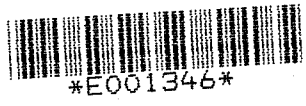
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REGIONAL MEDICAL PROGRAMS SERVICE

AND

COMPUTER ASSISTED EKG ANALYSIS SYSTEMS

Division of Professional and
Technical Development
Regional Medical Programs Service

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I. Introduction

The staff report of August 1971 entitled "Computer Assisted EKG Analysis and the Regional Medical Programs" described the difficulties encountered by four Regional Medical Programs in the development and implementation of a computer assisted electrocardiographic system (CAE). The information presented was obtained from review of appropriate materials contained in grant applications, correspondence files, site visit and progress reports. Statements pertaining to the functional capabilities of established CAE systems were derived from a limited review of pertinent literature, and attempted to define the practical advantages and the inadequacies of existing systems. The limitations inherent to a report based solely upon these sources are apparent. Accordingly, the report was submitted to experts in the field of computerized electrocardiography both within and without RMPS with the purpose of identifying major deficiencies and inaccuracies contained in it, and to offer appropriate suggestions. Additionally, an ad hoc panel of experts was convened by RMPS to discuss the report and to apprise RMPS as to the current state of the art. A list of participants at this meeting, and the agenda is included in Appendix I.

The present report has been prepared in direct response to the reactions generated by the initial paper and reflects the continued interest on the part of both the Regional Medical Programs Service and individual Regional Medical Programs with respect to CAE systems. Three sources of information have been utilized:

1. Background and descriptive material derived from the current medical literature included in the annotated bibliography accompanying this report. (Appendix II)

2. Written communications from the project directors of four ongoing RMP supported CAE programs.

3. The stenographic transcript of the proceeding of the ad hoc advisory panel assembled by RMPS on November 30, 1971.

The objectives of this report include the following:

1. To summarize the present functional capabilities of CAE systems with emphasis directed towards practical potentials and applications, and realistic limitations.

2. To establish suitable roles for RMPS with respect to design, development and implementation of CAE systems.

3. To provide guidelines with respect to system selection, deployment and marketing strategies for use by RMPs interested in CAE systems.

4. To provide suitable information for use by the National Advisory Council, RMPS, in establishing policy with respect to support of CAE systems.

5. To recommend appropriate RMPS policy in this area.

II. Need for Improved Electrocardiographic Services

Disorders of the cardiovascular system are the leading causes of morbidity and mortality in the United States. It has been estimated that over one million Americans die from acute coronary heart disease annually, and an additional several hundred thousand succumb to cerebrovascular diseases. The electrocardiogram is an essential tool in the evaluation and management of these and other disorders. It is acknowledged by experts, however, that many areas of the country lack adequate electrocardiographic services. The average practitioner, though often familiar with the rudiments of EKG interpretation, relies upon the assistance of associates more thoroughly trained in this specialized area. Ideally, an expert cardiologist should be available for this service, but this is frequently not the case. More commonly, an internist or general practitioner with an interest in electrocardiography assumes this function. Clearly, the quality of electrocardiographic services available in any particular area of the country may be quite variable. Many potential solutions to this problem exist.

Training more cardiologists or additional training for non-cardiologist physicians are two approaches. It must be realized,

however, that the existing deficiencies are as much due to maldistribution of trained personnel as they are to inadequacies in absolute numbers. It is all too common to find an abundance of highly trained cardiologists concentrated around a sophisticated medical center while the surrounding community lacks such expertise. The problem is even more obvious when one examines the services available to peripheral community hospitals in the more rural areas of the country. It is unrealistic to expect more equitable distribution of existing manpower in the near future. The extension of expert services available in modern medical centers into their surrounding regions through application of advanced technology is an attractive alternative. Computer assisted EKG systems represents one example of this approach.

Aside from the necessity of increasing the availability of EKG services, there exists a need to improve the quality of EKG interpretation. Conventional electrocardiography suffers from several shortcomings basic to which are the limitations of the human mind. Even the most skilled cardiologist is subject to fatigue. This affects both his observations and his analysis. Lack of consistency in the application of the multiplicity of diagnostic criteria is another characteristic that impairs the performance of electrocardiographers. Finally, human EKG interpretation is biased by factors other than the analytic data provided in the tracings. The electrocardiographer has variable access to information regarding the patient's age, sex, health status, medication, symptomatology, etc., and this

influences his estimation of various abnormalities of EKG waveform. Though such clinical correlation is essential to accurate patient evaluation, it distorts the interpretation of objective data presented in the EKG. All of these factors contribute to the variability of human EKG interpretation. This is reflected in the magnitude of disagreement found among experts analyzing the same EKG, and in the inconsistencies detected when the one interpreter reads the same tracing on different occasions. Skilled electrocardiographers exhibit a reproducibility of EKG diagnosis of approximately 80%; the performance of non-experts is more variable. The digital computer is well suited to EKG analysis, and, as will be subsequently discussed, is capable of overcoming many of the limitations inherent to human interpretation.

Any proposed system designed to improve the availability and quality of electrocardiographic services must do so within the restraints imposed by existing economic resources. The cost of a conventional EKG varies considerably throughout the country from a few dollars to thirty dollars or more. These figures represent the fee charged by the provider institution or physician and do not necessarily reflect the true cost of the unit cardiogram. Limited data are available analyzing component costs, i.e., technician salaries, software, maintenance, and overhead. One important objective for any EKG service including CAE systems must be cost-containment. Additional hardware, software and personnel costs should not add significantly

to existing expenditures. The service must be provided at comparable costs, or preferably, with cost savings.

III. Description of CAE Systems

The digital computer is capable of analyzing large volumes of specific electrocardiographic variables related to wave contour, magnitude, duration, and frequency. The recognition of deviations from programmed normal values in these parameters permits discrimination of abnormal EKGs from normal ones. Identification of patterns of deviation can then be translated into specific diagnostic statements. The computer, therefore, may serve only to select out abnormal tracings from a larger population of normal ones. Or, the computer may offer diagnostic interpretations with appropriate alternatives and exclusions.

Though individual systems differ with respect to specific hardware, they all share some common features:

1. A device to detect and record the electrical events of the heart and a preamplifier system to amplify the millivolt-range physiologic signals to a level that can be worked with conveniently (data acquisition cart).

2. A system for converting this signal into a mode suitable for computer input (analog-digital conversion).

3. A means of storing and transmitting the coded signal to the digital computer.

4. A digital computer and a suitable computer program

Available systems differ with respect to design of acquisition carts (single channel versus three channel), input mode, computer facilities, and printout equipment. The recording technique includes either standard twelve lead tracings, Frank orthogonal leads, or combinations of these leads. Several contour and rhythm programs are available, most using concepts of binary logic. The use of multivariate statistical analysis remains largely developmental. Differences also exist in the form of the computer printout (paper and microfilm), mounting, storage and retrieval capabilities. Finally, the types of service provided by any single system vary.

Recognizing the multiplicity of CAE systems currently in operation, and the variety of hardware, software, program and logistics involved, the succeeding section concerned with current functional capabilities of CAE systems will confine itself to general issues and avoid detailed analysis of any single system.

IV. Current Functional Status of CAE Systems

A. Range of Services

Screening: Large volumes of EKGs can be batch processed by existing CAE systems rapidly, reliably, and at reasonable cost. Patients with abnormal or borderline tracings may be selected out by the computer for further evaluation. In addition to separating normal

from abnormal EKGs, the computer may provide specific diagnostic statements. EKGs determined to be normal by the computer appear to require no further validation, since the incidence of false negative interpretations is less than 1%. Depending upon the rigidity of the diagnostic criteria, the incidence of false positive diagnosis may be as high as 20%; therefore tracings with suspected abnormalities require physician validation.

Definitive Interpretation: The succeeding sections dealing with the accuracy, volume capacity and cost factors of CAE systems relate primarily to those systems providing definitive interpretation. Some general comments are in order at this point. Several EKG wave contour and rhythm programs are currently available, and have met with varying success. Most offer standard twelve lead tracings along with vectorcardiographic display. Increased utilization of the vectorcardiogram (VCG) should be considered advantageous, since it provides the electrocardiographer with additional useful information. CAE systems have proven to be quite flexible in that changing diagnostic criteria can be accommodated for by appropriate alterations in programming.

CAE systems have also shown flexibility with respect to deployment. Computer centers have provided EKG services in a variety of environments including large medical complexes, small and medium sized hospitals, outpatient clinics, small group practices and solo office practices.

Multiple sources of funding have provided the necessary working capital including NCHSR&D, RMPS, commercial interests and institutional research and development grants. CAE systems are presently available both from commercial enterprises and from several large medical centers.

Critical Care Unit Monitoring: On-line EKG monitoring in coronary care (CCU), intensive care (ICU), and respiratory care units may provide continuous surveillance of cardiac rhythm and contour. Other physiologic variables often simultaneously monitored include blood gases, blood pressure, respiratory rate and temperature. Inadequacies of human senses with respect to continuous observation of multiple variables have been well documented. The application of CAE systems in these environments is largely developmental.

Exercise Testing: Several programs have been designed for continuous analysis of EKG wave contour and rhythm during graded exercise testing. These programs are essentially research oriented. Computerized analysis of exercise testing is not widely available, and must be considered in a developmental stage.

Comparative Interpretation: Though several computer programs are undergoing development, relatively few CAE systems provide for even limited comparative EKG interpretation. Improved technology is available for expansion of storage and retrieval capabilities which may be expected to facilitate comparative analysis. Disagreement

exists, however, as to which parameters should be compared. Additionally, it has been stated by some experts that comparative EKG analysis can be performed more effectively by human observers. All agree that comparative evaluation of multiple EKGs adds valuable information to patient assessment, and further development of this aspect of CAE systems is to be expected.

B. Accuracy

Computer analysis of EKGs may be subdivided into three distinct processes: signal acquisition and measurement, comparison of determined parameters against sets of normal values, and synthesis of patterns of deviation from normal values into diagnostic statements.

With respect to the measurement process, the computer appears capable of precision comparable to the most meticulous human effort. Though some variation in wave measurement is inherent to the sampling procedure, it is minimal. The computer experiences difficulties in areas similarly troublesome to human observers, i.e., P wave recognition, detection of minute r waves, and determination of initiation, duration and termination of Q waves, ST segment and T wave. Unlike their human counterparts, computers are not subject to fatigue, thus assuring consistency of repetitive determinations.

Recognition of deviations from normal values and synthesis of diagnostic statements rely upon both the precision of wave measurement and the adequacy of programmed normal values and logic. Computers

offer the distinct advantage of being able to retain large volumes of information, including the multiple parameters required for EKG analysis. The major limitations are the validity of the programmed normal values and diagnostic criteria, and these limitations apply equally to both computer and human interpretation. Most CAE systems in current use utilize binary logic and decision tables that attempt to duplicate the analytic processes of the expert electrocardiographer. The net effect of the computer interface is enhanced reproducibility of interpretation resulting from rigid adherence to programmed instructions. Errors of omission are minimized, though at the expense of 10-20% false positive statements.

If accuracy of CAE systems is defined as degree of agreement with expert human interpretation, then optimal performance should be reflected in 100% computer-physician agreement. In practice, less than the ideal is realized. Approximate figures from systems serving large inpatient populations containing a preponderance of abnormal tracings indicate that 85% of computer analyzed EKGs require no subsequent alteration or modification, i.e., the physician-computer agreement approaches 85%. Greater agreement has been achieved with contour analysis (approx. 90%), while rhythm statements are less reliable (75-80% agreement).

Two general reasons for computer-physician disagreement are identifiable: CAE system error and physician error. Factors affecting human performance have previously been alluded to and include

fatigue, forgetfulness, imprecise measurement, inconsistency of diagnostic criteria, and bias. CAE system failure may be separated into defects in data acquisition, data transmission, and data analysis.

The dominant sources of errors of acquisition are related to inadequate recording techniques, improper lead positioning, inadvertant omission of leads, respiratory variations, artifact, and background and transmission noise. Many of these problems are resolvable through improved technician training, and modification of the data acquisition carts. The design of more suitable electrodes and improved methods for signal filtering are under development, and can be expected to enhance the quality of the recorded signal. Similarly, distortion, noise, and artifact introduced during telephonic transmission appear to be potentially solvable technological problems.

Analytic errors may be further categorized into inadequacies of programming, errors in measurement, and disagreement as to diagnostic classification. Errors of measurement relate to the sampling process and, as previously mentioned, most often involve failure to detect P waves and QRS, QT and ST-T segment duration. Artifact, background noise, and unrecognized ectopic beats may further contribute to measurement error.

Instances where wave measurement is accurate but diagnostic classification is improper are usually due to remedial errors in programming. Disagreement with respect to diagnostic classification

often reflects minor discrepancies between computer and electrocardiographer. Physician inconsistency and ambiguity of diagnostic criteria are most often responsible.

In summary, though the degree of cardiologist-computer agreement is quite high, a significant incidence of major disagreement still exists, thus necessitating human validation of all computer analyzed EKGs. Except in screening situations in which the computer can be relied upon to separate normal EKGs from equivocal and abnormal ones independently, CAE systems serve to assist the electrocardiographer in his task. The value of the physician-computer interaction will be discussed in a subsequent section (V).

C. Volume Capacity

A decided advantage of CAE systems is their ability to process large numbers of electrocardiograms rapidly and continuously. The volume capacity of any CAE system is determined by three major variables: data acquisition time, computer time, and physician validation time. Acquisition time is affected by technician skill, number of leads recorded, and type of cart utilized. Using carts currently available for recording three leads simultaneously, the acquisition time for a twelve lead tracing is comparable to recording a standard twelve lead EKG on a one channel cart. Addition of three Frank orthogonal leads increases recording time slightly. The quality of the acquired signal is an important determinant of overall system

performance and this is directly influenced by the skill and motivation of the recording technician. Additional training is necessary to assure high quality signal acquisition.

Among the factors controlling computer time are the following: capacity of the computer, complexity of computer contour and rhythm programs, input mode (batch processing versus interrupted input), and range of services provided. Comparative interpretation requires additional time to allow for search and retrieval of stored records. A medium capacity, dedicated computer is capable of processing approximately two hundred EKGs per hour including analysis and data printout without comparative interpretation.

From a clinical standpoint, it is advantageous to provide the physician with an interpreted tracing with minimal delay. The key determinant of turn-around time, i.e., time from inscription of the signal to delivery of the definitive interpretation, is the additional time required for validation of the computer record. The computer can provide an interpretation within minutes of the inscription of the signal. All computer diagnoses, however, excepting those determined to be entirely normal in screening situation, must be authenticated by an electrocardiographer. At the present time this service may be provided by cardiologists associated with the computer center, local cardiologists, or physicians requesting the electrocardiographic service. It is generally agreed that the physician-utilizer should be provided with a validated record, and that review by an electrocardiographer is necessary. It is the degree of assistance offered by the CAE system to the electrocardiographer

that determines its effective output. Tracings identified as being normal by the computer require no more than casual verification. Similarly, many abnormalities are analyzed so reliably by the CAE system that the reviewer can accept these diagnostic statements with a high level of confidence. Complex contour abnormalities and arrhythmias require closer scrutiny. The computer interface accelerates analysis of routine tracings allowing the electrocardiographer more time to consider the more complicated ones. The interpretation time of a cardiologist reading predominantly abnormal tracings may be halved, thus potentially doubling his output. Utilizing batch processing, turn-around time for a computer assisted EKG interpretation with verification averages twelve hours or less.

D. Cost Factors

From the standpoint of the CAE systems provider it is convenient to examine component costs in three areas: data acquisition and transmission, computer processing, and physician validation. It must be emphasized that the figures mentioned are only approximations, with significant variations existing among individual CAE systems. Some of the factors responsible for these differences will be identified.

Aside from the computer, the data acquisition cart is the single most expensive hardware component of CAE systems. Cost of purchase varies from $6,000 to $10,000, whereas rental fees average $2,000 to $3,000 yearly. Assuming the functional life of this equipment to be five to seven years, cost per unit EKG based upon an annual

volume of two thousand tracings is $1.00 to $2.00. This is exclusive of maintenance, overhead, supplies, and technician salaries. These factors must be figured into the total cost of acquisition, and apply to both systems utilizing computer analysis, and to conventional EKG services. Where technicians function solely to record EKGs, the unit cost is increased by an amount calculated by dividing technician salary by annual volume of tracings. In institutions generating large volumes of EKGs, technician salaries add approximately $2.00 to unit acquisition costs. Smaller hospitals often use EKG technicians for a variety of functions in addition to EKG recording, thus obscuring the analysis of acquisition costs.

Computer costs are influenced by computer size, processing mode, range of service provided, and data display form. The most important determinant of computer costs is efficiency of utilization. Maximal utilization in terms of volume of EKGs processed results in optimal unit cost. Cost-effectiveness can be achieved on a medium sized (e.g., IBM 1800) dedicated computer with an annual volume of 100,000 tracings. Lesser volumes are more economically handled using a medium sized computer on a time-sharing basis. Uninterrupted batch processing is the most efficient input mode. Periodic "stat" or emergency tracings must be anticipated in any system designed to provide complete electrocardiographic services to inpatient populations, though these interruptions impair the operating efficiency of CAE systems. The addition of data storage and retrieval capabilities necessary for comparative interpretation increases unit cost, as do

modifications in the form and content of data display. Estimates of $1.00 to $3.00 have been made for direct computer costs exclusive of salaries for programmers, clerks, secretaries, maintenance, and overhead. Representative combined cost per unit EKG including acquisition, transmission, processing, printout and return varies from $5.00 to $7.50. However, accurate estimates of total direct and indirect costs are not available.

Finally, there is the cost of validating the preprocessed EKG. As already mentioned, the fee charged for a standard electrocardiogram shows marked regional variation and the total cost transmitted to the patient is not an accurate reflection of the component costs of the service. The fees charged by physicians for interpretation of tracings are highly variable. If the costs of computer preprocessing are simply added to the customary fee charged by the electrocardiographer, cost containment and reduction are not achieved. The obvious question remains: How can the benefits of computer assisted EKG analysis be realized without inflating the cost of the finished product?

Most commercial organizations marketing CAE systems essentially ignore the problem by not including physician validation as part of the service they sell. From both medical and legal viewpoints, computer processed electrocardiograms lacking individual verification by a skilled electrocardiographer are unacceptable. Whether or not these companies can provide CAE services with constantly available physician validation at competitive prices is uncertain at this time.

Two mechanisms to provide for validation may be offered. The first is employment by the computer center of electrocardiographers for the purpose of providing validation. A foreseeable problem is the availability of round-the-clock coverage. A second approach is validation by local cardiologists in the area being served by the computer center. To avoid increasing EKG costs by addition of computer costs to local ones, some adjustment of physician fees may become necessary. Theoretically, since computer preprocessing is estimated to reduce the time required for physician interpretation, a reduction in unit cost may be possible. However, this will depend upon the complexity of the tracings, the need for comparison and the number of tracings analyzed.

CAE systems situated in university medical center complexes have been able to provide EKG service with validation on a twenty-four hour a day basis and at a cost of - $4.50 to $6.50. There are several reasons for this. Most important are the investigative aspects of these programs and the interests of the participating cardiologists. It is obvious that the bulk of the money generated from the service charge covers the cost of acquisition and computer processing; a relatively small fraction goes to the physicians overseeing the operation. Secondly, several additional sources of funding are available to these programs including support from private industry, foundations, and internal research and development monies. Thirdly, at least some of the supervisory function is assumed by members of the house staffs, though all tracings are ultimately reviewed by senior staff members. Fourthly, the current service charges are

adequate for support of the ongoing programs but fail to include initial developmental and marketing expenses. Lastly, these programs operate on a large annual volume of tracings.

In summary then, several viable CAE systems are available that are capable of delivering high quality electrocardiographic services at reasonable cost. Though current service charges provide adequate support for established, ongoing systems, they do not compensate for start-up costs which may be considerable.

V. Advantages and Potential Advantages of CAE Systems

A. Quality of Electrocardiographic Services

Computer preprocessing of EKGs minimizes the adverse effects of physician fatigue, forgetfulness, and bias. Rigid adherence to programmed criteria diminishes errors of omission by alerting the physician to diagnostic possibilities otherwise overlooked. Similarly, sources of physician misdiagnosis become identifiable upon review of the analog data presented in the computer printout. The computer interface allows for greater standarization of diagnostic criteria, thus reducing inter-observer and intra-observer variation, and enhancing analytic reproducibility. Additionally, technicians must be more meticulous during EKG recording to insure optimal signals for computer input; this enhances the quality of the data display and serves as a built-in quality control mechanism. Overall, the quality of the EKG resulting from the computer-physician interaction is superior to that furnished by either one separately.

B. Utilization of Manpower

With respect to the EKG technician, utilization of the data acquisition carts is somewhat more complicated than conventional electrocardiagraphs, and additional training is required. This is not difficult to achieve and technicians readily adapt to the new carts. Recording time may be slightly increased when fourteen or fifteen lead positions are required; though in general, the recording time on

multichannel acquisition carts is comparable to standard machines.

The computer interface permits automation of cutting and mounting of tracings, thus freeing technicians from these time-consuming tasks. Similarly, computer processing provides automated determination of impulse duration, magnitude, direction and frequency, these tasks having previously been the responsibility of the individual interpreting the EKG. The net effect is a significant savings in personnel time.

Two positive effects upon physician utilization are discernible. Firstly, computer assistance enhances the speed of interpretation of the electrocardiographer, diminishing the amount of time necessary for the review of tracings. This is translatable into an increased volume capacity for the physician allowing him to examine more records in less time. The time saved can be invested in other areas demanding his attention. Secondly, CAE systems serve to expand the outreach of the electrocardiographic abilities situated within the computer center. As a result, the general quality of electrocardiography in the community is improved, and areas lacking the essential manpower can have access to high quality services, conveniently and at manageable cost.

C. Regionalization

One attractive aspect of CAE systems from the point of view of RMPS, is the potential for implementing planned delivery of

essential medical services on a regional basis. This is particularly true for those systems based in a medical center environment. The linkages established between provider institutions and peripheral medical facilities and personnel have the potential for developing beyond service relationships into viable communications networks. It is difficult to estimate the effectiveness and quality of cooperative relationships fostered by existing CAE systems.

D. Increased Interest

It is probable that the availability of CAE systems has and will continue to stimulate increased interest in electrocardiography among practicing physicians. This interest is expressed as increased utilization of the electrocardiogram in patient evaluation in both hospital and ambulatory care environments, on a more routine basis.

E. Continuing Education

It has also been suggested that the CAE data display is an effective educational device. Certainly the information contained in the printout, i.e., analog data, including diagnostic criteria and tracing reproduction, can increase the knowledge of the average physician. However, the extent to which it is utilized is determined by the motivation of the recipient. An evaluation of the educational aspects of CAE systems is not available.

F. CAE Systems as a Reference Point

As has been mentioned, little information is available with respect to cost and time factors associated with the recording and interpretation of conventional electrocardiograms. Similarly, relatively few studies attempt to define the quality of standard EKGs. The development of CAE programs has resulted in increased understanding of these and other aspects of electrocardiography. This has been evidenced by material presented earlier in this paper dealing with cost factors, volume capacity, and sources of physician-computer disagreement.

G. Data Base

Much of our current knowledge of electrocardiography is based upon analysis of relatively small numbers of tracings. In part, this accounts for the multiplicity of diagnostic criteria presently in use. It is in this area that computer technology will probably have the greatest impact. The enormous capacity of computers permits analysis and clinicopathologic correlation of hundreds of thousands of electrocardiograms, enabling us to more accurately define the limits of normality and the determinants of abnormality. The application of computer techniques has already pointed out the limitations of conventional electrocardiography, and will continue to add new knowledge. Further research in these areas, including the application of analog computers, multivariate analysis, and high frequency electrocardiography can be expected to alter the EKG of the future.

VI. Limitations

The preceding pages have dealt almost entirely with the positive aspects of CAE systems. Unresolved problems do exist, however, and need to be identified.

A. Costs

Provider

One persistent problem relates to program start-up. Established CAE systems with adequate support, in terms of operating volume, are able to sustain themselves on funds generated by service charges comparable to the fees received for conventional EKGs. In other words, a potential subscriber can purchase the service from one of several functioning systems rather than relying on local resources without increasing the cost to his patient. But the funds accumulated by the provider in this way cover only cost of operation. The money expended during program initiation, development and growth may not be recovered. The commercial interest or institution organizing a CAE system must have access to sufficient capital to cover the costs of start-up. In addition, a period of time must be planned for acquisition of an adequate market and overcoming technical difficulties. The magnitude of these variables have not yet been clearly defined.

Maintenance and operating costs will be determined by local needs, and by willingness of local physicians and institutions to subscribe to the

service. Several CAE systems have been unsuccessful because of their inability to establish an adequate market.

Utilizer

Those individuals and institutions interested in subscribing to a CAE system must first assess their needs and resources. Participation in such systems is expensive. Total direct and indirect costs have not yet been clearly delineated. At the present time, verification by an experienced electrocardiographer must be included in any CAE system. The potential cost benefits derived from the system must be analyzed to separate data acquisition savings, from the savings derived by reduction in the time required for EKG interpretation. The former is applicable to all EKG systems. The cost to a physician's office, or a small EKG laboratory must be evaluated against the costs of alternative EKG interpretation systems. Though CAE systems utilization may be the most advantageous arrangement in certain situations, other approaches exist, and should be considered when planning for improvement of electrocardiographic services.

B. Performance

Because of the rapid development of computer technology during the past decade, CAE systems should be considered to be in a transitional phase with respect to capabilities and range of services. Disagreement

among experts as to what constitutes optimal system components, both hardware and software, continues. Further refinements of data acquisition carts, rhythm and comparative programs, storage and retrieval capabilities are to be expected. Increased interest in alternative approaches, such as multivariate statistical analysis and increased usage of analog computers, will alter the nature of CAE systems of the future. How rapidly these changes will occur is difficult to predict.

Whether or not a completely automated EKG system is achievable is also debated. Artifacts, complex arrhythmias, minute inconstant deflections, the need for comparative interpretation, and transmission difficulties are all challenges to this goal. The advantages anticipated with utilizing a CAE system to provide physician assistance must be evaluated against the adequacy of existing services in the region or institution. Emphasis should be directed towards the delivery of high quality electrocardiography by physicians and institutions lacking this service to their patients. Of the various benefits described in section V, the most important, from the viewpoint of RMPS, is the potential for extending the outreach of the expertise within the computer center into the surrounding community. The development of a CAE system to serve a single large medical center complex, without linkage to surrounding institutions, is of lower priority. Though the quality of electrocardiography as practiced in these centers may be enhanced by the computer interface, such deployment would have little influence upon the EKG resources of the surrounding region, where the need is more apparent.

Related to this, though on a more philosophical level, are the inherent limitations of the most popular CAE systems; i.e., those programmed to reproduce human decision-making and logic. Designed to mimic the expert electrocardiographer, such systems assume the limitations of conventional electrocardiography. Some have suggested that greater benefit would be derived by employing computers to do what the human mind cannot do -- to examine parameters and variables ignored in currect practice.

VII. Potential RMPS Roles

In direct response to the question posed by RMPS, members of the ad hoc panel suggested several possible roles for involvement of individual RMPs with CAE systems. The following suggestions reflect the opinions of the panel members and are not necessarily in agreement with RMPS goals and policies. They are presented for information only.

A Information:

1. Assist in the evaluation of local and regional EKG resources and needs.

2. Identify appropriate methods for fulfilling such needs.

B. Education:

1. Serve as a source of information concerning the availability, capabilities, and potential advantages of CAE systems.

2. Inform local physicians and institutions as to the existence of this type of EKG service.

3. Encourage participation in such systems where local need is

demonstrated.

4. Assist in overcoming local resistence to implementation of CAE systems.

5. Provide similar information with respect to alternative approaches for the delivery of EKG service.

C. Organization:

1. Encourage communication between the health care providers and health institutions of the region so that common needs may be recognized.

2. Foster cooperative arrangements among local hospitals with the aim of improving the quality and availability of EKG services, whether utilizing CAE systems or some alternative.

D. Consultation:

1. Provide technical and organizational assistance to physicians and institutions interested in subscribing to or initiating a CAE system.

2. Serve as liaison between interested parties and experts in the field of computer assisted electrocardiography.

3. Provide similar consultative assistance to those interested in alternative EKG service system.

E. Support:

1. Make available limited monetary support to assist in the planning and implementation of regional EKG services including CAE systems.

2. Provide short term assistance until these systems become

self-supporting.

F. Research and Development

1. Encourage essential investigative work in areas related to CAE systems -- e.g., exercise testing programs, coronary care unit surveillance, etc.

2. Encourage and support projects concerned with the extension of advanced technology into the special care unit environment.

VIII Deployment

A. Computer Facilities

Both commercial and institutional computer centers have been utilized. Private industry has played a large role in the development and implementation of reliable CAE systems. Since they have proved successful, and because they can operate on a profit making basis, it is most appropriate that CAE systems be marketed by commercial organizations. Ongoing research and development are essential in all viable industries, CAE systems being no exception. Continued development of system hardware and software should properly remain the responsibility of private industry.

The use of computer facilities within the medical center environment offers additional advantages including a proximity to expert electrocardiographer, educational potential, availability for EKG research, and the possibility for establishment of a regional communications network.

The availability of both equipment and personnel, and the capacity for sharing computer time and programmer time are also attractive aspects of an institutional computer base.

B. Data Acquisition Terminals

A variety of sites for deployment of computer terminals have been explored. Most often, mobile data acquisition carts have been utilized. Efficiency is enhanced in situations where the carts are stationary and patients are required to come to some area set aside for the recording of EKGs. This is, however, impractical in many circumstances. Small and medium sized hospitals generally employ one or several mobile carts that record from patients in the general hospital area, special care units, and in emergency rooms. Multiple terminals from a number of these institutions are linked to a central computer base to furnish the necessary unit volume.

Larger institutions may employ many carts, both stationary and mobile. A computer serving a single medical center complex may receive data from terminals situated in the areas already mentioned, as well as from outpatient facilities, cardiac catheterization laboratories, and associated extended care facilities.

Terminals situated in ambulatory care facilities including clinics, medical foundations, and Health Maintenance Organizations are foreseeable. Provided that the individual facility can generate a suitable volume of tracings, the linkage of multiple ambulatory care areas

to a central computer base may be practical. This has not been demonstrated.

At this time, small groups and solo practitioners recording a limited number of tracings daily would be better served by some other arrangement. In these situations, the cost of data acquisition carts becomes prohibitive.

IX. Conclusions and Recommendations

Electrocardiographic services are inadequate in many parts of the country, and a need for improving these services exists. The magnitude of this need is quite variable, both among different regions and in different areas of a single region. Organization of, or subscription to, a CAE system may be one approach towards fulfilling these needs. Several existing CAE systems have demonstrated their ability to improve both the quality and the availability of electrocardiographic services, though problems of cost containment continue. RMP involvement with CAE systems may be appropriate in some instances with the following qualifications:

1. Regional needs with respect to electrocardiography must be assessed as part of a more general evaluation of regional resources for the management of cardiovascular disease. Attention should be directed to areas of greatest need, and priorities established. Improvement of EKG services should not be considered alone but should be part of a coordinated plan for enhancement of regional health services.

Isolated attempts to upgrade regional EKG capabilities are not considered to be appropriate roles for RMPs.

2. Regions concerned with upgrading EKG services should consider several courses of action. Depending upon the availability of existing resources this may be the establishment of cooperative arrangements between neighboring hospitals, linkages between local institutions and larger medical center complexes, or use of CAE systems. The thorough consideration of all approaches, and selection of the one best suited to fulfill local needs, is of prime importance.

3. Institutions and individuals in regions lacking the necessary personnel, technology, or volume required for support of an entire CAE system may consider subscription to an established system outside of the region if such action best serves local needs. Individual RMPs may make available to interested parties, pertinent information related to the existence of and the capabilities of these systems. Such information should be accompanied by the following recommendations:

a. The CAE system must provide for validation of individual EKGs by an experienced electrocardiographer.

b. The service must be available on a twenty-four hour a day basis.

c. The services offered by the CAE system must be compatible with the needs of the utilizer.

d. Careful consideration must be given to all cost factors including physician validation fees, equipment rental or purchase costs, transmission charges, and maintenance.

4. Regions possessing the necessary technological expertise, facilities, and capability for providing a volume of EKGs sufficient to support a CAE system, may receive RMP assistance. This may take the form of technical consultation, organizational counseling, institutional liaison, and participation in the assessment of regional needs, resources, and priorities. RMPs should not assume the responsibility for provision of start-up and maintenance funds. The potential profit factor inherent to CAE systems makes this the concern of private industry. Limited monetary support by RMPs may be justified during the organizational phases of CAE system implementation. Such funding is specifically intended to assist in establishing suitable working relationships between participants, provide for technical consultation, and assist in the evaluation of the proposed system.

5. EKG systems receiving RMP assistance should possess the following characteristics:

a. The service offered must be compatible with the needs of the region and should include both unit validation and twenty-four hour a day availability.

b. Priority is to be given to extension of the service into the region so that small and medium sized institutions may benefit; computerization of electrocardiographic services within a

medical center complex, serving only the components of that complex, is not of the highest priority. The major objective of the EKG system should be enhancing the quality and accessability of EKG services throughout the region.

c. Utilization of proven hardware, software, and programming components, so that immediate benefits can be realized. Emphasis is to be directed at delivery of service rather than research and development.

d. An adequate marketing strategy, i.e., provision for the necessary volume, assurance of local support and utilization of the system, and a service charge compatible with system viability.

e. Total cost to the patient, including validation, should be comparable to the customary EKG costs of the region, and preferably less.

6. RMPS should encourage individual RMPs to seek assistance from acknowledged experts in the field during the planning and initiation phases of any program. RMPs should act as liaison between the two so that appropriate technical consultation is available to project proposers.

7. With respect to extension of computer technology into the areas of exercise testing and on-line critical care unit monitoring, both areas must be considered developmental. As such, at the present time, they lie outside of the direct objectives of RMPS, i.e., improved delivery of medical care.

APPENDIX I

PARTICIPANTS OF AD HOC COMMITTEE
ON COMPUTER ANALYSIS OF ELECTROCARDIOGRAMS
AND THE REGIONAL MEDICAL PROGRAMS SERVICE
November 30, 1971

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HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

REGIONAL MEDICAL PROGRAMS SERVICE

AD HOC ADVISORY COMMITTEE TO REVIEW STATEMENT ON COMPUTER ANALYSIS OF ELECTROCARDIOGRAMS

Conference Room C - B Wing, 3rd Floor Parklawn Building
10:00 - 3:30 Tuesday, November 10, 1971
Chairman: Leonard Scherlis, M. D.

AGENDA

I. Introduction and Statement of Purpose - Dr. Harold Margulies

II. Summary of Staff Report on Computer Analysis of Electrocardiograms (CAE) - Dr. Kenneth Gimbel

III. Questions Conerning the Current Functional Status of CAE systems

- A. What are the limitations of CAE systems currently being utilized with respect to accuracy, precision and reliability?
- B. Can physician validation of CAE be eliminated?
- C. What are the actual time savings in physician man-hours? (Also in Allied Health and Clinical)
- D. Under what conditions are current systems cost-effective? What are the total unit costs?
- E. What services should be considered essential to the operation of CAE? (Optimal turn-around time; interval between analysis and validation; 24 hour day availability?)
- F. What are practical locations for the acquisition units? What is minimum volume to be cost-effective?
- G. What are alternatives for delivery of improved electrocardiographic services in areas of need.
- H. What is the role of private enterprise in the development and monitoring of CAE?

I. Have CAE programs met with acceptability from the physician community in which they are provided? In your practice, do you accept CAE without further verification?

J. In existing programs, what percentage of operation can be considered research and development?

K. Under what conditions are CAE justified even if unit cost exceeds cost for the same service in the same area?

L. Under what conditions would you use CAE as a screening tool?

IV. Additional questions or presentations (10 minute limit) from participants.

V. Adjourn