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COMPUTER ASSISTED EKG ANALYSIS

AND THE

REGIONAL MEDICAL PROGRAMS

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COMPUTER ASSISTED EKG ANALYSIS

I. Definition

II. Description

III. Potential Advantages and Critique

IV. Current RMPS Participation

V. Current Usuage and Potential

VI. Conclusions

Prepared by:

Kenneth S. Gimbel, M.D.
Herbert P. Dunning
John R. Farrell, M.D.

COMPUTER ASSISTED EKG ANALYSIS

I. Definition:

Electrocardiographic interpretation utilizing a digital computer programmed to recognize specific characteristics of EKG wave contour and/or rhythmn.

II. Description:

The digital computer is capable of analyzing a large volume of electrocardiographic variables related to wave contour, magnitude, duration, direction, and frequency. The recognition of deviations from programmed normal values in these parameters permits discrimination of abnormal electrocardiograms from normal ones. Identification of patterns of deviation can then be translated into specific electrocardiographic diagnosis.

The computer, therefore, may serve to select out abnormal tracings form a large population of normals, with definitive interpretation being reserved for conventional methods. Or, the computer may offer diagnostic interpretations with alternatives and exclusions.

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

1. An electrocardiographic preamplifier system designed to amplify the millivolt-range physiologic signals to a level which can be worked with conveniently.

2. A means of converting this signal into a mode suitable for computer input (an analog-digital converter).

3. A means of transmitting the converted signal to the computer, either directly via telephone input, or by magnetic tape recording: on-line or delayed input.

Major differences exist with respect to the number of variables analyzed. Most systems utilize standard twelve lead electrocardiograms, while others use a special three lead (Frank orthogonal) approach. Still others record from a single lead and are principally concerned with continuous monitoring of rhythmn.

Most programs approach EKG analysis utilizing concepts of binary logic. Multivariate statistical analysis has been used less frequently.

Systems also differ in their modes of data transmission, computer printout form, and storage and retrieval capabilities.

III. Potential Advantages and Critique:

1. Physician Assistance - Automated electrocardiographic interpretation relieves the physician of a time-consuming task allowing him additional time for more critical functions. If computer-EKG programs

were fully automated at present, this assertion might be valid. In practice, however, most programs are of a developmental nature and since the computer interpretation is evaluated by a trained physician, no time benefit is accrued. Automatic measurement of intervals and durations by the computer does save time for the physician. Many of these determinations, however, are carried out in some institutions by technicians, thus no advantage to the physician is realized.

The complexity of the computer program creates new personnel problems. One obvious hindrance would be the increased demand for skilled computer programmers. In addition, the time required for acquisition of the EKG on the computer unit exceeds that of the conventional EKG.

2. Accuracy - By adhering to programmed diagnostic criteria, observer variation is eliminated, uniformity of interpretation is enhanced, and accuracy is improved. In addition, expert EKG interpretation would be available to areas lacking skilled interpreters. While observer variation is reduced, in practice, the computer interpreted EKG has been found less accurate than EKGs read by conventional methods. Specifically, the incidence of false positive (abnormal) EKGs has varied from 2%-20%, and the incidence of false negative interpretations has been reported from 3%-5%. (5, 6, 7, 9) The inability of the computer to accurately measure certain variables, e.g., the termination of the QRS complex; failure to detect waves of diminutive amplitude, e.g.,

small P waves; and artifacts created by poor recording and transmitting techniques, all contribute to error. Though accuracy has improved during the past three years, considerable disagreement still is found between computer read and physician read EKGs (approximately 20%). Disagreement with respect to the nature of the abnormality in an abnormal EKG accounts for most of the difference, along with false positive interpretations. Separation of completely normal EKGs from those with borderline or gross abnormalities is achieved with a high degree of accuracy. (9)

3. Volume Capacity - If current problems in diagnostic accuracy can be overcome, then automatic (interpretation of) EKGs will permit the increased utilization of this parameter as a diagnostic tool. Since the actual computerized interpretive operation occupies only a few minutes time, the major determinants of volume capacity are data acquisition time, transmission time, and printout time. Recording the standard twelve lead EKGs on a data acquisition unit takes somewhat longer than with a conventional electrocardiograph. This is offset, however, by computer data printout and EKG plotting, freeing the technician from the task of cutting and mounting the EKG. Even if the EKGs are reviewed subsequently by a physician-interpreter, he benefits from premeasured intervals provided in the computer data printout.

Aside from the physician-sparing function, therefore, a major potential benefit of the computerized EKG is its volume capacity. In

order for this advantage to be realized, however, the computer system must be situated in the proper milieu, i.e., one providing an optimal volume of input. This optimum will vary among computer systems depending upon their degree of sophistication. It has been estimated that the computer must perform 100,000 EKG "readings" yearly in order for maximal cost-effectiveness to be achieved. (11)

4. Cost Effectiveness - The cost of conventional EKGs is approximately fifteen dollars per cardiogram. It has been estimated that a computerized EKG should cost $2.50, thus representing a considerable savings. (9) This figure, however, will be arrived at only when two conditions are fulfilled:

1. optimal volume input is established;

2. reliability and accuracy improve so that physician supervision is no longer required (in terms of comparative interpretation).

Current systems have not yet approached a level that will provide any economic advantage over conventional electrocardiographic interpretation. In addition to the present unfavorable operating costs, the considerable expenditure for the computer and the recording and transmitting equipment must be recognized.

Assuming that the necessary degree of accuracy is achievable, identification of a suitable (in terms of minimum input volume) environment is necessary. Since most hospitals require far less than 100,000

EKGs yearly, in most instances independent hospital based computer EKG systems are impractical. A single computer base subserving multiple hospitals utilizing telephone linkages represents one approach. Similar relationships between a computer base and multiple HMOs is also foreseeable. The potential of bringing the expertise of the university hospital to outlying community hospitals and out-patient facilities is attractive from an RMPS viewpoint, both because it might improve the quality of medical care delivered in the smaller hospitals, and because it might promote interhospital cooperation. One must question, however, whether or not a need exists for other than conventional EKG interpretation in the community hospital; whether the computer would fulfill that need; or whether some other alternative would be more practical.

IV. Current RMPS Participation

At present, five regions are involved with computer assisted EKG analysis: Missouri, The Intermountain Region, Florida, Rochester and Memphis. This section will describe the variations in computer EKG application as effected in the regions mentioned, and will indicate their success or failure in fulfilling RMPS goals.

A. Missouri

Computer-bioengineering projects accounted for a considerable part of the Regional Medical Program in Missouri during its initial three years of activity. Project #19 entitled "Automated Electrocardiogram for Rural Areas" attempted to develop a computer system for EKG interpretation serving remote areas. Fifteen remote data acquisition units linked by ordinary telephone to a dedicated computer in Columbia, Missouri, were established to evaluate the feasibility of such a system. The remote locations included several community hospitals, a private clinic, a prison, an individual GP practice, and a medical center. This project was reviewed during a site visit in October of 1969, attended by several leading experts in the area of the automated EKG. It was noted that, (1) no need for the computer EKG service had been established and, (2) no cost savings had been demonstrated. There were also several specific defects with reference to project design and management. The National Advisory Council acknowledged that the endeavor had potential value. Because, however, no clear advantage in terms of regionalization

or health care delivery was foreseeable for the immediate future, Council advised reduction in funding with complete RMPS withdrawal by June 1971. Continuation of the project utilizing support from some other agency was recommended.

Many of the technical criticisms concerning this project are no longer applicable as improvements in program design and management have been instituted. Cost-efficiency has improved, cardiologist back-up interpretation has been provided, and reliability is improving. In addition, a demand for this service of sufficient magnitude to make it economically feasible, has been identified.

The past four years experiences have (it appears) resulted in a program of improved technical quality. Economic justification demands that 50,000 yearly EKGs be analyzed in order to make the program financially self-supporting. At present, only 12,000 EKGs are being recorded, far fewer than required. However, a survey concluded in February 1971 by Donald L. Wilson (Mo. RMP) seems to have established a need for this service. Based upon an estimate of the average number of EKGs performed in the region, the expressed interest of various physicians and hospitals, and the apparent lack of sufficient numbers of skilled interpreters presently available, such a project may be justifiable. On the basis of this survey and because of their past experience with the computer EKG, project #69 has been submitted - "Computer Processed Diagnostic Aids in a Rural Area."

The proposal aims at extending both the scope and magnitude of the previous computer-EKG program by:

1. Placing remote stations in suitable areas to generate 50,000 EKGs yearly, enough to be cost effective.

2. Increasing the range of services provided: pacemaker follow-up, arrhythmia analysis, exercise-testing, phonocardiography and spirography.

3. Providing for planned decremental RMP support, including eventual financial independence by establishing a fee for service system on a suitable unit volume.

Two major problems remain:

1. Computer accuracy, though improving, does not yet appear to be at an acceptable level.

2. Even if the necessary volume-input is achieved, the high cost of the analog data acquisition units, in terms of purchase and maintenance, has to be reckonned with.

Admittedly, these are essentially technical problems that are solvable; the question is when?

B. Florida

Project #3: Regional Computerized EKG Processing Center

This project was designed to provide inexpensive, rapid and reliable EKG analysis to small hospitals in the North Central Florida area presently lacking this service. Objective data identifying a need for this service in the area mentioned is not presented. An initiation period of three years with yearly increments in the number of EKGs performed and the number of hospitals participating was proposed. Financial independence was to be achieved by charging a fee for service, $3.50 per EKG (though $7.50 was indicated to be a more realistic figure).

A technical site visit conducted in January 1970 was generally favorable. Continued funding was recommended for six months at which time the region would be required to provide:

1. marketing strategy
2. quality control plans
3. cost analysis, utilization and evaluation study
4. clinical EKG validation study
5. choice of arrhythmia interpretation program
6. a minimum of 100 EKGs daily.

During the 02 year, 31,000 EKGs were generated from ten participating hospitals. Only one of these institutions has agreed to pay for the service, the agreed fee being $3.50 per EKG. This figure had previously been admitted to be unrealistically low by the project's

director. A time schedule for initiation of fee for service EKG analysis in institutions presently receiving this service on a non-payment basis provides for $100,000 by the end of the grant period (03 year). Current interest levels of those nineteen additional hospitals representing potential purchasers in an area within a hundred mile radius of Gainesville need to be identified. Marketing strategy appears to be incomplete. Procedures for clinical validation of the EKGs, and quality control have been started.

Project #12: Computerized EKG Screening Program

A computerized EKG is one of multiple variables measured in this cardiovascular disease screening program. Patients with abnormal EKGs (or abnormalities in any of the parameters measured) are referred to a designated private physician. The computer identifies abnormal EKGs and provides a specific diagnosis. The computer program being utilized is that described in Project #3. Major expenditures are allotted for purchase of data acquisition units ($42,750) and telephone service (49,000). Estimated initial costs are $102,650, and yearly cost subsequent to start-up is estimated at $76,000.

A technical site visit in January of 1970 observed that the volume of EKGs screened was small, statistical data was lacking, and plans for patient follow-up were not clear. The projected unit cost per EKG of $3.00 appeared to be unrealistic. Project #12 has been combined with Project #10, "Cardiovascular Screening Program in Four Rural Counties" to form Project #10, "A Program for Cardiovascular Screening and EKG Analysis."

C. Memphis

Project #8: Regional Electrocardiographic Diagnostic Center

This project, now completing its third year, was intended to:

1. Improve the efficiency of service electrocardiography in the hospitals of the University complex by utilization of a central small computer linked to data acquisition units in member hospitals by telephone transmission.

2. Provide this service on a regional basis.

3. Improve the quality of EKG analysis in the region.

Because of delays in equipment delivery and installation, the program has been operational for only one year. Notably lacking in the original grant application were:

1. Documentation of a need for the intended services within the region.

2. Detailed plans for marketing and expansion of the service.

3. Demonstration of any potential cost-saving value.

Apparently, the proposed expansion of routine computerized EKG analysis into the region met with resistance from the established medical community. Plans now center around development of an arrhythmia screening center serving local and regional coronary care units on a 24-hour

basis. Two units are functioning, with plans to service an additional "ten or fifteen" units in the region. Notable by their absence are:

1. Documentation of a regional need for this service and evidence of willingness to participate by the medical community at large.

2. Marketing strategy.

3. Details concerning the specific arrhythmia program to be utilized, and provisions for clinical validation and quality control.

4. Potential cost savings: The original grant application hoped to achieve a fee for service "compatible with the customary electrocardiographic charges in this community."

A progress report containing the specifics of the past year of operation with reference to the number of EKGs performed, clinical correlation, accuracy and reliability of the system, problems encountered and the proposed solutions, and objective evidence demonstrating improvement of EKG interpretation in the region would be most helpful.

D. Intermountain Region

Project #10: Physiologic Data Monitoring System

Funded since 1967, this project provides computer monitoring and analysis of multiple physiologic variables related to the cardiovascular and respiratory systems:

1. Automated data analysis for four cardiac catheterization laboratories.

2. Automated spirometry (two hospitals).

3. Automated EKG Analysis by Computer: This service is utilized at two of the five hospitals presently involved in the computer program. To date, 14,170 EKGs have been analyzed by computer.

4. On-line patient monitoring in a variety of intensive care unit situations.

A technical site visit in October 1969 commented upon the overall qualitative excellence of this project - "..... demonstrated great sophistication and technical expertise in the development of computer techniques for automating physiologic measurements of cardiovascular function." However, the member hospitals were noted to be highly sophisticated centers intimately concerned with cardiac catheterization and cardiac surgery. With respect to electrocardiography, none of these institutions lacked skilled cardiologists in EKG interpretation. No plan for applying the developing capabilities to other areas in the region, especially the less sophisticated small community hospitals, was proposed.

No change in this policy is in evidence in the 1970 progress report. Attention is predominantly directed towards five advanced hospitals in the Salt Lake City Area. Specifically, demonstration of a need for a computer EKG program in the remainder of the region and plans for extension of this activity into the region are lacking.

E. Rochester

Project #11: Telephone EKG Consultation

The original grant application proposed the establishment of three networks consisting of five transmitting hospitals and one receiving center each, linked by telephone (dataphone) for the purpose of improved EKG analysis. The system was to provide:

1. A mechanism for transmission of EKGs on an emergency basis for immediate interpretation by conventional means thus offering expert electrocardiographic services to outlying hospitals.

2. A framework for the establishment of a computer base for the automated analysis of routine EKGs transmitted from the participating hospitals.

3. An arrhythmia detection and monitoring service.

Estimated cost of equipping twenty transmitting stations and four receiving stations was $131,127, excluding salaries and floor space rental ($105,600). Council approved $30,051 yearly for two years for the establishment of the appropriate telephone network. Funds were withheld from the computer aspect of the project until such time the region provided:

1. Documentation of a clear need for the proposed service.

2. Evidence that such a service would be accepted by the medical community in which it would be implemented.

3. Plans for development of clinical applicability, systems management, and marketing.

The requested information was not included in the current grant continuation application, and plans for computer analysis seem to have been abandoned for the present. A survey of the twenty-nine hospitals in the ten counties comprising the region revealed that roughly 50,000 EKGs were done yearly in the region (figures from 1965). Thus even if all of the hospitals in the area were to participate in the proposed computer program, the total number of EKGs generated would barely meet the minimum level required to make the operation cost effective.

COMPUTERIZED EKG IN REGIONAL MEDICAL PROGRAMS

Region	Project No.	Project Title	Project Years	Total Direct and Indirect Costs to Date
Missouri	19 (49)	Automated Electrocardiogram for Rural Areas	4	$1,551,700
Intermountain	10	Physiologic Data Monitoring System	4	1,365,400
Florida	03	Regional Computerized EKG Processing Center	3	274,400
Florida	12	Computerized EKG Screening Program	3	105,200
Rochester	11	Telephone EKG Consultation	2	66,300
Memphis	08	Regional EKG Diagnostic Center	3	310,200

SUMMARY OF CURRENT RMPS ACTIVITIES WITH THE COMPUTERIZED EKG

The projects discussed were analyzed on the basis of written material submitted by the regions for the grant review process. Additional insight was gained from appropriate correspondence files and reports of past site visits. Admittedly, the depth and effectiveness of a review limited to these sources is less than maximum. Nevertheless, some valid observations can be made.

1. Necessity - Lack of objective data demonstrating a need for a computer-EKG system is common to all of the grant applications reviewed. A high level of intrinsic value is assumed to exist, and consumer interest is taken for granted, with predictable results.

2. Acceptability - Failure to ascertain whether or not the automated EKG met with the approval of physicians practicing in the area of proposed implementation created difficulties in one region. Certainly a minimal level of regional acceptance is mandatory in order to assure survival of the project.

3. Alternatives - In regions possessing a real need for improved electrocardiographic services, a computerized service is (apparently) assumed to be the most effective mode available. Little discussion of alternative approaches is evident, though such alternatives have proved to be of value in other regions.

4. Expense - All of the projects are outstanding with respect to the considerable expense encountered in purchase of appropriate data acquisition units, accessory electronic apparatus, and telephone rental costs.

5. Cost-savings - None of the projects reviewed is able to provide reliable electrocardiographic interpretation at a cost sufficiently low so as to provide a clear economic advantage over conventional methods of interpretation.

6. Reliability - The various contour and rhythmn programs used must be considered to be in a developmental stage. All require subsequent interpretation and confirmation by a skilled electrocardiographer. At the present time the computerized EKG is able to assist but not supplant the electrocardiographer.

7. Volume-capacity - Although all of the grant applicants appreciate the capacity of the computer to analyze large numbers of EKGs, much less attention is directed towards the problem of assuring the computer a volume sufficient to make the operation cost-effective.

8. Physician self-education - This particular potential benefit is referred to loosely by all of the projects. Little or no documentation of such an achievement is available. Nor is objective evidence demonstrating any improvemnet in the quality of care delivered by physicians utilizing this service apparent.

9. Regionalization - The establishment of telephone linkages between one or more peripheral community hospitals and a Medical Center computer base is a rational way of promoting working relationships among the hospitals in a region. Such cooperative arrangements are of enormous importance to the efficiency of the health care system of a region, and represent an important objective of the RMPS. It is impossible to evaluate the quality of the interhospital relationships fostered by computer-EKG programs. Accurate quantification of this function is not possible on the basis of the written material available. Therefore comment on this important area must be reserved.

10. Future Prospects - Realistic and detailed plans for phase-out of RMPS support through implementation of a sound fee-for-service schedule and marketing strategy are generally lacking. Estimations of additional time required to reach such a stage are ambiguous.

V. Current Usage and Potential

The electrocardiogram is a diagnostic tool essential for the recognition and evaluation of a variety of disturbances affecting the heart and cardiovascular system. Application of computer techniques to electrocardiographic analysis may be considered on several levels:

1. The Fully-Automated EKG - The definitive interpretation of electrocardiograms with respect to specific diagnosis and alternatives without validation by conventional physician analysis. Clearly, computer technology has not yet reached the stage of sophistication required to provide this service both reliably and economically. The automated EKG remains an objective. The amount of time required to achieve this goal is undetermined. Though of potentially great value, projects directed towards this goal are investigative and developmental.

2. Preliminary Analysis - Premeasured and mounted EKGs with suggested interpretations are of value because of the time-savings earned with the computer print-out. Diagnostic statements alert the physician reviewing the EKG to possibilities he may have overlooked, and serve as a self-education device. The value of such a service is a function of the skill and motivation of the utilizer. The highly motivated and knowledgeable physician may derive much from the computerized EKG. The capacity and speed of the conventional electrocardiographer may be enhanced when assisted by the computer.

To the average physician seeking an authoritative analysis, the computerized EKG offers less. Ultimate interpretation resides with the physician-utilizer, and thus its quality varies with his skill. Unless the computerized EKG has been reviewed by a skilled interpreter, its validity remains uncertain, and its value to the physician requesting the service is diminished.

3. Screening - At present, the computer is capable of separating normal EKGs from those with questionable and gross abnormalities, both efficiently and reliably. Abnormal EKGs are then subject to conventional analysis for exclusion of false positives. From an epidemiological standpoint, therefore, the computerized EKG is of great potential value. Epidemiologic surveys are outside the realm of RMPS (direct) concern. From the standpoint of disease detection for early diagnosis and management, several questions arise:

a. Is the incidence of clinically important EKG abnormalities great enough to justify the expense of a computerized detection program?

b. What is the incidence of clinically silent abnormal EKGs? Can symptomatic disease be detected more readily and more inexpensively through other means (e.g., questionnaires, blood pressure determinations, etc.)?

c. Practically speaking, what is the importance of identifying those patients with abnormal EKGs and presumably underlying heart

disease? Are we capable of altering the natural history of the disease? Can we offer any therapeutic intervention to asymptomatic patients with clearly abnormal EKGs? These questions are of obvious importance.

VI. Conclusions

The fully automated EKG is still in a developmental stage. Both technical and logistical problems have delayed realization of potential benefits attributed to a computerized system. Current systems rely upon subsequent validation of computer-interpreted EKGs by physician review. Though he is capable of doing this more efficiently when assisted by a computer, his presence is essential.

No clear demonstration of improvement in the quality of medicine practiced is available within the four regions currently using such a system. It, therefore, seems inappropriate for RMPS to support new project proposals designed along similar lines. While the potential value of the computerized EKG remains attractive, its uncertain future and considerable expense makes RMPS support impractical. Nevertheless, development of an effective computer-EKG system is desirable. Interested parties should be encouraged to seek financial support from sources outside of RMPS.

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