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Computers, Health Care, and Medical Information Science

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Summary. The clinical laboratory is examined as a microcosm of the entire health care delivery system. The introduction of computers into the clinical laboratory raises issues that are difficult to resolve by the methods of information science or medical science applied in isolation. The melding of these two disciplines, together with the contributions of other disciplines, has created a new field of study called medical information science. The emergence of this new discipline and some specific problem-solving approaches used in its application in the clinical laboratory are examined.

Over the last 15 years, the medical sciences have provided both physician and patient with dramatic new diagnostic and therapeutic tools. Many of these new technologies are coupled to computers and electronics: intensive care monitors, computerized axial tomography, and automated laboratory instrumentation are familiar examples.

Such increased capability has provided data at remarkably low cost per procedure, but the overall demand for such services has significantly increased the total cost of health care. Unfortunately, data produced are not equivalent to information gained or used. The management of data generated by scientific and technological medicine and the orchestration of medical activities that depend upon information have not kept pace with advances in information science. Attempts to address this situation have led to the emergence of medical information science (MIS) as a distinct discipline that concentrates on the problems that arise when one attempts to integrate the rich knowledge base and behavioral variety of health care with the logical constraints of computer-oriented information processing. In this article we examine the niche newly occupied by this discipline, some typical problems that have been addressed, and some of the requirements that will shape future directions of investigation. Throughout the article, the clinical laboratory will be used as an example, representing a microcosm of information processing in health care.

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General Perspectives

The health care system in the United States has come to depend heavily on "data." There are many sources for this new emphasis. Driven by research, clinical medicine seeks quantitative measurements and concrete observables in an increasingly elaborate definition of disease. Detailed requirements for documentation rest on medical, scientific, educational, and legal considerations, as well as those for reimbursement and the audit of quality of care. The coordination of modern technological services has added further clerical tasks. It is no exaggeration to state that "clerical medicine" is the most rapidly growing aspect of medicine today. The volume of data now associated with medical practice has made manual methods of collection, manipulation, and display nearly untenable.

Data consist of numbers and text. Information is defined here as data in a useful format. Only if reliable data can be collected, manipulated effectively, displayed in proper context, and then communicated to the appropriate individual at the appropriate time do they become information. Present computer technology argues strongly for an integrated computer system to provide information in a timely fashion, thereby improving the effectiveness of clinical practice and introducing audit procedures that are a true by-product of health care activity. Such systems could provide both the capability for continual improvement in services rendered and a reduction in their cost to the patient.

These goals are easy to state but difficult to achieve. Although in some fields the computer has made major contributions, effective applications in medicine have been slow and hard won, despite the strong and obvious need (*1*). Why is this so? First, it has proved insufficient merely to adapt information processing procedures and programs of proved success in other fields, largely because of the complexity of the medical context, the diversity of medical data, and the vagueness, disparity, and variety of health care objectives. Even "billing packages" have proved difficult to adapt. Furthermore, it has proved unsatisfactory to automate medical information flows as health care professionals naïvely perceive them. Medical rules of procedure are generally stated as paradigms, that is, guidelines that depend on informal conventions to manage exceptions—and exceptions to such rules are frequent. (There is a suggestive analogy to the rules laid down for air traffic control which, when followed to the letter, can bring air traffic almost to a halt.) Thus the procedural rigidities of computer systems often stand in the way of appropriate medical information process-

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ing and may generate additional clerical work to meet actual requirements.

The problems addressed by MIS are those that have not been successfully approached by medical science or computer science alone. The goal of MIS is to resolve the apparent dissonance between the rigid structure of computer logic and the often inherently ambiguous structure of medicine. The materials are the full range of patient care data and their applications. Figure 1 outlines three overlapping domains. MIS concentrates heavily on these overlaps. The methods employed encompass a wide range of disciplines, including not only information processing and communications but also the management, behavioral, and fundamental sciences. However, despite the application of these varied tools, much of the methodology remains heuristic.

The Clinical Laboratory as a Microcosm of the Health Care System

The clinical laboratory is particularly well suited to the study, analysis, and implementation of logical concepts and procedures that concern the processing of medical information in the modern context of the hospital and the community. First, the laboratory is actively a part of the practice of medicine, but it is also well defined as a separate unit with respect to goals and responsibilities. Further, it is simpler than medical practice as a whole. Laboratory activities can be described as a set of structured procedures directed toward the analysis of tissue specimens and body fluids—a self-contained industry that produces data designed to enhance clinical decision-making, to monitor the course of a patient's illness and treatment, and to screen for unsuspected abnormalities.

The progress of the specimen through the laboratory, from the time it is received until the results of the requested tests are reported, involves a set of intricate information paths and often requires the expertise of numerous individuals. The computer automation of these activities raises many of the same data-handling questions that must be addressed in the broader medical arena (*2*).

We can describe laboratory work flow to emphasize the parallels with information handling in the hospital as a whole. It will also serve as an informal introduction to those unfamiliar with the details of laboratory operation. To start the laboratory process, specimens are "admitted" to the laboratory (that is, accessioned), and are given a unique identifier or index. Each specimen is linked to the patient and to the clinical context by demographic data such as name, age, sex, presumptive diagnosis, responsible physician, time, and place (ward, bed, or clinic). The specimen is prepared for the measurements requested and must commonly wait in a queue with other specimens of the same type. Provision must be made for specimens that arrive on an emergency basis. Some services are available around the clock, others must be scheduled. Measurements and observations are made that define either the chemical content of the sample, the number and types of cell constituents, or the presence of microorganisms and their specific attributes. These data are evaluated for validity and, where necessary, measurements are repeated or corrected. There is continuous quality control of both procedure and instrumentation. When the specimen is ready for "discharge," an interpretation may be made. A report is then prepared that identifies the data with the patient and the report is returned to the proper destination. A bill for services is prepared, and the report is filed with other reports on the same individual. Other reports are prepared to monitor laboratory activities for both management and accreditation. These provide the "census" of specimens in the laboratory or define the laboratory workload, the cost, the value added by trained personnel, or the reliability of the operation.

This is the paradigm. However, there are numerous exceptions and special cases that must be handled in a consistent manner without loss of documentation. The progress of the specimen through the laboratory in information processing terms is much simpler than the progress of a patient through a hospital facility, but the information processing components are analogous in many ways.

Some Typical Operational Problems

To automate information processing in medicine is to automate the complexity of the everyday. Although the examples may not appear exciting when taken out of context, important computerizable tasks are stymied by such recalcitrant detail. For example, because of clinical difficulties, some specimens are inadequate but cannot be collected again. Therefore, attempts must be made to provide the best information under the circumstances. Other specimens may require special procedures designed to eliminate interfering substances. Clinical limitations in patient identification and demographics can make consistent record linkage difficult and complicate the reference indices. There may be several patients with the same name in the hospital. An unconscious patient without identification may be provisionally admitted as John Doe and later identified by his proper name. For reasons of their own or through ambiguities of cultural convention, patients may be registered under different names at different times. (Vietnamese place their last names first; there is the dual Spanish last name; there are informal first names; there are altered names through marriage and ambiguous last names due to divorce or common law relationships.) Birth date and age are often imprecisely known by relatives and are sometimes misrepresented by patients. Indexed number codes associated with hospital admission have been introduced to overcome such difficulties in identification, but other numbers may be needed for clinic visits or still others to maintain a unified patient record. Separate indexing conventions may be used for employees of the hospital, for specimen referrals from other hospitals or clinics, or for research. Thus even the notations introduced to establish consistency have their own exceptions.

Data transcriptions introduce error. A 3 percent raw error rate in transcription has been found to be a nearly irreducible minimum in an environment free of stress and distraction. Numerical indices are particularly difficult to proofread. In medicine, it is precisely in the stressful emergency situation with many conflicting priorities where accurate information is most necessary and where potential errors are most common. Verbal orders and verbal reports can further complicate the situation. Error rates of such magnitude are not acceptable. Thus, significant professional time must be allocated to procedures that attempt to catch such errors in an effort to reduce them to below 1 percent.

If a laboratory is small, the volume of requests limited, and the services offered uncomplicated, the clerical effort can generally be easily handled by pencil and paper. However, as demand rises, as automated instruments are introduced, as the variety of reports increases, and as the range of tests available widens, there is a marked increase in data management overhead. The same is true of the hospital.

A large hospital laboratory may offer 500 to 600 different tests and may prepare more than 3000 reports per day with from one to 20 results per report. Within the laboratory, a request may lead to

many separate measurements. A specimen may be split and measured in several different ways, leading to an "explosion" and reassembly of the data, requiring careful controls to maintain linkage. Other controls are also needed. Automated instruments may drift or they may measure an unanticipated constituent and lump it with an expected one. Specimens may also be "lost" for a time, reports may be misfiled because of error or ambiguities in clinical linkage or they may be delivered to the wrong place. Rarely, a specimen may be assigned to the wrong patient. Concern for such problems increases the work to check and recheck laboratory procedures. In the large laboratory and in the large hospital offering complex services, manual systems introduce delays that are costly to the patient and frustrating to the health care staff.

These rather general examples of exceptions, ambiguities, and errors mirror similar difficulties with information flow in the clinical setting. The greater the needed attention to detail, the greater the number and variety of such exceptions and the work generated to control or organize them.

Within the limited domain of the laboratory, how can a computer be introduced to address these problems of data management and control? A computer can: (i) structure and screen input; (ii) handle the necessary bookkeeping; (iii) organize, file, and retrieve data; (iv) call attention to unusual results; (v) print specimen labels and completed reports; (vi) keep track of specimen status, laboratory decisions, workload, and quality control checks; and (vii) can also post charges to patient accounts for work completed. Data from high-volume automated instruments can enter the system directly, without transcription, to be reviewed and verified on a formatted screen. Interactive video terminals at each work station tied to a common data base can provide consistent interactive communication.

However, the formatting of such screens and the interaction with such terminals remains a significant design problem (*3*). The user should be concerned only with the data manipulation dialogue and not with logical constraints imposed by the underlying computer programs. If such a system is to replace work sheets and other paper documents, the video terminals should be at least as fast and as easy to use as paper forms—readily available at all times, serving as a notepad for exceptions as well as an outline to structure work and observations. The interaction should be patient with the new user and efficiently available to the expert. The development of such systems demands not only an understanding of the capacities of computer hardware and software, but of equal importance, a sympathy for the specific characteristics of medical and health care data, particularly flaws and exceptions, and an understanding of the multiple purposes for which such data are required.

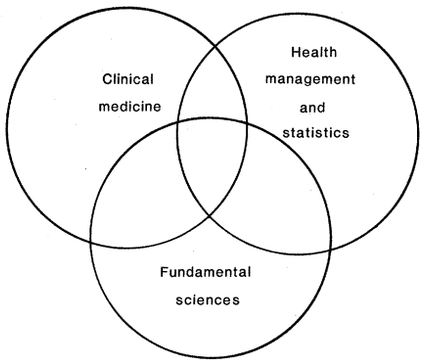

Fig. 1. The three overlapping domains of the health care field. Medical information science concentrates not on any one domain but specifically on the overlaps between domains.

One challenge, therefore, of MIS has been to introduce a set of programming utilities directed toward medical applications that can accommodate the requisite diversity of health care practice and its ambiguities. The challenge extends from the development of computer operating systems and languages to specific kinds of utilities aimed at the end user.

At least one new type of operating system together with a programming language, MUMPS (*4*), has been specifically designed to meet medical requirements. MUMPS differs from structured languages such as PASCAL, FORTRAN, and COBOL that emphasize the delineation of data sizes and types to restrict data definition in favor of control. These last three languages presume that the problems that may arise can be anticipated in advance. In medicine, this is seldom the case. MUMPS accepts definitional ambiguity at programming time, and resolves the issue at the time of actual use, relying on special routines to screen for errors and to establish control. The slowness of early MUMPS implementations has been gradually overcome by improved operating systems and by the increased capabilities of modern hardware.

A laboratory system is an interactive data management system. Filing and data management depend critically on unambiguous indices that define how records are filed and retrieved. As noted above, the indices associated with the patient are commonly flawed. In the end, the computer system must deal with indexing ambiguity, as difficult as this may be, and work to minimize the very real potential for confusion and error. How does MIS begin to address these substantial problems? SOUNDEX is one example of the extensive work to meet this challenge. SOUNDEX can identify a subset of names in a file that are phonetically similar. Thus, lists of patient names can be displayed so that a patient named "Schmidt" can often be identified, even if on a previous admission he was entered as "Schmitt."

Indexing difficulties apply not only to patients but also to the names of their diseases. There are multiple overlapping and conflicting disease name classifications. Some represent differences of opinion with respect to disease mechanism, but others reflect linguistic variety based on source of training or specialty perspective. The coding schemes that have been developed to overcome this diversity are also multiple: SNOP, SNOMED, ICD9, ICDO, for example (*5*). In any institution, the investment in the use of one or more schemes makes change difficult. Computer-based translation schemes and concordances offer the only means of providing long-term consistency.

In medicine, accurate dates are an important index. For example, in chemotherapy and other time-dependent treatment regimens, the time interval between drug dosages can be critical. The problem of checking dates for calendar consistency and storing them in manipulable format is susceptible to an elegant solution developed for astronomy, but often ignored (*6*). A simple arithmetic calculation will encode a date into a sequential Gregorian number. The reverse calculation gives the corresponding date if the date is valid. When the Gregorian number is divided by 7, the remainder identifies the day of the week, adding information to the input for further error checking. The Gregorian notation provides accurate differences between dates and the rapid calculations allow the usual human conventions for date input and display to be maintained. It is by attention to such programming detail that the clerical load in medicine can be markedly lightened.

Interactive data entry can check data for plausibility and expected limits as they are entered. It may also allow the review of past patient records in context for verification and check for other errors. Check digits may be appended to number codes that check for consistency by means of an arithmetic function.

Computerized dictionaries of technical terms can check for spelling. Bar code readers, alphanumeric readers, and magnetic charge plates have been adapted from other applications to eliminate transcription where possible, always with the caveat that these systems may not be error free or worth the cost. How such checks should be introduced is not merely a matter of mechanics, but involves an analysis of the workplace interactions that gave rise to the errors in the first place. When the computer replaces paper as a communications device, fewer transcription errors are made because there are fewer transcriptions.

Impacts on the Clinical Laboratory

Systems responding to the above considerations have been implemented in the laboratory. Table 1 summarizes one such experience associated with an almost paper-free system which allocates the clerical tasks to the computer and places a video terminal at each work station (*7*). This system has measurably changed the allocation of technologists' time and effort (*8*), the number of the clerical support staff in the laboratory, and the speed and accuracy of laboratory response. The improvements noted reflect the marked reduction in clerical tasks that must be performed by professionals.

The capacity of such systems to audit the specimen as it passes through the laboratory, fixing responsibility for measurement, for verification, and for the verbal reports of critical and life-threatening values (by whom and to whom) provides the laboratory with a management awareness of its own functions—functions that were previously undocumented or dependent upon labor-intensive manual checks. These goals are not achieved by the isolated application of computer technology or medical management.

Impacts on Health Care Delivery

Computer automation in the clinical laboratory can affect health care delivery in at least four interrelated ways: (i) by improving the timeliness of patient care, (ii) by improving the format of reports to the physician, (iii) by providing a data base to improve the quality of the health care process, and (iv) by introducing management controls for the containment of health care costs.

The timeliness of patient care. Laboratory data are ingredients in clinical decision-making. Decisions made by the patient's physician which lead to diagnosis, therapy, and hospital discharge are often the rate-limiting steps that define hospital stay. (Other rate-limiting steps are the patient's physiological response, the appearance of complications, and the availability of adequate care mechanisms outside the hospital.) A timely and appropriate response by the laboratory can reduce the time delays for physician-dependent decisions, and by proper organization of the data can alert the physician to early complications.

The interaction of the physician with the laboratory has been examined recently in some detail (*7*, *9*). In both diagnosis and therapy, the physician entertains certain hypotheses, and then orders laboratory tests to confirm or refute these hypotheses. Because the clinical expression of disease exhibits a broad variety of detail, this is not a simple process. However, it is difficult to deal with more than six or seven potentially significant variables in a single judgment (*10*). Thus, there are repeated cycles of test-diagnostic or test-therapeutic iterations seeking a patterned consistency. At critical decision points in diagnosis and patient monitoring there are three types of data elements: those that are unknown and may be of significance; those that have been defined and appear significant; and those that have been defined and are of no further interest. Many laboratory tests are obtained solely to reduce the number of unknown elements. The stepwise procedure is an attempt by the physician to put bounds on the patient's problem and to identify important parameters. In many health care settings, this procedure is carried out once each day, paced to the response of the laboratory. It may be speeded up by resorting to emergency requests, but this introduces other penalties. Bull and Korpman (*7*–*9*) and Miller (*10*) focused on this care pattern. The introduction of a laboratory information processing and communication system allows multiple regular test/diagnostic or test/therapeutic cycles per day where previously there had been only one. Significant changes at a typical site are shown in Table 2.

Formats for clinical judgment. The efficacy of clinical judgment is influenced by data display as well as by speed of response. Laboratory instrumentation and computers have enhanced the display capabilities for laboratory data so that significant results and relationships between results can be highlighted. The examination of laboratory reporting strategies represents a further area of analysis for MIS.

The importance of format in laboratory reports cannot be overemphasized, since the report is the primary means used by the laboratory to return data to the physician. Rapid assessment depends upon establishing certain conven-

Table 1. Sample effects of a laboratory computer on intralaboratory work flow. A properly designed laboratory computer system can increase the throughput of laboratory tests and thus the productivity per hour per employee, and can make work increasingly rewarding for professional staff. Multiple functions contribute to increased efficiency. Typical examples include a decrease in data collation times (purely clerical operations) and decreased numbers of inquiries to the laboratory, due to more effective dissemination of laboratory results and more rapid performance of laboratory tests.

Work	Before computerization	After computerization
Percentage of time allocation of technologists on two typical laboratory tests		
White blood cell (WBC) differential	53 percent clerical; 47 percent professional	7 percent clerical; 93 percent professional
Operation of 20-channel chemistry analyzer	40 percent clerical; 60 percent professional	13 percent clerical; 87 percent professional
Throughput rate of technologists at WBC differential*	10 differentials per hour	34 differentials per hour†
Average work units per full-time equivalents (1 unit = 1 minute)	34 per hour	39 per hour
Data collation times		
Two-item test	9 minutes	None†
Three-item test	21 minutes	None
Clerical staff for telephone result queries	Nine per 10,000,000 work units	Two per 10,000,000 work units

*Examination procedures and types of specimens are invariant. †See (*8*).

tions that provide predictability of format. Where appropriate, graphic displays can provide an assimilation of the results based on pattern recognition.

The format limitations of screens are related to those of paper reports. A limited amount of information can be placed on a single screen or page. Sorting data into tabular form, by date and by time, is a useful thing for a computer to do in some cases. In this format, a limited number of laboratory results can be neatly summarized and trends can be detected by scanning down or across columns of test results. However, the volume and diversity of modern laboratory data have subverted this format as the sole reporting mechanism.

Because of the increase in the number and variety of tests, the amount of data often exceeds the neatness of the single page. Moreover, new requirements have encroached on the space available. Changing instrumentation has made it necessary to introduce normal values on the same sheet. Enzyme studies can take on large values, forcing the reservation of wide columns per data element. More and more tests involve data interpretation to make the results clinically meaningful. This interpretive text is difficult to represent in cumulative tabular form in conjunction with the relevant data. Tables crammed with data are also difficult to scan. This has led to other reporting strategies, for example, special reports in panel or graphic form to consolidate subsets of information and special reports for trend analysis when enough values are available in an appropriate time interval to determine a trend.

One of us (R.A.K.) has examined the laboratory test results from a selected set of institutions, ranging from small primary care hospitals to large tertiary care facilities located across the country which now provide computerized trend summary reports. The results are shown in Table 3. Three data points for the same test in a reasonable time interval were taken as the minimum criterion for a useful trend analysis. As can be seen, only 18 to 28 percent of the patients in any institution met this criterion. Furthermore, if the generation of a trend report was left to the discretion of the patient's physician (that is, it was available immediately on demand any time the physician felt it would be useful), then only 4 to 10 percent of the patients in the same cross section of hospitals have such a trend analysis prepared in the course of an admission. The production of a special form to unify data over time that may require considerable data base manipulation and the allocation of storage for sorting files causes a justifiable anxiety that system performance could be degraded. However, the provision of such a report by exception, rather than as a matter of routine, is not an onerous task for present-day equipment, because the number of patients processed are substantially reduced.

Table 2. Sample effects of a laboratory computer on physician-requested test order-result cycles. By decreasing the turnaround times for many of the most commonly performed tests in the laboratory a higher number of test order-result cycles can be completed per patient per day. This allows a potential shortening of patient stay and thus a reduction in health care costs.

Example	Before computer	After computer
Turnaround times for typical tests		
Complete blood count (routine)	4.5 hours	1.6 hours
Electrolytes (routine)	4.0 hours	2.1 hours
Test order-result cycles per day	1.4	2.3

Where laboratory data can be presented on the clinical services by interactive inquiry video terminals, the experience curve of clinical personnel in the use of formatted data is facilitated and fewer arbitrary demands are placed on the laboratory for special paper reports. The direct availability of such results to the clinician can further reduce the time delays in problem-solving.

Data bases to improve the health care process. One of the goals of MIS is the integration of information from the basic sciences into clinical practice. In the laboratory, for example, computer systems are poised to become the data source for a more ambitious analysis of laboratory and health care data. Such analyses can link scientific studies to clinical practice, review test procedures for their impact on diagnostic certainty, and examine alternative strategies in the acquisition of laboratory data for cost effectiveness and scope. To bring these analyses to a broad fruition, machine readable data bases from the laboratory must be combined with accurate clinical information acquired via a clinical information system that serves the hospital in the same way that the laboratory information system serves the laboratory.

Tools for the heuristic and systematic exploration of clinical data bases by computer have been developed by the National Institutes of Health (*11*) and by others (*12*). However, with the exception of prospective clinical trials, few clinical data bases are sufficiently accurate and complete to provide more than superficial results. Good data bases have required a major manual effort and the introduction of modern computation has been limited by data acquisition. Partially for this reason many investigators have been content with simple estimates and two variable correlations.

The relations between medical observations are almost always multivariate. Medical questions have long provided problems of both practical and theoretical interest to the statistician, and powerful formal tools are available (*13, 14*). To explore the potential of a well-documented data base to field useful predictive variables from clinical experience, one of us (T.L.L.) has examined the data from a well-organized university surgical practice specializing in carcinoma of the breast. The objective was to obtain a best estimate of the expected disease-free interval from data available shortly after surgery. Eight predictors could be identified and used to compute an estimate. This represents a "laboratory value" of assistance in decisions concerning adjuvant chemotherapy (*15*). Similar studies have been carried out to predict the success of heart transplants (*16*) and coronary bypass operations (*17*).

Within the laboratory, there are practical multivariate questions that can be addressed immediately without additional clinical data. For example, the complete blood count has recently been studied as an indicator of patient disease states in a 117,000 sample study (*18*). The results, the first available on an active data base of this size, showed significant problems with the current interpretations of this test.

Under present conventions, the normal range for a test is defined using the 95 percent confidence interval, flagging one normal value in 20 as "abnormal" and setting the stage for unnecessary work-ups. The use of single laboratory variables as predictors of disease has recently become a major and legitimate area of concern (*19*). The multivariate analysis of the normal range may serve to identify some of those arbitrary outliers in laboratory determinations that are without clinical significance. Such analyses are one means of formalizing the recognition process by which insignificant outliers are discarded clinically.

Also useful for integrating science with clinical practice is the simulation of

physiological processes by computer. Such simulations test the completeness of our understanding of certain quantitative relations reflected in laboratory determinations. The most successful studies concern the dynamic distribution of drugs (*20, 21*), particularly those used in cancer chemotherapy (*22, 23*) where critical decisions with respect to dosage, therapeutic effectiveness, and toxic side effects must be made. The extracellular and intracellular distributions of antitumor agents as a function of dose, administration strategy, and renal clearance have been simulated to consolidate biological observations with clinical experience. Similar studies have been carried out with respect to the cardiac glycosides (*24, 25*) and heparin (*26, 27*). Often, the results of such simulations can be reduced to nomograms and other simple decision-making tools that allow the controlled use of such drugs without the computer.

Simulations are also useful as powerful exploratory and educational tools (*28*). The medical decision process itself has been subjected to analysis by simulation, clarifying the logical steps taken in the diagnosis of disease states such as bacterial infection (*29*), renal disease, and glaucoma (*30*). Here the computer plays an investigative role rather than a service function, and the results are more commonly applied directly to teaching than to practice.

Containment of health care costs. One of the hoped for results of MIS is a reduction in health care costs by improving the efficiency of health care delivery. By far the most effective cost containment demonstrated in the laboratory results from the automation of clerical procedures. In the uncomputerized laboratory, most such costs are hidden in the busy work of the day. Technical personnel must stop their work to answer questions about the status of a particular request, clinicians must wait while test results are retrieved from manual files, and supervisors must allocate significant time for manual record keeping, management, and quality review. Improved productivity, largely through the automation of clerical detail has been achieved in components of the computerized laboratory with a consequent reduction in personnel (see increased work units per hour in Table 1). Similar cost savings can be projected for properly designed hospital information systems.

Modern technology presents numerous instruments that are designated to replace classical techniques. It is a different problem to determine the efficiency and efficacy of such instruments. Different ways of obtaining a white blood cell differential count are a case in point (*31*). When new automated methodologies are compared for completeness in their detailed discrimination of significant disease process with the manual methods, especially in a sick population, they cannot yet replace the trained human eye in the identification of all relevant parameters (for example, the varied significant defects in red blood cell morphology). This calls into question the cost effectiveness of such instruments where the effort must be duplicated by a classical microscopic examination. The determination of the cost effectiveness of technology is made possible by recently acquired abilities to conveniently store and analyze large data bases to derive the relevant evaluation parameters.

Table 3. Institutional requirements for laboratory trend summaries. The most commonly used first-generation laboratory reporting format has been the trend summary. Trend summaries appear to be justifiable only if three or more data points for the same test item occur for the same patient over a reasonably short time period. The last column shows the percentage of patients that have trend reports generated when they are generated only on physician request, rather than automatically.

Institution description		Tests with three or more data points (%)	Patients on whom physician requested summaries (%)
Number of beds	Type of care		
550	Tertiary	22	8
900	Secondary	22	10
700	Primary	18	4
500	Tertiary	19	
600	Secondary	22	
250	Tertiary	28	
600	Secondary	25	

In addition to the cost control of laboratory operations (and by extension, the operations of the hospital) the analysis of data bases and of the decision-making process outlined above can put requests for laboratory and hopsital services in a more appropriate perspective. For example, the question of how often it is of value to obtain a PAP smear for carcinoma of the cervix could be addressed by analysis more than 15 years ago (*32*). The results are in conformity with the recently introduced change of policy that extends the interval from 1 to 3 years (*33*).

To cite a further example, parathyroid hormone (PTH) determinations ($75 per test) from a university hospital have been analyzed for their contribution to the diagnosis of primary hyperparathyroidism. Very high values confirm the diagnosis established by other means. However, when used as an immediate follow-up test to an increased calcium concentration in the blood (often the result of a malignancy), 75 percent of the positive PTH determinations were misleading (*34*). Although skilled clinicians may avoid such pitfalls, it is the task of MIS to identify such behavioral patterns when they arise and to find persuasive means to reduce their impact.

The most sought after forms of cost control are the reduction in the number of unfruitful diagnostic procedures, the incidence of treatment-induced complications, and the temptations to act on laboratory values that may not correspond to or predict illness. This can be approached by providing information where it is clinically relevant. "After-the-fact" manual audit and review processes, now the focus of regulatory agencies and third party payers, appear to be too labor-intensive and too late to achieve this goal.

Conclusion

Medical information science is the hybrid child of medicine and those logical sciences that are supported by computer technology. This logical challenge is much more important than the technology itself. In this article we have focused on experience gained in the automation of the clinical laboratory, which represents one of the most successful applications to date of MIS. The recent extraordinary enhancements in computer capacities and available configurations now make it possible to consider an integrated approach to broader problems in health care. This new discipline will be the key in the effective execution of the next steps.

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Biomedical Implantable Microelectronics

James D. Meindl

Summary. Innovative applications of microelectronics in new biomedical implantable instruments offer a singular opportunity for advances in medical research and practice because of two salient factors: (i) beyond all other types of biomedical instruments, implants exploit fully the inherent technical advantages—complex functional capability, high reliability, lower power drain, small size and weight—of microelectronics, and (ii) implants bring microelectronics into intimate association with biological systems. The combination of these two factors enables otherwise impossible new experiments to be conducted and new prostheses developed that will improve the quality of human life.

The key ingredient of the present electronics revolution has been the microelectronic integrated circuit or microchip (*1*, *2*). From 1960 to 1980 the number of transistors fabricated in a microchip increased from one to more than 10,000, while the cost of the chip remained essentially constant and its reliability improved. This rate of progress is projected to diminish only modestly during the next two decades, and it is likely that innovative applications of microchips in implantable biomedical instruments will result in new opportunities for improving the quality and availability of health care.

Biomedical instruments can be classified according to their orientation relative to the subject and their function (*3*). In the matrix shown in Table 1, implantable instruments installed during surgery (shown in the row marked "subcutaneous") offer a singular opportunity for advances in medical research and practice for two salient reasons: (i) Beyond instruments of all other types, implants exploit fully the inherent technical advantages—complex functional capability, high reliability, low power drain, small size and weight—of microchips. (ii) Implants bring the microchip into a uniquely intimate association with the biological system, thereby enabling otherwise impossible measurements and prostheses.

In most instances custom-designed as opposed to standard integrated circuits and sensors are required for implantable applications. Thus some of the outstanding benefits of low-cost standard microchips are sacrificed. With regard to function, research with implantable instruments is confined almost entirely to animals, whereas diagnostic, monitoring, therapeutic, and prosthetic uses of implants are largely pertinent to human patients and therefore clinical practice. The generic performance requirements imposed on implantable instruments include: (i) small size and weight, (ii) low energy consumption, (iii) low supply voltage, often a single cell battery, (iv) long operating life, (v) high reliability, (vi) very novel sensors and transducers, and (vii) biological compatibility.

Implantable Instruments in Research

Animal models of human disease are indispensable in biomedical research for a host of ethical, legal, scientific, and economic reasons. Implantable telemetry systems are invaluable in animal models because they enable investigators to collect data that are not available from the surface of the body, and to obtain these data over prolonged periods of time when the animal is not anesthetized, restrained, or interfered with in any way. In such research, automated storage techniques can be used for 24-hour data collection. Totally implantable telemetry and telestimulation systems offer an absolute minimum of interference with and by the subject with no risk of infection from percutaneous wires in physiological, pharmacological, and pathological studies of animals. In addition, they provide an essential step in the development of new implantable instruments for use in man.

A block diagram of a general-purpose multichannel telemetry system that is totally implantable is shown in Fig. 1 (*4*). This system is capable of accepting input signals from a variety of transducers in-

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