluation is completed?
4. What level of system-manager support can we project as necessary for a widely disseminated system?
5. Would satisfactory working relationships develop between system managers and system users?
6. What other kinds of support are necessary?

Answers to these questions came from the system managers and system representatives, who reported on their roles in assisting users. Additional information was obtained from user interviews concerning the kinds of support provided. The system managers also reported how their time was spent doing routine hardware and software maintenance, carrying out system operations, and developing special programs for users.

Answers to Questions

The system managers perform an important role in introducing users to the system and supporting their efforts to make effective use of it. They have generally performed three kinds of activities:

- User support: assisting users with the CLINFO system and writing Basic programs or running utility programs for them.
- System support and routine system operations: dealing with computer, terminal, and environmental problems, dealing with software problems, and carrying out routine and nonroutine system procedures, including backup.
- CLINFO experiment participation: carrying out activities associated with the CLINFO experiment that otherwise would not have been required, e.g., processing tapes, writing reports, and attending meetings.

During the CLINFO experiment, the three participating system managers averaged approximately 17 hours per week assisting users, 14 hours per week on system-related tasks, and the rest of their time carrying out activities as part of the CLINFO experiment. The time required for system support varied considerably as hardware problems occurred.

In the future, the system managers will have more time to spend with users because report generation and other activities associated with the experiment will no longer be required and because there will be fewer installations of new software. System support for a future CLINFO system should also require less time, because a new system should have more reliable hardware, more stable software, and improved operating procedures. Also, after a year or two of system operation, a core group of users will probably develop. These users will require less system-manager support and can help new users. In some cases, users have taken over some of the user-support activities. At one site, users are located several miles from the installation and use the system over a telephone line. One of the users at this remote location acts as a local system manager. In other instances, one person in a large research group performs much of the user support and training for his group. Thus, in some situations, a full-time system manager may not be necessary.

The amount of time a system manager or acting system manager would have to devote to users and system support for a future system has yet to be determined. However, we believe that full-time coverage is necessary. This requirement may best be satisfied with an arrangement like that at Vanderbilt. The system manager there is part of a user-oriented biomedical engineering group which also supports other minicomputers. If user and system support does not require his full-time attention, he can spend part of his time on other biomedical engineering tasks. If the system manager is unavailable, e.g., because he is on vacation or ill, other members of the group can temporarily take over for him.

The system managers appear to have developed good working relationships with system users. For some users, the system managers provide continuing support and guidance; for others, the clinician/project directors perform this function; and for others, this function is shared. The nature and amount of support and guidance provided and who provides them are determined not only by user requirements but also by traditions already established at the site, as well as the skills and personalities of the participants. The fact that the system managers are not clinicians does not appear to constrain their interactions with users.

The system designers/implementers have provided support in a number of areas, including site staff and user training, software maintenance, and hardware and software troubleshooting. A vendor of future CLINFO systems would be ex-

pected to provide similar kinds of support and might well go beyond what was done for the prototypes.

System representatives were particularly important in support activities as the CLINFO system evolved. All the system managers and some of the clinician/project directors spent several days at Rand with the system representatives, learning about using and operating the system. Additional training sessions were conducted at the sites when the prototype systems were installed. During frequent visits to the clinical sites (two or three days at each site every six to eight weeks), the system representatives explained and demonstrated new capabilities to system managers and users, provided help in using the system for unusual problems, and provided statistical guidance when that capability was not locally available. They also brought information about problems and suggestions for changes back to the system designers/implementers. The system representatives were necessary to smooth the transition to new and changed capabilities, and they would continue to be necessary as long as the system was evolving. If the system were stable, they might still be useful in providing different problem-solving perspectives and in supplying services, such as statistical guidance, that were not readily available locally. They would also be useful as communicators in carrying information and techniques from site to site.

All software development and maintenance for the prototype systems was done at Rand, and new versions of the system were released at frequent intervals. This made it possible for all three sites to be using the same software at any given time and discouraged the development of local versions of the system. Providing support to the system managers in troubleshooting hardware and software problems served to enhance their individual capabilities, facilitated interactions with vendors, and created a central repository of information about problems and their solutions.

OPERATING PROCEDURES

Questions and Data Sources

A set of hardware and software operating procedures was developed and tested and was documented in the form of an operations manual. The manual is used at the sites and is modified as new procedures are added and system managers adapt the procedures to better fit their environments. These procedures are specific to the particular hardware and software that comprise the CLINFO system. Evaluation is limited by the small sample size, that is, three system managers making use of these procedures under different conditions.

Efforts to safeguard investigator and patient data fall into two categories: providing system procedures and programs, and developing guidelines. The system is designed to minimize possibilities for unintentional destruction of data. Procedures and programs have been developed to facilitate preserving data and recovering data that have been accidentally lost. We have provided system users and site personnel with privacy guidelines, have included privacy safeguards in the hardware and software, and have taken precautions to prevent confidential information from leaving a site.

We formulated the following questions concerning operating procedures:

1. Were the operating procedures adequate for normal operations?
2. Were the procedures usable by individuals who might substitute for the system manager?
3. Would the procedures and guidelines be adequate in unanticipated or emergency situations?
4. Would investigator and patient data be adequately protected from loss?
5. Would user and investigator privacy be maintained?

The information to answer these questions came from reports by the system managers and system representatives and from discussions and interviews with users.

Answers to Questions

The operations manual has been revised during the course of the evaluation. The system managers are now familiar with most procedures and only rarely refer to the manual. In the absence of a system manager, other individuals, including clinician/project directors, secretaries, technicians, and research assistants, have temporarily taken over his duties and have successfully used the operations manual. In some cases, the substitute system managers have preferred to deal with problems by telephoning the system designers/implementers at Rand and being led through the appropriate procedures.

We have little concrete evidence to indicate that any of the procedures should definitely be changed. Two particular procedures, however, one for system backup and one for merging new data into an existing data base, do deserve further attention.

Current operating procedures require system backup (i.e., copying user data from disk to tape) to be done once each weekday plus once more either before or after each weekend. The backup procedure itself takes between 10 and 15 minutes, barring tape errors. Because it is not very time-consuming and because user dissatisfaction with the system would be great if data were lost, it appears to be worthwhile to continue daily system backup as a precaution.

The merge procedure (which merges newly entered data into the Study Data File) is now run by the system manager at the request of a user. The user can make the request directly or can leave a message on the system. The system manager usually reads these messages when he is about to do system backup. As a result, he usually runs merges once a day right before or after system backup, but he is not restricted to this schedule. Occasionally a user wants a merge run immediately and cannot locate the system manager. This situation has led to requests to allow users to run merges themselves. We believe that this is not, in general, a good policy, because the data base is exposed to the introduction of errors during the merge process.

Although CLINFO systems have been powered down in emergency situations caused by flooding, fire, and air-conditioning and power failures, major hardware components have failed, and software errors have been detected, no significant loss of user data has occurred. Occasionally a system failure or operational error has made it necessary to repeat part of a data entry session or has caused a problem in a data base. In the latter case, either the data base has been restored from a previous version saved on tape or has been repaired by the Rand system designers/implementers.

CLINFO privacy guidelines were developed to comply with the spirit of the Privacy Act of 1974. Although Department of Health, Education, and Welfare regulations indicated that the system of records kept by CLINFO contractors was exempt from the Privacy Act, it was nonetheless important to review the legal obligations of both CLINFO contractors and system users with regard to federal, state, and local privacy law. The guidelines address system safeguards (e.g., password protection, system access limitations, data validation, and limitations on patient identification) and operational safeguards (e.g., system backup procedures, control of access to computer equipment and media, and disposal of paper records). These guidelines have been followed by CLINFO personnel. System users have been informed of the guidelines and have been further encouraged to review their legal obligations with regard to privacy for their own research. We have not received any complaints nor do we know of any problems regarding investigator or patient privacy and the CLINFO system.

IV. ESTIMATING BENEFITS AND COSTS

PERCEIVED BENEFITS OF USING THE CLINFO SYSTEM

Questions and Data Sources

In the 1973 survey of clinical investigators, we asked 88 investigators what benefits might result from the use of a specially designed computer-based data management and analysis system for clinical research. During the next phase of the CLINFO project, Rand system representatives frequently visited the clinical sites where they had extensive interaction with both users and CLINFO personnel. During these visits, the representatives, sometimes with the local system manager, formally interviewed users. Thirty potential users (7 at Baylor, 12 at Washington, and 11 at Vanderbilt) were interviewed before they used the prototype or after they had used it briefly. They were asked about the benefits that might result from using a computer system like CLINFO. Included in the list of questions were most of the benefits discussed in the initial survey plus a number of others. Twenty-seven users (7 at Baylor, 9 at Washington, and 11 at Vanderbilt) were interviewed after they had made extensive use of the prototype and were asked to what extent they agreed that the benefits had been obtained using CLINFO. The questions and tabulations of the results are contained in Appendix A.

Answers to Questions

Since the responses to the interview questions comprised ordinal data (e.g., 1 = strongly agree, . . ., 5 = strongly disagree), a nonparametric test (the sign test) was performed to determine the significance of the difference between the median response to each question and a hypothetical median representing disagreement or no opinion. A p value of .01 (one-tailed) was chosen as the confidence level. For questions yielding a $p \leq .01$, the hypothesis of disagreement or no opinion may be rejected in favor of the alternative of agreement.

The responses to the three different surveys are compared in Fig. 17. Using the sign test, we found significant agreement about benefits, as indicated by asterisks. The investigators interviewed in the 1973 survey and the investigators interviewed before using the CLINFO system showed similar patterns of agreement for the questions asked of both groups. Investigators interviewed after using the system agreed that they obtained all the benefits anticipated and also obtained unanticipated benefits in two areas.

Many benefits were brought out during discussions with users and during formal presentations at site visits. One user observed that CLINFO was helpful in learning about the use of computer systems in clinical research studies and was interested in the possibilities of its use in clinical trials, particularly with regard to shared data access. Another user commented that, in contrast to his experiences with other computer systems, he was able to master the CLINFO system himself and did not have to communicate with it through a programmer. Several users commented that the use of CLINFO resulted in better experimental design, im-

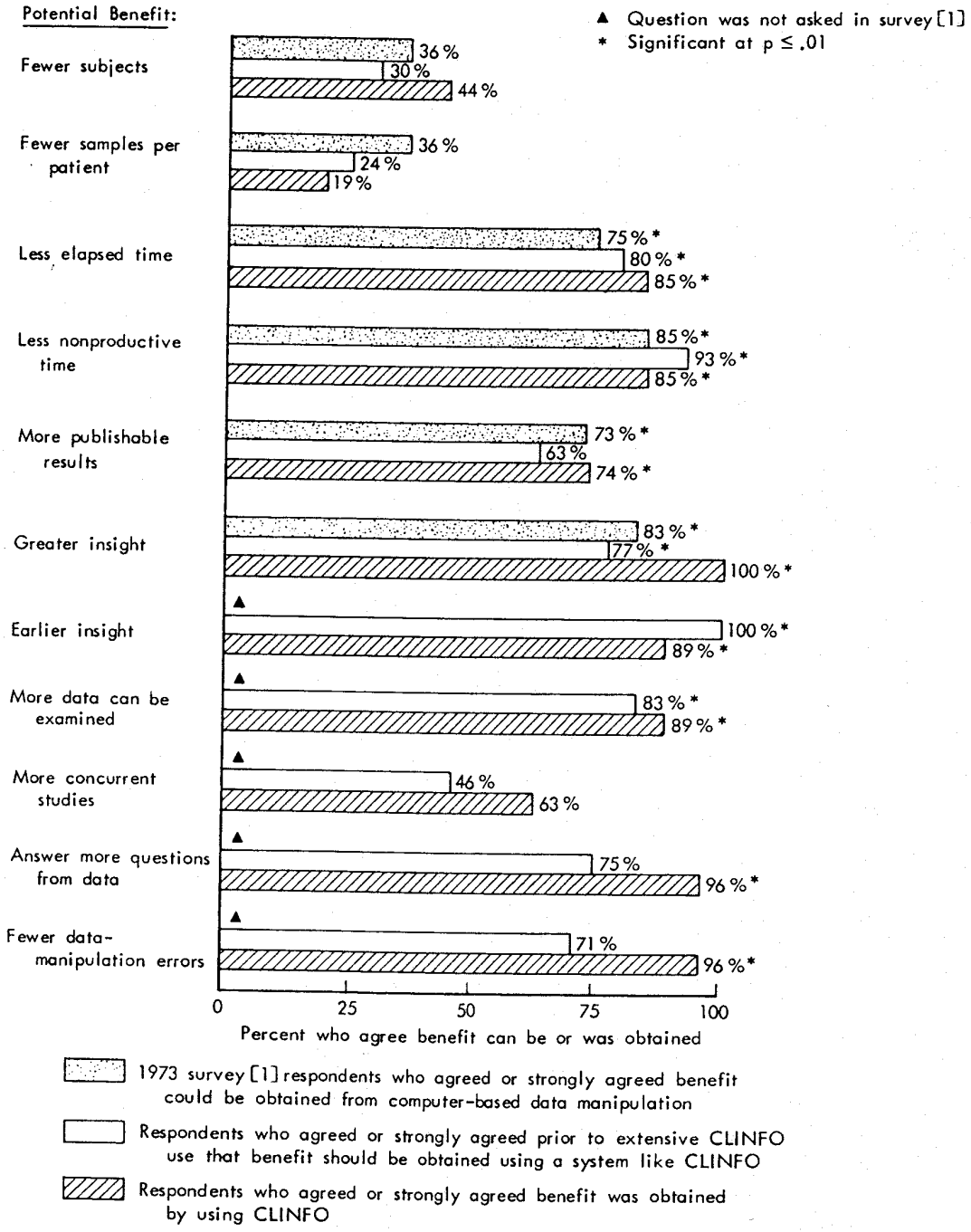


Fig. 17—Extent of agreement that a potential benefit can be obtained with a computer-based data management and analysis system or was obtained using the CLINFO system

proved data organization and analysis, and improved communication between investigators. The system was easily accessible to them, and the capability for rapid data reduction and analysis allowed them to complete studies in a shorter time. One user expected that this enhanced ability to deal with his research data would enable him to plan future studies more effectively and to use smaller patient populations for epidemiological studies. Users also suggested that CLINFO can play an important role in the training of fellows and can provide continuity for long-term studies implemented by fellows or other staff members on temporary assignment.

PERCEIVED IMPEDIMENTS TO CLINICAL RESEARCH

Questions and Data Sources

The same three groups of investigators were given a possible specification of the major steps involved in carrying out a clinical research study. Eighty-nine investigators in the 1973 survey and 35 investigators who were about to begin using the CLINFO system (10 from Baylor, 14 from Washington, and 11 from Vanderbilt) were asked to what extent each of the steps unnecessarily impeded their research. Twenty-eight investigators (8 from Baylor, 9 from Washington, and 11 from Vanderbilt) were asked to what extent the use of CLINFO had influenced these steps. The questions and tabulations of the results are contained in Appendix A.

Answers to Questions

The responses to the three surveys are compared in Fig. 18. Following the same statistical procedures that we used for benefits (with the median response compared to a hypothetical median representing little or no impediment), we found significant agreement that several steps were unnecessary impediments for the first two groups interviewed. A design goal of the CLINFO system was to facilitate two of these steps (organizing and storing data and retrieving, reducing, and analyzing data), and users showed statistically significant agreement that these steps were facilitated. Improvements in these two steps should allow investigators to have a greater understanding of their research results (as their responses to the "greater insight" and "earlier insight" benefits indicated). This, together with facilities for producing tables, graphs, and analyses, should make it easier for investigators to report their results and, although no major impediment had been perceived, users showed statistically significant agreement that reporting to sponsors and publishing papers were made easier by using the CLINFO system.

Interviewed users also indicated that developing and altering a research plan was easier with the CLINFO system, although research plan construction had not been perceived as a major problem. The rigor imposed by CLINFO in the identification of which data are to be collected and how they are to be organized initially is probably responsible for facilitating research plan development and alteration. If, in fact, the result of facilitating this step is a better research plan, then many of the subsequent steps should also be facilitated and the final outcome should be higher-quality research.

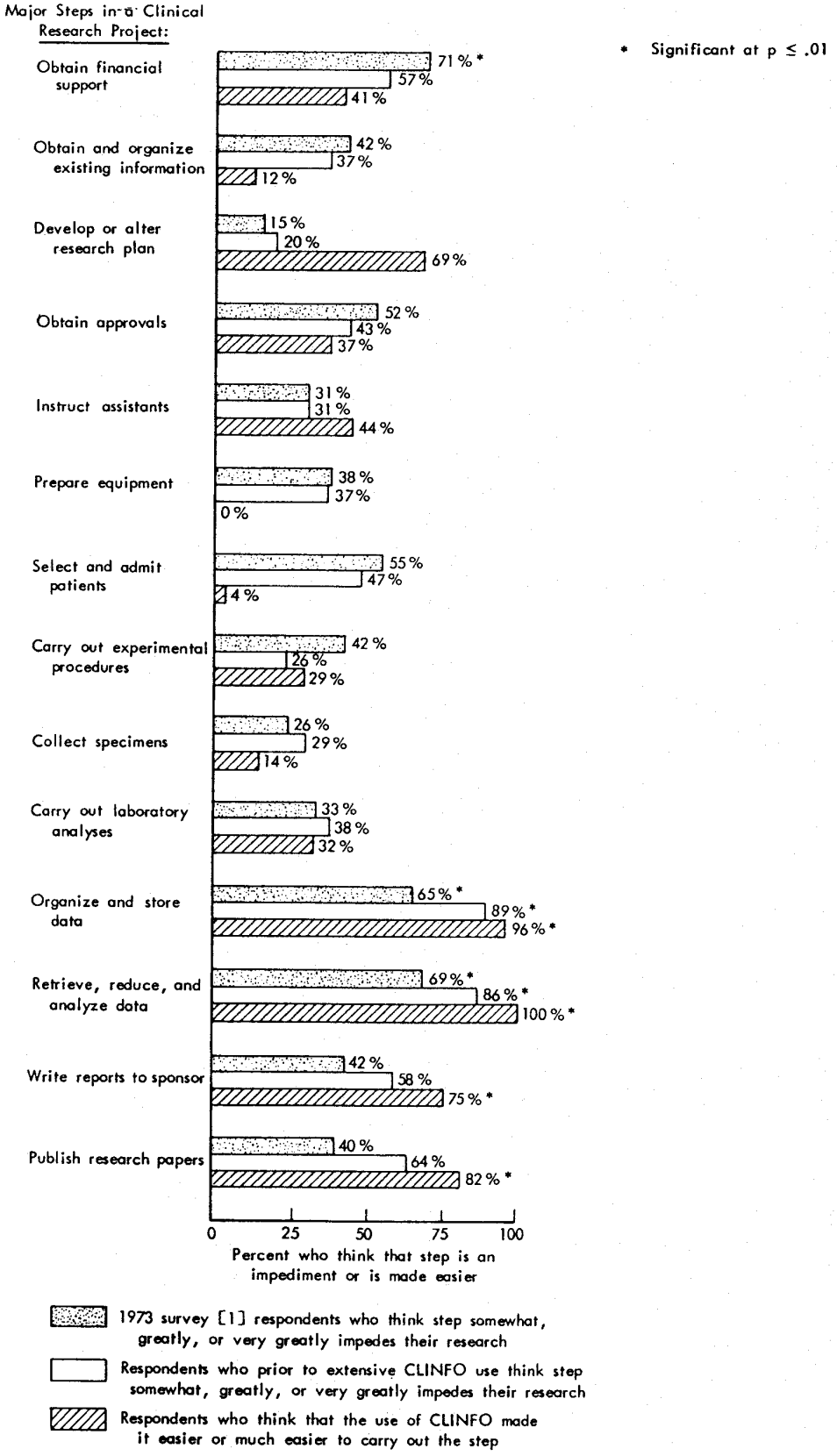


Fig. 18—Extent of agreement that major steps in carrying out a clinical research project were unnecessary impediments or were made easier by the use of the CLINFO system

COSTS OF OWNERSHIP

Questions and Data Sources

A major goal of the CLINFO project was to make the CLINFO system and its support personnel fiscally acceptable to CRCs. Thus we planned to identify costs for equipment acquisition and maintenance and for personnel. Because the NIH pays most of the costs associated with CRCs and because CLINFO was treated as a CRC resource, fiscal acceptability was something NIH personnel would have to decide. Thus, we asked the following questions about costs of ownership:

1. What were the equipment costs associated with the prototype?
2. What were the personnel costs associated with the prototype?
3. How might these costs change in the future?
4. Are these costs fiscally acceptable to CRCs?

Information about costs came from records of equipment prices and salaries kept by the authors.

Answers to Questions

The costs associated with owning and operating a CLINFO system and providing support to users fall into two categories: equipment costs and personnel costs. We have included both direct and indirect (overhead) costs. Equipment costs for the prototype system include

- The basic computer system.
- Charges for shipping the computer to the site.
- Hardware maintenance.
- Insurance.
- Supplies.
- Site preparation.
- Space rental.

The personnel costs are salaries and overhead for a full-time system manager plus the costs of secretarial support and supervision by a clinician. If we depreciate the fixed initial cost of the computer equipment over five years and average other costs over that same period, the total annual cost of owning and operating a CLINFO prototype system and supporting users is about $77,000. These costs are shown in detail in Table 2.

The basic computer system used for the CLINFO prototype is a Data General Eclipse S/200 with 48K (i.e., 49,152) 16-bit words of core memory, a 25-megabyte (i.e., 25 million 8-bit bytes) moving-head disk drive and controller, a 1-megabyte fixed-head disk drive and controller, a 9-track 800-bpi magnetic tape drive, a Centronics 101A 80-column line printer, eight ports, four 40-line Ann Arbor terminals with attached Data Terminals & Communications (Diablo-type) printers, and a Texas Instruments Silent 700 console terminal. The list price for this configuration is approximately $120,000. (Each CLINFO site also has auxiliary computer equipment with a list price of approximately $10,500.) If the configuration were being chosen now, some items would be cheaper. However, additional disk storage, main

Table 2

COSTS OF OWNING AND OPERATING A CLINFO PROTOTYPE SYSTEM

Item	Approximate Annual Cost
Computer system[a]	$24,000
Shipping[b]	200
Hardware maintenance	14,500
Insurance	250
Supplies	850
Site preparation[c]	1,000
Space rental	1,200
System manager salary plus 50% overhead	27,000
Quarter-time secretary salary plus 50% overhead	3,200
One-tenth-time clinical investigator salary plus 50% overhead	4,500
TOTAL	$76,700

[a]One-time cost of $120,000 distributed equally over five years.

[b]One-time cost of $1,000 distributed equally over five years.

[c]One-time cost of $5,000 distributed equally over five years.

memory, and terminals would probably be included, thus keeping the hardware cost close to $120,000. Shipping costs might add another $1,000.

Hardware maintenance costs have continued to rise since the first CLINFO prototype was installed. For the basic configuration, the cost is presently approximately $1,200 per month.

No costs are shown for software or software maintenance. Licenses for the Data General operating system (RDOS) and the Basic interpreter cost $1,200 if purchased with the hardware listed above. The CLINFO prototype application software has taken about eight person-years to develop, including considerable redesign and reprogramming. Requirements analysis, the initial design, and ongoing evaluation and user support have taken considerable additional time. We have not attempted to allocate the costs of these efforts across the sites.

The hardware and hardware maintenance costs are applicable to the prototype only. The cost of a commercially available CLINFO system would be influenced by the configuration, the pricing policies of the hardware manufacturers, the type of technology used, software development costs, services included, and the vendor's profit.

Normally, federal-government-owned automatic data processing equipment is not insured; rather, the government acts as a self-insurer. In this analysis, we have provided for insurance, at an estimated cost of $2.13 per $1,000 of replacement cost, should the site own the equipment or otherwise choose to provide insurance.

Start-up supplies include 4 disk packs, 20 magnetic tapes, printer ribbons, type wheels, and paper, at a total cost of approximately $1,000. Annual supplies include 10 additional magnetic tapes and more printer ribbons, wheels, and paper totaling approximately $650.

Charges for site preparation were between $3,000 and $5,000 at two sites and $10,000 at the third site. We believe that $5,000 should be sufficient for site preparation at most CRCs. The major items in site preparation are

- Electric power: A stable, transient-free power source or appropriate isolation equipment and an emergency shut-off switch are necessary. Both 120-volt and 208/230-volt single- and 3-phase power sources are required for the prototype.
- Air conditioning: Approximately 18,000 Btu per hour are produced by the prototype computer equipment and two or three people working in the computer room. One ton of air conditioning is needed for every 12,000 Btu per hour produced. (Air-conditioning instability has been a problem at all three clinical sites.)
- Acoustics: The principal sources of noise are mechanical devices such as the line printer and the cooling fans in both the main equipment cabinet and the moving-head disk drive. Acoustic treatment is necessary to prevent these noises from disrupting adjacent work and patient care areas.

The cost for renting office-quality space (including power, light, and air conditioning) for computing equipment varies considerably, but $0.50 per square foot per month seems to be a good estimate. The CLINFO configuration, including storage cabinets and work space, occupies a room approximately 14 feet square. Thus, we estimate that space rental would cost $100 per month. Typically, space would not be rented, but costs would be included in the overhead for operation of the CRC.

Personnel costs are a large part of the costs of ownership. For the prototype system, we assumed that a full-time system manager and a quarter-time secretary were necessary. As indicated earlier, a part-time system manager may be sufficient once a relatively stable user community develops. Also, we assume that a CRC director or one or more other clinical investigators will spend 10 percent of his time supervising the system manager administratively and scientifically, interacting with other investigators regarding CLINFO, and reviewing applications for the use of CLINFO.

Because the NIH has decided to disseminate a CLINFO system based on the prototype and with similar hardware and personnel requirements, we conclude that costs similar to those in Table 2 are acceptable.

V. RECOMMENDATIONS AND DISCUSSION

Based on the results of the CLINFO evaluation, controlled dissemination of the CLINFO system to other CRCs should begin. The prototype systems are used by many clinical investigators and satisfy most of their research data management and analysis needs. Among the perceived benefits of using the CLINFO system, investigators claim that they produce more publishable results, thus enabling them and their sponsors (usually the NIH) to make more effective use of research funding. Having access to a CLINFO system might then provide a competitive advantage to investigators, particularly if, as is now the case, only 55 percent of the approved NIH grant applications are funded [11]. The system has been useful in educating fellows and others, and its use in many CRCs would provide standardization of computing facilities, thus eliminating data transfer problems for mobile investigators. The availability of the same computing resources at many locations would also facilitate data sharing and collaboration among investigators. Finally, the CLINFO prototype system is cost-competitive with commercial computer systems.

Recommended characteristics for a system to be further disseminated are described below. Because the prototype system has been well accepted, the recommended characteristics closely match those of the prototype. A few improvements to the prototype are included in the characterization, however, and these are based on both user requests and our experiences at the CLINFO sites.

The CLINFO project succeeded in producing a well-accepted prototype system because of the careful way in which the project was conducted. Our approach is briefly described below. A carefully planned approach should also be followed in the dissemination phase. And finally, a number of issues must still be explored before the full impact of the CLINFO project, and the benefits and costs of the CLINFO system, can be ascertained.

RECOMMENDED SYSTEM CHARACTERISTICS

Based on the evaluation results, a follow-on CLINFO production system (i.e., one designed for widespread distribution rather than for evaluation of concepts) should have the following characteristics:

- The capabilities of the prototype should be replicated both in function and in mode of operation. Some suggested improvements (e.g., larger worksheets, new modes of data entry and retrieval, greater use of defaults, and the capability to include more patients) should be incorporated if these do not noticeably reduce ease of operation or system responsiveness. System responsiveness should be less sensitive to load than it has been in the prototype, and responsiveness for four users should be similar to that for a single prototype user. Hard copy of text and line drawings should be provided, but not necessarily at each user terminal.

- Computer hardware should be selected that can support these capabilities and that will meet the needs of the users at a single CRC. The hardware should include four user terminals with provision for eight or more, one industry-compatible tape drive, one or more disk drives with a total capacity of at least 50 million characters, one medium-speed printer, provision for remote access, and provision for additional devices such as paper tape readers. Requirements for space, air conditioning, special electric power, acoustic treatment, and maintenance should be minimal. The total hardware/software system cost should be no greater than about $125,000 (about one-quarter of a CRC's annual budget).
- Each system should be under the administrative control of a CRC or perhaps two or three nearby collaborating centers. At each major site there should be full-time system-manager coverage provided by one or more individuals. These individuals should provide user support, system support, and system operation. They should have experience in biostatistics and computer applications programming and an understanding of computer hardware, and each of them should have good communication skills and should be interested in helping the investigator/users with their problems.
- The user terminals should be readily accessible. Reliability and maintenance strategies should ensure that the system is available at least 95 per cent of the time between 7 A.M. and 7 P.M. during the work week and should be directed toward obtaining 24-hour-a-day, 7-day-a-week availability. User data should be regularly copied onto tape to ensure their viability in case of inadvertent changes, system malfunction, or other forms of destruction. Passwords, avoidance of recognizable patient identifiers, careful handling of data, and other techniques should be used to protect the investigators' and patients' privacy.

THE CLINFO PROJECT APPROACH

Because of the approach taken, the CLINFO project has been able to determine the information processing activities and needs of clinical researchers in CRCs and to provide computer technology to meet a majority of their data management and analysis needs. We believe that our success has been due to a number of factors:

- The project was conducted by a consortium whose members had diverse backgrounds. This necessitated the exploration of a variety of viewpoints.
- Our approach emphasized designing and following a research plan, learning about problems, and verifying our results at each step. Eighteen elapsed months and more than a third of the total effort were spent on problem definition and initial system design. Approximately 37 person-years have been expended over the five years of the CLINFO project. Of these, approximately 13.5 years have gone into problem definition and initial system design, 8 into system implementation and redesign, 8 into user support, 6 into evaluation, and 1.5 into future planning.

- The involvement of clinical investigators from different geographical locations and with different medical specialties in the consortium meant that a variety of users' interests were represented from the beginning.
- The prototype system is designed to satisfy recognized needs; to be easy to learn to use and easy to remember; to provide an adequate integrated set of capabilities and appropriate data structures and data base sizes; to allow each user to establish his own data definitions and use the system flexibly for his specific needs without requiring programming; to protect the user's data; and to be extensible.
- The ongoing evaluation conducted by the consortium provided the mechanism for gathering information to be used in refining the system as new needs arose and as users with different problems were encountered.
- As soon as systems were installed, users were involved in evaluating the systems. They were usually willing participants because their comments often led to system changes that were of direct and immediate benefit to them.
- Each participating CRC has its own computer system under its administrative control, and the CLINFO system is supported by an on-site system manager.

SYSTEM DISSEMINATION ISSUES

Because of the prototype's acceptance, the NIH has decided to acquire, over the next four years, up to 30 systems based on the same design and to install them in CRCs. The next phase of the project will involve two or more contractors in building competing production versions of the system; one of these contractors will be selected to supply systems to the CRCs. The original group of computer scientists and clinical investigators will continue to participate in the project, but because none of them will be directly involved in the development of the production system and because of the competitive nature of the diffusion phase, it is expected that technology transfer to the competing contractors will proceed with some difficulty.

There are a number of issues yet to be explored before the full impact of the CLINFO project can be ascertained. These include determining

- The long-term benefits of the CLINFO system and support personnel to the quality of research.
- The manifestations and consequences of users' rising expectations.
- The long-term need for direct NIH subsidies and for special support personnel.
- The outcome of NIH diffusion efforts.

Appendix A

QUESTIONNAIRE EXCERPTS AND RESPONSES

This appendix contains excerpts from the instruments used in the 1973 survey of clinical investigators, the interviews with potential users before they used the CLINFO system, and the interviews with users after they had used the system extensively. The first set of excerpts includes questions dealing with potential or perceived benefits of using a data management and analysis system. The second set includes questions dealing with perceived impediments to carrying out the major steps in a clinical research project and the influence of the use of the CLINFO prototype system on accomplishing these steps.

Results have been added by hand so that the reader can examine them in the original context of the questions. For each question, the results include the frequency with which each response was given, the percentage of responses in each category, the number of responses to the question, and the median response.

BENEFITS OF USING A DATA MANAGEMENT AND ANALYSIS SYSTEM

1973 Survey of Clinical Investigators

Listed below are benefits that might result from improvements like those we have just discussed. To what extent would you agree that these benefits can be obtained?

SA - Strongly agree
A - Agree
N - No opinion
D - Disagree
SD - Strongly disagree

226) A reduction in the number of experiments required to get similar results. 226)____ 20

freq: 9 30 5 40 4 n = 88
SA A N D SD
%: 10 34 6 46 5 median = N-D

227) A reduction in the number of subjects necessary for a similar study. 227)____ 21

freq: 7 25 7 46 3 n = 88
SA A N D SD
%: 8 28 8 52 3 median = D

228) A reduction in the number of samples collected from each patient to get similar results. 228)____ 22

freq: 4 28 8 45 3 n = 88
SA A N D SD
%: 5 32 9 51 3 median = D

229) A reduction in the elapsed time needed to complete a study. 229)____ 23

freq: 12 54 2 20 0 n = 88
SA A N D SD
%: 14 61 2 23 0 median = A

230) A reduction in the amount of nonproductive time that I must spend on a study. 230)____ 24

freq: 32 43 3 10 0 n = 88
SA A N D SD
%: 36 49 3 11 0 median = A

231) An increase in publishable results. 231)____ 25

freq: 13 51 5 19 0 n = 88
SA A N D SD
%: 15 58 6 22 0 median = A

232) A greater insight into the meaning of my research data. 232)____ 26

freq: 18 55 3 11 1 n = 88
SA A N D SD
%: 21 63 3 13 1 median = A

233) Are there other beneficial results that might result from those improvements? 233)____ 27

1 - Yes 2 - No

_____

_____

_____

Interview Prior to Use of the CLINFO System

Listed below are benefits that might result from using a computer system like CLINFO. To what extent would you agree (anticipate) that these benefits can be obtained?

SA - Strongly agree
A - Agree
N - No opinion
D - Disagree
SD - Strongly disagree

7) A reduction in the number of subjects necessary for a similar study.

	SA	A	N	D	SD	
freq:	1	8	0	15	6	n = 30
%:	3	27	0	50	20	median = D

8) A reduction in the number of samples collected from each patient to get similar results.

	SA	A	N	D	SD	
freq:	1	6	4	14	4	n = 29
%:	3	21	14	48	14	median = D

9) A reduction in the elapsed time needed to complete a study.

	SA	A	N	D	SD	
freq:	7	17	4	2	0	n = 30
%:	23	57	13	7	0	median = A

10) A reduction in the amount of nonproductive time that I must spend on a study.

	SA	A	N	D	SD	
freq:	14	14	2	0	0	n = 30
%:	47	47	7	0	0	median = A

11) An increase in publishable results.

	SA	A	N	D	SD	
freq:	3	16	7	3	1	n = 30
%:	10	53	23	10	3	median = A

12) A greater insight into the meaning of my research data.

	SA	A	N	D	SD	
freq:	9	14	3	4	0	n = 30
%:	30	47	10	13	0	median = A

13) Earlier insight into the meaning of my research data.

	SA	A	N	D	SD	
freq:	9	15	0	0	0	n = 24
%:	38	63	0	0	0	median = A

14) An increase in the volume of data that can be examined to obtain results.

	SA	A	N	D	SD	
freq:	7	12	1	3	0	n = 23
%:	30	52	4	13	0	median = A

15) An increase in the number of studies that can be performed concurrently.

	SA	A	N	D	SD	
freq:	0	11	4	8	1	n = 24
%:	0	46	17	33	4	median = A

16) An increase in the number of questions that can be answered from a single data base.

	SA	A	N	D	SD	
freq:	8	10	1	5	0	n = 24
%:	33	42	4	21	0	median = A

17) A reduction in the number of errors in data manipulation.

	SA	A	N	D	SD	
freq:	10	7	5	2	0	n = 24
%:	42	29	21	8	0	median = A

18) Are there other benefits that might result from using a system like CLINFO?

1 - yes
2 - no

_____

_____

_____

Interview After Extensive Use of the CLINFO System

Listed below are benefits that might result from using the CLINFO prototype system. To what extent would you agree that these benefits were obtained using CLINFO?

SA - Strongly agree
A - Agree
N - No opinion
D - Disagree
SD - Strongly disagree

42) Reduction in the number of subjects necessary for a similar study.

	SA	A	N	D	SD	
freq:	1	11	8	6	1	n = 27
%:	4	41	30	22	4	median = N

43) A reduction in the number of samples collected from each patient to get similar results.

	SA	A	N	D	SD	
freq:	0	5	13	9	0	n = 27
%:	0	19	48	33	0	median = N

44) A reduction in the elapsed time needed to complete a study.

	SA	A	N	D	SD	
freq:	8	15	3	0	1	n = 27
%:	30	56	11	0	4	median = A

45) A reduction in the amount of nonproductive time that I must spend on a study.

	SA	A	N	D	SD	
freq:	10	13	4	0	0	n = 27
%:	37	48	15	0	0	median = A

46) An increase in publishable results.

	SA	A	N	D	SD	
freq:	5	15	5	2	0	n = 27
%:	19	56	19	7	0	median = A

47) A greater insight into the meaning of my research data.

	SA	A	N	D	SD	
freq:	8	19	0	0	0	n = 27
%:	30	70	0	0	0	median = A

48) Earlier insight into the meaning of my research data.

	SA	A	N	D	SD	
freq:	10	14	3	0	0	n = 27
%:	37	52	11	0	0	median = A

49) An increase in the volume of data that can be examined to obtain results.

	SA	A	N	D	SD	
freq:	15	9	2	1	0	n = 27
%:	56	33	7	4	0	median = SA

50) An increase in the number of studies that can be performed concurrently.

	SA	A	N	D	SD	
freq:	4	13	7	3	0	n = 27
%:	15	48	26	11	0	median = A

51) An increase in the number of questions that can be answered from a single data base.

	SA	A	N	D	SD	
freq:	11	15	1	0	0	n = 27
%:	41	56	4	0	0	median = A

52) A reduction in the number of errors in data manipulation.

	SA	A	N	D	SD	
freq:	10	16	0	1	0	n = 27
%:	37	59	0	4	0	median = A

53) Are there other benefits that might result from using a system like CLINFO?

1 - yes
2 - no

Explain _____

_____

_____

IMPEDIMENTS TO CLINICAL RESEARCH AND THE INFLUENCE OF CLINFO SYSTEM USE

1973 Survey of Clinical Investigators

A possible specification of the major steps involved in carrying out a clinical research project is shown below. We understand that all of these steps are difficult, but in your experience to what extent do they unnecessarily impede your research?

Please respond:

N - Not at all
L - Little
S - Somewhat
G - Greatly
VG - Very greatly

REC#) 3 (1)
SER#) ____ (2-5)

86) Obtain financial support. 86) ____ (6)
freq: 12 14 24 18 21 n = 89
N L S G VG
%: 14 16 27 20 24 median = S

87) Obtain and organize existing literature and other information. 87) ____ (7)
freq: 32 20 24 9 4 n = 89
N L S G VG
%: 36 23 27 10 5 median = L

88) Develop or alter research plan. 88) ____ (8)
freq: 47 29 10 2 1 n = 89
N L S G VG
%: 53 33 11 2 1 median = N

89) Obtain approvals for research plans and protocols 89) ____ (9)
freq: 23 20 29 10 7 n = 89
N L S G VG
%: 26 23 33 11 8 median = S

90) Instruct assistants. 90) ____ (10)
freq: 37 29 24 3 1 n = 89
N L S G VG
%: 42 27 27 3 1 median = L

91) Prepare equipment. 91) ____ (11)
freq: 32 23 27 4 3 n = 89
N L S G VG
%: 36 26 30 5 3 median = L

92) Select and admit patients. 92) ____ (12)
freq: 25 15 25 21 3 n = 89
N L S G VG
%: 28 17 28 24 3 median = S

93) Carry out experimental procedures and care for patients. 93) ____ (13)
freq: 34 18 23 12 2 n = 89
N L S G VG
%: 38 20 26 14 2 median = L

94) Collect specimens. 94) ____ (14)
freq: 36 29 18 5 0 n = 88
N L S G VG
%: 41 33 20 6 0 median = L

95) Carry out laboratory analyses. 95) ____ (15)
freq: 32 26 20 9 0 n = 87
N L S G VG
%: 37 30 23 10 0 median = L

96) Organize and store data. 96) ____ (16)
freq: 17 14 23 22 13 n = 89
N L S G VG
%: 19 16 26 25 15 median = S

97) Retrieve, reduce, analyze data. 97) ____ (17)
freq: 14 14 19 24 18 n = 89
N L S G VG
%: 16 16 21 27 20 median = S

98) Write research reports to sponsor. 98) ____ (18)
freq: 33 29 21 9 7 n = 89
N L S G VG
%: 36 33 24 10 8 median = L

99) Publish research papers. 99) ____ (19)
freq: 29 24 31 12 3 n = 89
N L S G VG
%: 33 27 24 14 3 median = L

100) Which of these steps represents the most severe bottleneck? 100) ____ (20,21)

Interview Prior to Use of the CLINFO System

A possible specification of the major steps involved in carrying out a clinical research project is shown below. We understand that all of these steps are difficult, but in your experience to what extent do they unnecessarily impede your research?

Please respond:

N - Not at all
L - Little
S - Somewhat
G - Greatly
VG - Very greatly

25) Obtain financial support.

	N	L	S	G	VG	
freq:	4	11	14	6	0	n = 35
%:	11	31	40	17	0	median = S

26) Obtain and organize existing literature and other information.

	N	L	S	G	VG	
freq:	9	13	10	2	1	n = 35
%:	26	37	29	6	3	median = L

27) Develop or alter research plan.

	N	L	S	G	VG	
freq:	12	16	6	1	0	n = 35
%:	34	46	17	3	0	median = L

28) Obtain approvals for research plans and protocols.

	N	L	S	G	VG	
freq:	7	13	11	3	1	n = 35
%:	20	37	31	9	3	median = L

29) Instruct assistants.

	N	L	S	G	VG	
freq:	9	15	7	2	2	n = 35
%:	26	43	20	6	6	median = L

30) Prepare equipment.

	N	L	S	G	VG	
freq:	8	14	9	3	1	n = 35
%:	23	40	26	9	3	median = L

31) Select and admit patients.

	N	L	S	G	VG	
freq:	10	8	10	6	0	n = 34
%:	29	24	29	18	0	median = L

32) Carry out experimental procedures and care for patients.

	N	L	S	G	VG	
freq:	11	14	9	0	0	n = 34
%:	32	41	26	0	0	median = L

33) Collect specimens.

	N	L	S	G	VG	
freq:	7	17	7	3	0	n = 34
%:	21	50	21	9	0	median = L

34) Carry out laboratory analyses.

	N	L	S	G	VG	
freq:	10	11	8	5	0	n = 34
%:	29	32	24	15	0	median = L

35) Organize and store data.

	N	L	S	G	VG	
freq:	0	4	17	10	4	n = 35
%:	0	11	49	29	11	median = S

36) Retrieve, reduce, and analyze data.

	N	L	S	G	VG	
freq:	1	4	10	12	8	n = 35
%:	3	11	29	34	23	median = G

37) Write research reports to sponsor.

	N	L	S	G	VG	
freq:	6	8	11	8	0	n = 33
%:	18	24	33	24	0	median = S

38) Publish research papers.

	N	L	S	G	VG	
freq:	6	6	13	8	0	n = 33
%:	18	18	39	24	0	median = S

39) Which of these steps represents the most severe bottleneck?

Interview After Extensive Use of the CLINFO System

A possible specification of the major steps involved in carrying out a clinical research project is shown below. How has the use of CLINFO influenced them?

Please respond:

MD - Made much more difficult
SD - Made somewhat more difficult
N - Made no change in difficulty
SE - Made somewhat easier
ME - Made much easier

9) Obtain financial support.

	MD	SD	N	SE	ME	
freq:	0	0	16	6	5	n = 27
%:	0	0	59	22	19	median = N

10) Obtain and organize existing literature and other information.

	MD	SD	N	SE	ME	
freq:	0	0	23	1	2	n = 26
%:	0	0	88	4	8	median = N

11) Develop or alter research plan.

	MD	SD	N	SE	ME	
freq:	0	1	7	14	4	n = 26
%:	0	4	27	54	15	median = SE

12) Obtain approvals for research plans and protocols.

	MD	SD	N	SE	ME	
freq:	0	0	17	8	2	n = 27
%:	0	0	63	30	7	median = N

13) Instruct assistants.

	MD	SD	N	SE	ME	
freq:	1	0	14	8	4	n = 27
%:	4	0	52	30	15	median = N

14) Prepare equipment.

	MD	SD	N	SE	ME	
freq:	0	0	27	0	0	n = 27
%:	0	0	100	0	0	median = N

15) Select and admit patients.

	MD	SD	N	SE	ME	
freq:	0	0	26	1	0	n = 27
%:	0	0	96	4	0	median = N

16) Carry out experimental procedures and care for patients.

	MD	SD	N	SE	ME	
freq:	0	0	20	5	3	n = 28
%:	0	0	71	19	11	median = N

17) Collect specimens.

	MD	SD	N	SE	ME	
freq:	0	0	24	3	1	n = 28
%:	0	0	86	11	4	median = N

18) Carry out laboratory analyses.

	MD	SD	N	SE	ME	
freq:	0	0	19	6	3	n = 28
%:	0	0	68	21	11	median = N

19) Organize and store data.

	MD	SD	N	SE	ME	
freq:	0	1	0	3	24	n = 28
%:	0	4	0	11	86	median = ME

20) Retrieve, reduce, and analyze data.

	MD	SD	N	SE	ME	
freq:	0	0	0	3	25	n = 28
%:	0	0	0	11	89	median = ME

21) Write research reports to sponsor.

	MD	SD	N	SE	ME	
freq:	0	0	7	11	10	n = 28
%:	0	0	25	39	36	median = SE

22) Publish research papers.

	MD	SD	N	SE	ME	
freq:	0	0	5	11	12	n = 28
%:	0	0	18	39	43	median = SE

23) Which of these steps represents the most severe bottleneck?

Appendix B

COLLECTION AND MANAGEMENT OF EVALUATION DATA

Carrying out the CLINFO evaluation required extensive prior planning, the active participation of a number of people, the cooperation of CLINFO system users, continuous monitoring of the progress of the evaluation, and the ability of the evaluators to adapt to changing experimental conditions and to resolve problems as they arose. This appendix reviews the data collection and management methodology developed and used during the course of the evaluation. To present a coherent discussion, we have repeated some material contained in the main body of this report.

The goals of the CLINFO evaluation were to assess the prototype's acceptability, to determine the benefits that resulted from prototype use, and to enumerate the improvements to the prototype that should be incorporated into future systems. As part of the assessment of acceptability, information provided by the evaluation was used to drive the ongoing evolution of the system. Because the system would evolve as information became available, the evaluation process had to be viewed as a natural experiment. We expected the constraints resulting from the lack of stability in the experimental environment to preclude, in general, the possibilities of statistically significant conclusions.

FORMAL EVALUATION PLANS

Prior to completion of the initial functional description, four general evaluation plans were developed by the information scientists and clinical investigators collaborating on the CLINFO project. The plans and their goals are described in some detail in Ref. 3. These initial plans were intended to help us pose questions, the answers to which would enable us to determine if the CLINFO system was fulfilling the needs for which it was designed. Additional plan details, including data collection, management, analysis, and reporting, were developed by the information scientists as the project progressed. All four plans were carried out between January 1976 and November 1977.

One evaluation plan was designed to evaluate the functional characteristics of the system hardware and software. It was particularly directed toward investigating the utility of the system capabilities and user interface, the potential need for additional features, and the system capacity in terms of both the amount of data and the number of simultaneous users it could support.

The second plan examined the operational and organizational implications of a system in the CRC environment. This included evaluating the roles of the personnel who assisted in the use of the system, the accessibility and availability of the system, and operating procedures for maintaining the hardware and software and for safeguarding investigator and patient data.

The third plan attempted to estimate the benefits and costs of the prototype system. A precise assessment of benefits, particularly regarding the impact of the system on clinical research, would require both more data and a longer time span than was possible in a three-year project. Thus, this plan looked for user-perceived benefits such as savings in investigators' time. It also attempted to determine system operating costs.

The fourth plan attempted to determine what needs relating to research data management and analysis were left unmet. This plan looked at issues such as which research data were not processed using the system and why, and what other computational aids were used by investigators. As unmet needs were identified, capabilities that could satisfy those needs were discussed and, if feasible, were added to the CLINFO system.

EVALUATION DATA COLLECTION

The data collection methods used were designed and implemented as an integral part of the CLINFO system. Some evaluation data were collected automatically, i.e., with no (or minimum) human intervention, as the CLINFO system was used. The remaining data were collected through interviews, from observations, and from the records of the system manager. Some of the data collected would normally be recorded for a computer system, e.g., as on a console log. Other data would otherwise go unrecorded, e.g., data collected through interviews. In almost all cases of manually collected data, data collection instruments and forms were used to promote consistency and completeness in data recording.

Of these methods, we much preferred automatic data collection, because it minimizes the burden on users and data collectors, is likely to be more accurate, and is uniform across sites. Collecting data that would normally be recorded anyway was not considered to be a burden for the system managers. Special manual data collection methods were used only when data could be gathered in no other way.

The initial criteria used in selecting the data to be collected included likelihood of accurate and consistent collection and likelihood of sufficient volume to avoid being solely anecdotal. Anecdotal information, however, was to be heavily used in suggesting the evolutionary changes to the system.

The Transaction Log

A major source of data about how and when the CLINFO system was being used, and by what categories of users, was the transaction log. This is a comprehensive log of user/system interactions collected automatically on magnetic tape as the system is used. Each log entry contains an encoded user identification, the date and time of interaction, the system port number, the entry type, and an optional text field. The user identification uniquely identifies the user, his category (e.g., faculty investigator, fellow, or technician), and his study. Entries were made on the log for every sign-on and sign-off, user input line, entry into a CLINFO module, error message, and occurrence of a special condition being monitored. A log entry was made by executing a system call from a CLINFO module.

The Role of the System Manager in Data Collection

The bulk of the data collection was the responsibility of the system managers. Before they were hired, they were told that they would have to devote part of their time each week to processing magnetic tapes and generating reports to be sent to the information scientists at The Rand Corporation for use in evaluation. Descriptions of each task involving evaluation data collection, tape processing, and report generation were provided to them in an operations manual.

The system manager at each site kept records which included cost data for supplies and services (e.g., maintenance contracts), descriptions of all hardware and software failures, reports summarizing his allocation of time to his various duties, summaries of user progress, and descriptions of all user-initiated requests for modifications to the CLINFO system. In addition, the system manager maintained a console log with the computer system and recorded all conditions that might have been considered unusual.

We found that system managers had difficulty in formally interviewing users. Interviewing appeared to conflict with the system manager's role as a provider of support to CLINFO users. For example, many of the questions on the interview forms were viewed as asking for an evaluation of the system manager. After this became apparent, the interviewing activity was conducted primarily by system representatives (whose duties are described below). Thereafter, system managers either did not participate in formal interviews or acted only as recorders.

The Role of System Representatives in Data Collection

In addition to the CLINFO personnel normally at each site, CLINFO system representatives (members of the Rand system design, implementation, and evaluation team) visited each site at regular intervals. The system representatives documented the suggestions that arose during their interactions with users and on-site CLINFO personnel as well as their own suggestions based on their experience with the prototype.

System representatives also interviewed individual investigative users before they began to use the system and after they had completed a research study using it. The pre-use interview was based on a questionnaire intended to elicit background information, a description of a previously completed study including its data volume and the data management and analysis problems encountered, expectations for the use of CLINFO, and a description of the study to be conducted using it. The post-use interview elicited information about the completed study, including its data volume, problems encountered using CLINFO, and costs and benefits perceived by the user. Both interview questionnaires contained some of the same questions used in the 1973 survey of clinical investigators [1].

Cooperation of CLINFO System Users

Users of the CLINFO system were willing participants in the CLINFO experiment, and they were aware that the system might not continue to be available after the end of the experiment. Although they expressed some concern about future system availability, this did not seem to deter them from making extensive use of the system. They received a great deal of support from project personnel, and

perhaps because of this support, they were willing to discuss their work and be interviewed repeatedly during the course of the CLINFO experiment. They were also, in general, conscientious about reporting problems and making suggestions for system improvements.

EVALUATION DATA MANAGEMENT AND UTILIZATION

As data were received at Rand, they were logged in and missing information was noted. Some initial processing was also done, and this occasionally revealed problems such as tape errors. These difficulties could usually be resolved by a telephone call to the appropriate system manager. Other problems arose from misinterpretation of the intent of the data collection. These usually could be resolved for future data collection, but they sometimes resulted in inconsistencies in data already collected.

The most effective monitoring tool was the regular generation of reports. These put the data in context and not only enabled us to look, for example, at system use each reporting period and trends over time, but also pointed out inconsistencies in the data and areas where presentation of results could be improved.

As was our intention, the CLINFO system was used to manage and analyze almost all of the evaluation data. Reports included tables, charts, and graphs made using the system. The evaluation data were entered into one of several CLINFO studies (i.e., separately accessible computer data bases, each with its own data and data description). One set of studies contained data about CLINFO system usage, another study contained data about failures and errors in individual hardware and software modules, and still another contained data obtained from interviews.

As evaluation data were collected, they were sent to Rand, where they were processed and entered into studies. Frequent reports were generated and much of the information was used to determine changes to the CLINFO prototype. This part of the evaluation required a substantial portion of the time of one information scientist and two (and sometimes three) half-time research assistants.

System-use data for each site were tabulated monthly. System availability, use, and failures were summarized and were also broken out for each day. The data included information about the number and average length of sessions, the number of distinct users, system availability during prime time, system load, the classification and extent of failures, and information on the use of CLINFO capabilities by different categories of users (e.g., clinical investigators, research aides, and laboratory technicians). System use data were also summarized graphically for all previous months, and monthly summaries were produced showing the use of CLINFO capabilities by each research study. A similar summary was produced reflecting total CLINFO use.

The hardware problem data were tabulated but were not presented in any formal way. Rather, they were used to influence the selection of hardware configurations for future CLINFO systems and to specify the computer-hardware familiarity desirable in a CLINFO system manager. The software problem data were used as soon as they were received to make corrections or to plan changes for future versions of the system. The interview data were tabulated and, where appropriate, were compared with data from the earlier survey of clinical investigators [1].

Evaluating Functional Characteristics

Much of the information used to evaluate the functional characteristics of the CLINFO prototype system came from informal discussions and interviews with users. Additional supplemental information came from the transaction log and from records kept by the system manager, particularly those describing user progress and system failures.

Discussions with users provided most of the impetus for system evolution. We were helped most by particularly perceptive, insightful, and communicative users who stressed the system in various ways—often ways that we had not anticipated. The one-to-one interchanges between system designers/implementers and these users led to most of the approximately 1100 recorded system-change requests generated during the two years of prototype operation. The system designers reviewed these change requests weekly. Each request was assigned an implementation priority, was rejected, or was put aside until more information was obtained. As a result of these requests, the prototype system evolved in ways we had not initially anticipated.

The information obtained from user interviews was corroborated and expanded upon by information obtained from the transaction log. The system-use data extracted from the log made it possible to determine which capabilities were being used. They also made it possible to determine which capabilities were not being used and thus led us to seek further information.

Completed printed records of user sessions were useful in trying to improve user interaction and eliminate system errors. To do this, we first had to learn about the mistakes users made and the system errors they encountered. The users readily reported these problems, so little new was learned from looking at transaction log entries for errors alone. However, users often could not accurately recount the events which led to the problem. In order to avoid losing important information about errors during the CLINFO software development stage, the user was temporarily prevented from continuing his session whenever he encountered an error not anticipated by the system. Under those conditions, his terminal was locked and a message was displayed telling him to call the system manager. The system manager recorded error information (which was also displayed), perhaps saved a copy of the state of the system, and released the terminal so that the user could continue with his session. Thus the immediate circumstances surrounding the problem were recorded and these could be supplemented by the transaction log. After software development was completed, terminal locking was discontinued; instead, errors were recorded on a disk file and the user was allowed to continue his session.

System Responsiveness

It was necessary to produce a system that was sufficiently responsive that people would use it and thus provide information for evaluation. Our first approach to gathering information about responsiveness was to ask users to type a comment about response time at the end of each session. These comments would be recorded in the transaction log and could then be tabulated. We also had questions in the interview forms dealing with responsiveness. Neither of these approaches resulted in much information.

We then considered recording on the transaction log the elapsed time between

each user input and the system response. This idea was rejected for two reasons. First, the amount of information to be recorded on the transaction log would be nearly doubled and this in itself might interfere noticeably with system responsiveness. Second, the resultant information would be difficult to use. The complexity of the task performed by the system between user input and system response varies considerably among the possible input/response pairs. Also, these pairs by themselves have little meaning in terms of how the system is used. Thus, it is more meaningful to look at responsiveness in terms of scripts, each of which includes the steps a user might follow in arriving at some result.

With this in mind, we developed scripts and measured how long it took to execute those with no other users on the system, in order to establish a baseline. We executed those same scripts on the systems at the clinical sites under normal use conditions and compared these execution times with the baseline times. We determined that this did not yield useful results, for several reasons:

- The CLINFO software was being changed and thus the baseline kept changing.
- The prototype systems each had one port for remote access, and we were using this port to conduct the tests. At one site we were usually unable to access the system via the remote-access port because others were using it. In fact, it was the most heavily used port at that location.
- Even when the systems could be accessed, we did not have the resources to execute the tests sufficiently frequently to achieve meaningful results. Because each system has a small number of simultaneous users (four or fewer), a change in the number of users signed on or in the intensity of one user's activity can have a major impact on system load.

Despite these difficulties, this method could have been effectively used over a short period of time after the system had stabilized. However, we needed information before the system capabilities stabilized, so we rejected this method as well. We chose instead to handle the evaluation of system responsiveness in two ways. First, we raised the subject of responsiveness in informal discussions with users and recorded their impressions. Second, we measured the execution times associated with several common tasks.

Examining Operational and Organizational Implications

Most of the information used to assess operational and organizational implications came from the records of the system managers, from interviews, and from informal discussions. The transaction log data were sometimes used as a supplement—for example, to determine how much time the system manager spends using the system.

The system managers and system representatives reported on their roles in assisting users. Additional information was obtained from interviews with users concerning the kinds of support they provided. The system manager also reported how much of his time was spent doing routine hardware and software maintenance and systems work and developing special programs for users.

Information on system availability came from the records of the system managers, from console logs, and from failure reports and was sometimes verified with

transaction log data. Accessibility was somewhat more difficult to determine. Two sites have more terminals available than can be simultaneously used; this situation is created at all three sites when a remote user with his own terminal signs on. We could determine if a user attempted to sign on to the system when no more simultaneous users were permitted, and we recorded that information in the transaction log. However, if all terminals (or all conveniently located ones) were in use, then the system was also inaccessible to an additional user, but we did not know that unless he reported it or the information was elicited in an interview.

Evaluation of operating procedures considered both system operating procedures and techniques for interacting with users. We developed, tested, and documented a set of hardware and software operating procedures in the form of an operations manual. This manual was used at the sites and was modified as new procedures were added and system managers adapted the procedures to better fit their environments. These procedures are specific to the particular hardware and software that comprise the CLINFO system. The small sample size—three system managers making use of these procedures under different conditions—limited our evaluation. Moreover, techniques for interacting with users, apart from gathering data for the evaluation, could not be written in a manual. These depended heavily on the personalities of the users, system managers, clinician/project directors, and system representatives.

Efforts to safeguard investigator and patient data fell into two categories: providing system procedures and programs and developing guidelines. The system was designed to minimize possibilities for unintentional destruction of data. Procedures and programs were developed to facilitate preserving data and recovering data that had accidentally been lost. We provided system users and site personnel with privacy guidelines, included privacy safeguards in the hardware and software, and took precautions to prevent information of a confidential nature from leaving the site.

Estimating Benefits and Costs

Cost estimation was the easier part of the plan to carry out. Each system manager reported costs of supplies and services at his site, and he also reported how much time he spent performing his various duties. From this we determined how much of a system manager's time would be required to carry out normal duties after the evaluation effort was completed. Costs for space, air conditioning, and so forth were also determined.

A more difficult task was determining the costs to clinical investigators and their staffs. A number of users were interviewed, but it was difficult to obtain information about how their time had been spent doing data management and analysis for studies before the CLINFO prototype system was available. We encountered similar difficulty in trying to determine which staff members carry out what activities, and for how long, on a typical study. Thus, there was little historical data with which to compare system use data. We could have performed experiments to determine how long it takes to carry out a study with and without the CLINFO system, but we did not do so because of practical problems (discussed below). As a result, we had to rely on subjective assessments made by investigators.

Benefits were even more difficult to estimate than costs. We did receive testimonials that indicated that users were satisfied with the system and achieved

greater insight into their data while using it, but these can only indicate that there may be benefits. A more precise benefit analysis could be made, for example, by looking at changes in the number and value of contracts and grants awarded to users and changes in the number of articles published by users and then comparing these changes with parallel statistics for a like group of nonusers. Positive changes in these categories are often viewed as indications of improved quality of research. However, it is very difficult to establish a control group of nonusers. Moreover, this kind of analysis cannot be done until a significant number of contracts and grants have been awarded and articles have been published and cited; this project will be concluded before then. Because of time constraints, then, we sought to identify, in as precise a manner as possible, changes in users' perception of the need for and value of the CLINFO prototype system.

User Needs That Have Not Been Met

Although the CLINFO systems at the clinical research centers are each used between 250 and 450 hours during each four-week period, some potential users have not used them, or have used them for only part of their research data management and analysis. From discussions and interviews with users and potential users, we found both technical and sociological explanations of how and why the CLINFO system does not meet their needs. We have attempted to overcome some of the technical problems, for example, by adding capabilities, but we have not tried to influence the local sociological decisionmaking process.

ADAPTING TO CHANGE AND RESOLVING PROBLEMS

The CLINFO evaluation was not a controlled experiment. There were no control groups of nonusers; the system was made available to all qualified users until the limits of the resource were reached. And we did not seek the information necessary for having users act as their own controls. We could have spent several months at each site prior to system installation or collected information about a potential user for several months prior to his use, but we did not do so because

- This would have been costly.
- Investigators would probably have been reluctant to cooperate, especially without any tangible benefits.
- Many investigators had no previous experience comparable to the kind of data management and analysis capabilities provided in the CLINFO system, as evidenced by the amount of unanalyzed research data they had accumulated.
- We could not predict in advance who the users would be.
- The results would not have been statistically significant because of changes in the system, the users' staffs, and the environment.

As evaluation results were obtained, they were used to change the system. The incremental addition of specific new system capabilities had been planned from the outset, and their introduction also changed the system. The system changes and the normal turnover in clinical investigators and other research personnel in turn led to changes in the user community. Each of the sites had a different user community

with different usage patterns. Finally, because the number of active users during any given period was small, one or two research groups could have a major impact on usage statistics for that period.

With this background of changing conditions, it was unreasonable to expect to obtain statistically significant results from the evaluation; in some cases, it was unreasonable to expect to be able to even measure results directly. For example, we could not measure changes in the quality and quantity of investigators' research results because such data would not be available within the time frame of the project and because no controls were available for comparison purposes. Thus, we had to rely on interviews to elicit measurements of benefits from users.

We expected that evaluation data collection and analysis would change as the experiment progressed. Because we had not anticipated all possibilities, some decisions, e.g., regarding classification of new types of users, had to be made as new situations arose. Data collection forms were revised to make them easier to use, some data collection was discontinued, and new collection was added. For example, we had not initially planned to record automatically the numbers of times terminal-screen contents were copied onto the attached printer or line drawings were produced on the printer. We expected to get that information from weekly discussions with users. After several months it became clear that the system managers could not obtain that kind of information accurately on a regular basis. After some discussion, we determined that a minor modification to the Basic interpreter would enable us to record the desired information on the transaction log.

Problems sometimes arose because the evaluation was being conducted remotely; that is, the evaluation was being directed by information scientists at The Rand Corporation, while much of the data collection was being done by system managers at the clinical sites. Despite written documentation of procedures and training sessions, there were occasional misunderstandings regarding the intent of the evaluation and the procedures to be followed. As a result, some data were lost or misclassified and delays were introduced which led to problems being detected too late to be corrected.

In addition, data were occasionally lost through system failure or operational error. Users also sometimes failed to report problems or (apparently) reported them incorrectly.

All of these difficulties did not substantially affect the course of the evaluation, but they did introduce delays in tabulation and analysis. They further strengthened our conviction that results of such evaluations should be used to discern trends and relative percentages, but it is unrealistic to attach importance to particular numbers.

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