Even then frustrations are sure to occur during implementation. Duplicate data collection increases work and confusion. System failures can frustrate decision making. Failure to interact with the system as the designers envisaged causes delays where improved performance was expected. Changes in documents require new procedures of searching and filing.

The situation is worse when users are already suspicious. There have been instances in which hospital administrators have imposed systems without prior discussion with the staff. In some hospitals, it seemed that hospital administrators have been afraid to interact with the medical establishment to the extent that they hired additional personnel on the wards in order to operate the terminal. The indirection reduces the benefits and increases the cost. Having mainly clerical personnel using terminals also increases the psychological inhibition for professionals to use the system. Furthermore, clerical personnel are less likely to complain about system problems, so that improvements are less likely to occur.

In the end, acceptance by professionals depends largely on the perceived benefits versus cost to the user. For independent physicians who admit their patients to community hospitals, while remaining their primary care providors, the benefits are minor. Since these physicians tend to have only a few patients on the ward at a time, the cost of learning to utilize the system will be high versus the benefits they can obtain. However, if the systems are reasonably easy to use, the majority of them will follow the hospital's direction and cooperate if it appears to be of benefit to the patients and the institution.

"Easy to use" means that the time needed to recall the patient's record and to enter orders is not much longer than the time needed without the HIS. Terminals with visual displays, high response rates, convenient data entry, and located near the patients are essential to achieve user cooperation. Unacceptable are requirements to remember and type command sequences, or scroll through many display screens having little information content.

**Message Communication.** Informal communication is an important activity in a hospital. The reduction of direct face-to-face interaction when computers are used can be a serious loss. An effective computer-based message system, which does not impose structure upon communication paths and contents, can replace a fair fraction of such informal communications. The need and the benefit of an electronic message system is rarely realized when an HIS is considered. Because of the lack of initial demand and evaluation of message communication services, most HISs provide either none, or very weak, services in this area.

### After Implementation

Once the hospital information system is running, it must be exploited, maintained, adapted, and evaluated. Some constant level of attention must be devoted to these systems, otherwise they will soon become a liability rather than a benefit.

**Benefit Realization.** A successful implementation of the HIS will not automatically yield all expected benefits. Major benefits will only be available to those hospitals that actively intervene to effect them (33). Benefits have been grouped into three areas: (1) fallout, (2) spin-off, and (3) realizable.

Fallout benefits occur automatically as a direct function of a well-designed and successful system. Rapid communications and data processing are typical fallout benefits.

Spin-off benefits occur automatically with limited management intervention. A department, which is relieved of the need to prepare a manual report for another department, because the other department can access the information directly, experiences a spin-off benefit.

The realizable benefits require management intervention to effect them. An example is displaced time: personnel time savings occur in small amounts. With many people on the staff, a reassignment of responsibilities enables aggregation of these time savings so that the amount becomes sufficient to make a difference. Only when productivity is increased or the payroll is reduced will the benefit be realized. The process of intervention is called benefits optimization.

**Benefits Optimization.** Optimizing the benefits requires a number of steps. In order to initiate the process in a hospital, there has to be a model of how this hospital operates and where benefits are apt to occur. Expectations of changes of work effort have to be transmitted to the staff that will be affected. Once a system is installed, the correctness of the expectation has to be verified and, if indeed such savings occurred, then some organizational changes must be made. A redistribution of responsibilities can involve performing tasks on other shifts. Personnel reductions are most likely for those periods and tasks that involve many people, since it is easier to aggregate the savings to an extent that they can be realized.

If the expected savings do not occur, an analysis is in order to determine why the system does not function as expected. Often, there are minor tasks that were overlooked in the design of the HIS, which now may take a larger effort, since they are not integrated into the system. It is best if these are integrated as well, even if they do not provide benefits relative to the pre-HIS environment.

**Utilization of the System.** A system that does not provide benefits will see minimal use and a system that is largely unused will be able to provide fewer benefits. This destructive cycle must be avoided. When systems are installed in a hospital, it is important to track the utilization and to determine rapidly if certain failures of data collection or interrogation occur, and in what pattern they fall. Once the problems are defined, they may be easy to diagnose. Treatment may be more complicated. If the system is not being used for rational reasons, it is best to go back and review what the objectives were and whether the imposition of the system is worth its benefits. If the benefits are significant, then it should be possible to marshal the resources in order to overcome the problems; although solutions such as hiring more qualified personnel or providing a better computer are not always easy to accomplish.

**Need for Flexibility and Changeability.** In order to deal with the changing world of health care, the HIS has to remain adaptable. Sometimes required changes are obvious, particularly when they are imposed by outside agencies. When a system becomes less useful because of gradual internal changes, the problem can be hard to recognize.

The problem is that people will adapt themselves to unsatisfactory systems. A rapid change may cause complaints. A gradual reduction of performance or relevance of results may

never be recognized. The HIS will not automatically adjust itself as demand patterns change.

Operational staff rarely have the time and incentive to go around looking for problems. Some indications of potential problems can be monitored automatically: greatly increased data entry times, reduced frequency of user inquiry into the system for information, and greater error rates in entered data all point to problems.

Few hospitals today have the staff to deal with the issues of maintaining the relevance of the HIS. While the importance of long-term adaptation is clear, short-term problems tend to demand priority. Since the cost of information processing is a significant fraction of hospital information costs continuous monitoring to determine what changes and improvements are necessary can easily pay off. It may be necessary to bring in outside consultants, but when the important task of long-term planning is delegated, much useful continuity may be lost.

**Problems of Evaluation.** To aid in adapting to change, there should be tools built into the system that evaluate the system into various levels. We have already mentioned the measures at a lower level, namely the intensity of utilization. At higher levels, one may want to measure the effect of the system on the medical process. In order to measure the effect on medical output, outcome comprehensive studies are necessary.

## THE FUTURE OF HOSPITAL INFORMATION SYSTEMS

In the previous section we considered dealing with current hospital information systems and found problems in effectively satisfying the variety of requirements outlined in the first section. But systems and requirements keep changing. In this section we will concentrate on the changes that we see occurring due to factors that already exist today. We will not extrapolate beyond visible boundaries.

We can distinguish two types of pressures on HISs: there is a pulling effect as administrators and health-care personnel increase their demands, and there is a pushing effect due to technology, since once new techniques have been shown to be feasible pressure to disseminate and implement them arises.

### Human Factors

The increase of knowledge that is needed to operate in the modern hospital forces the adoption of modern technology. The pressures on health-care personnel to perform reliably and productively stimulate demand for information technologies.

The ubiquity of computers generates expectations by many that they will be helpful. The model seen by users is one of direct interaction through terminals. Only few hospitals provide an HIS that satisfies such expectations.

Active use of an HIS in health care first of all implies a high degree of human interaction with the system. The systems have to be nearly always available, they have to respond rapidly, required information must be easy to specify, and the information presented has to be up-to-date and reliable. These requirements arise early in the system's growth. As soon as a census function is placed on a computer for retrieval, some degree of interaction becomes desirable because a census is valuable only if it is up-to-date.

**Health-Care Knowledge.** Even when an HIS provides all the required data, there remains the problem of recalling the knowledge that is needed to deal with the problems presented. Here new systems technologies are needed. The HELP system is an HIS that permits the encoding of advice rules (34). Bayesian evaluation of conditions helps with decision making. Other systems, such as PROMIS (35), are also being expanded in that direction.

The demands also cause more specialization of health care professionals. Here an HIS can help directly, by providing a data base from which users can obtain the information needed for their domain of expertise.

**Increased Sharing of Data.** Extending the hospital information system into broader health-care activities changes its operating paradigm from simple communications to data sharing. When data are shared, the user of the data will expect the information to be correct and up-to-date. The departments in the hospital that have assigned operating authority, such as the laboratories and pharmacies, etc., will be responsible for keeping the corresponding portions of the data base up-to-date. As the responsibilities associated with ownership of data are delegated to labs, the pharmacy, clinics, and so on, management styles will change as well. Fighting for central control will cause frustration and isolation.

As data are accessed directly by the users, the quality of shared data will be more visible. Identification of data ownership permits shorter linkages in the feedback, which are critical to quality control.

### Factors Influencing Change

Both medical and administrative requirements drive the development of hospital information systems. Although the forces may be at times divergent, it is clear that hospital administrative data are meaningless without the medical component, and that the consistent collection of medical data requires administrative support.

**Internal Factors Influencing Change.** Accurate tracking of the activities that comprise patient care will permit better cost accounting throughout the hospitals. A great extent of factual data will be needed to resolve differences when groups argue for allocation of funds. Hospital administrators may feel that a certain type of medical service is overutilized, and will need facts to support the contention. Medical staff may have the impression that the pricing of certain services, which they wish to use more often, does not reflect their true cost. Again, having facts on hand can reduce strife and rationalize politics.

Improved knowledge on the physicians' side of the capabilities of computer systems will put pressure on hospital administrators to provide up-to-date and modern computing facilities. When this implies the acquisition of costly data collection or hardware, it may be impossible for hospital administrators to accommodate such wishes. Often such requests will require only improved use and perhaps new software. For software, one continues to look at vendors. In the long range, only vendors who are able to be responsive to the demands of hospitals will be able to survive in this field.

**External Factors Influencing Change.** The factors forcing change on HIS are predominantly due to desires for cost control. The precise form will change over time, as views about the effectiveness and feasibility of alternate methods change.

We can expect that any mandated requirements will require detailed accounting. Under the DRG scheme such accounting has to be related to disease category. As indicated earlier, since physicians control most of the cost, they will be held increasingly accountable and will demand a level of quality and clarity of record-keeping not seen earlier. The linkage to health care functions will have to increase.

**Improving the Systems.** We see administrative and medical demands pressing for improvements in the systems. Typically, much effort is required to integrate a good idea into an operational HIS. The level of expertise required includes an understanding of the general operation of the HIS and detailed knowledge of all the interactions among program modules. The people who have that type of expertise rarely have the health-care expertise to contribute to significant applications.

Traditionally, large programming tasks are preceded by a specification phase, in which systems analysts provide much detail about the new applications and ways to deal with all conditions that can occur in the operational environment. Preparing technically precise specifications is outside of the scope of health-care personnel. New techniques of software development must be tried when exploring new areas for HIS involvement.

Mutual understanding and cooperation is one prerequisite for innovation. Sample systems, developed by health-care personnel on personal computers, can provide useful models of applications, and can be developed without understanding the internals of an HIS. Such programs can obviate the need for specifications when shown to a responsive data-processing staff.

The use of standards in modular systems will make a distribution of software development possible and reduce dependence on single sources.

## Technological Factors

Not all demands for changes to HIS are generated by the users. Improvements in technology force system changes in order to stay in concert with the field. Just as it is costly in terms of risk to lead the field, there is cost of incompatibility and incompetence as the world passes by. We will discuss some of the trends affecting HIS concepts now.

**Distributed Systems.** Increased use of hospital information systems and their merging with medically oriented systems increases their complexity. Large, complex systems become difficult to maintain. A wholesale change of the central support systems for a busy HIS is frightening to contemplate. The use of modular software helps, and often new computers are compatible with older ones. Yet, at some point the entire structure may have become unsuitable.

A viable alternative to modular software is to use multiple, distributed computers. This approach was the final choice in the summarization of the first section. By having specialized systems, for example, hardware and software combinations to carry out specific functions, the functions can be somewhat isolated from other activities in the hospital. Now the module interfacing standards become external standards, standards of communications and data protocols. Hospital systems using distributed hardware are still relatively novel.

**Interactive Software.** The interaction at the terminals will move much more to selection procedures using not only light pens or fingers, but voice-triggered selection as well. The menus will graduate from the simplistic tables shown in Fig. 2 to more innovative, graphical representations. Rapid interaction will be provided by having considerable computing power within the terminal.

## A Prognosis by Hospital Class

The adoption of HIS technology will continue to differ by type of institution.

**Large Hospitals.** Large health-care institutions will be able to maintain a sufficient staff to control their own hospital information systems. Since most large hospitals support specialized functions for tertiary care activities, their demands tend to be somewhat unique, although rarely as much as they would like to believe. These centers often have complex financial arrangements with schools, other hospitals in their area, and governmental institutions. To accommodate their needs, it may well be necessary for them to keep their own staff since they cannot rely heavily on vendors nor on contributions by other similar hospitals.

**Sharing over Multihospital Institutions.** Community hospitals and moderately sized institutions will have to depend greatly on shared services, although the equipment is moving into the hospitals. Membership in some hospital organizations can help them acquire these services at a reasonable rate and also acquire the consultation and the systems advice needed in order to make decisions. It is in this arena that standardization will show its greatest benefits.

**Systems for Small Hospitals.** Smaller institutions will depend largely on turnkey systems provided by vendors. Few specialized accommodations will be made. Since the simple billing, the order entry, and the reporting functions are now mature, those will be the primary functions available to the small institutions. Medical records will not be a major part of the services provided for these institutions, except as needed to document reimbursement requests.

**Health Maintenance Organizations (HMOs).** The growth of HMOs may place new demands on HISs as well. The responsibility for the health care of the patient no longer rests continuously with a single individual; it becomes an institutional concern. It now becomes important to integrate the findings of all previous encounters into a consistent record. The hospital medical record is only one component, although one that is often relatively large, because it covers major critical episodes of the patient's health history.

An integrated record might reside in a health maintenance organization. Today we find only selected information, abstracted from the HIS, in the files of HMOs. That abstract represents, however, a high cost to be paid by the HMO.

**Access by the Community.** As access to computers increases, more physicians will expect to have access to the data base being maintained on the hospital with which they are associated. Some hospitals provide such services now, so that the

medical record is shared between the hospital and the patient's physician.

Although obvious barriers exist for full community access to the medical data base, we can expect that such sharing will increase. A hospital that can provide quality information services will be considered a more attractive hospital to deal with, and will be preferred both by its patient population and by the physicians who control much of the admitting process.

### Likely Outcome

We do not expect hospitals to show much technological leadership in the future. Whereas a decade ago the hospital was often a unique environment filled with innovative people and suffused with technological promise and excitement, this aspect is less prevalent today. There will continue to be islands of innovation and activity. The pressure of cost containment, accounting, and reduced expectations will not permit the same breadth of activity.

The interaction of administrative and health-care demands, with increasing technological capabilities, will continue to push the development of hospital information systems. The participants are becoming increasingly sophisticated. We expect that in most instances we will find in development a reasonable balance between the short-term practical demands and long-term scientific developments.

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## HOSPITAL SAFETY PROGRAM.

*See* SAFETY PROGRAM, HOSPITAL.

## HUMAN FACTORS IN MEDICAL DEVICES

The human factors aspects of medical instrumentation involve explicit consideration of the physical and psychological needs of all of the people who must interact with a medical device, the collection of medical devices that make up a system of equipment used in a particular setting, or an even broader perspective that includes the physical environment and other nonhardware operational factors such as personnel, policies, and local procedures. Depending on the specific type or types of equipment involved, the relevant individuals may include physicians, nurses, medical technicians, clinical engineers, biomedical equipment technicians, and other clinical and nonclinical personnel, including, in some cases, the patients themselves. Inherent in these considerations are one or more of the following objectives:

1. To make the use of the device or system as efficient as possible so that the demands on the users are consistent with their capabilities and so that costs are controlled.
2. To make the use of the device or system as safe as possible with respect to the human inputs and responses so that human limitations or failures will be reduced or not result in injury to any of the participants, or damage to the equipment.
3. To minimize the physical and psychological stresses that users or subjects experience in equipment or system operation.
4. To enhance the acceptability of a device or system as an adjunct to marketing.

These multiple and interconnected considerations can be summarized by the term "user friendly" which, although it has been popularized with respect to computer software, can be applied equally well to any designed device or system with which a human operator must interact. From the patients perspective this concept can be extended to include "subject friendly" and medical systems and procedures should be designed so that unnecessary discomfort and psychological stress to the patient is minimized along with the minimization of physical risks. For patient used devices, as in rehabilitation or geriatric engineering, this includes in addition designing equipment that meets the express physical needs of the subject consistent with psychological factors such as self-image. These user- (or subject) oriented perspectives can be contrasted with the general emphasis in biomedical engineering, medical device design, and clinical engineering that has focused more on the development and application of new technologies rather than on the integration of these technologies with the people who must use them. This emphasis on capability is of course important in that medical devices which are not at least technically capable of performing their intended function are of no use to the clinician. However, even when a device has been designed such that it is technically competent, in order for it to be effectively used by clinicians, it must also meet human factors requirements. Some manufacturers have begun to reflect the increasing interest in this aspect of medical device design in their advertising programs which emphasize the ease of use of their equipment. Additional indications of the growing realization of human factors is demonstrated by increasing FDA involvement in identifying user problems with equipment. Medical product liability litigation has also frequently included allegations about the human factors aspects of the equipment in question.

As noted above human factors analysis, or human factors engineering, can be applied at several levels of operator or patient interaction. The basic level is that of the individual item of equipment that must, on its own, meet requirements of usability. The next level is that of an individual item and its accessories or disposables. At this level the basic hardware unit can be considered along with the design of these accessories, their packaging, their handling characteristics, and the overall task requirements involved in setting up and using the device. Since in many clinical settings multiple types of equipment are in simultaneous use, the next level is that of the group of equipment that constitutes a typical clinical situation. A further level is the total equipment, personnel, and environmental factors that characterize the clinical setting. Ultimately, this latter level is the one that corresponds with the real world of use and therefore human factors, as well as other design and organizational features, must be integrated to this point to achieve the desired overall objectives. In this regard it must be remembered that medical personnel commonly must deal with an assemblage of equipment, often obtained from different manufacturers and acquired over extended periods of time. Such assemblages generally require on site integration and therefore the overall system becomes a function of both the individual device designs and local decision making with respect to configuration and use.

In addition to specific hardware considerations, the environment of use can also be of special interest because of possible effects on one or a combination of the operator, the patient, or the equipment itself. Such analyses must be done in the appropriate context of the real use scenario and therefore human factors considerations can again be extended to include a focus on the overall demands that are placed on the equipment operator as a result of their multiple tasks and activities. Thus, not only the design of the equipment or system but also the design of the work to be done and the workplace are important components of human factors with respect to the operator. Likewise the total design of the patient care setting can have direct effects on the overall acceptance, efficacy, and efficiency of the treatment process. For each of these application areas it is necessary to have a basic understanding of human needs, capabilities, and limitations that can then serve as the essential basis for the design process. This understanding and its