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AUTOMATION RESEARCH AND DEVELOPMENT
AND OTHER MAJOR EQUIPMENT INVESTMENTS
IN A REGIONAL MEDICAL PROGRAM

GUIDE TO PROJECT REVIEW

An effective Regional Medical Program bases its grant, contract and core staff activities upon continuing objective appraisal of the match between medical services available to the people of its Region and their needs for care. Unsolicited action proposals, like those originating within the Regional Medical Program organization, are subjected to rigorous tests of the system analysis and planning processes through which they reach the stages of initial, continuation, or renewal review.

Internal or voluntary proposals that involve RMP investment in equipment, research, or development for automation are subject to all the tests of necessity and timeliness that apply to other activities. Automation frequently involves high initial costs, rapid obsolescence, and a high probability of failure. Automation research and development are important concerns of other granting programs.

Regional Medical Programs frequently are importuned to make major investments in equipment purchase, rental, or time-sharing that is oriented toward clinical service, or continuing education, rather than research, and may not involve automation. Many such projects share the risks of loss that are attendant upon automation research and development. A partial list of such projects include

- . . . Medical record and information systems
- . . . Medical reference and consultation networks

- . . . Television or other continuing education systems
- . . . Multi-phasic screening projects
- . . . Mobil emergency care
- . . . Heart sounds or ECG transmission systems
- . . . Dosimetry networks
- . . . Special purpose hospital units: radiation therapy, CCU, etc.

In addition to the usual tests of necessity, timeliness, potential gain and feasibility reviews of any of these projects requires certain special tests.

1. RMP investment in projects that have research components shall be confined to:
 - a. Studies of the regionalization of clinical procedures, equipment or systems whose clinical values and economic values are predictable for specified conditions; or
 - b. incidental contributions of minor amounts of staff time or other items that also contribute to the RMP objectives.
2. RMP investment in automated equipment for any project shall be:
 - a. Confined to the minimal rental, time-sharing or purchase amount required to pilot the project; and
 - b. Withheld until it is demonstrated that:
 - 1) the proposed application of automation is feasible within the limitations of available time, funds and talent; and
 - 2) all contributions to any proposed system of automation

and all users of its product have agreed to any compromise in terminology and technology the system requires; and

- 3) the initial specifications for the proposed automation have been completed.

3. RMP investment in special laboratory, transportation, or communications equipment shall be confined to:

- a. minimal rental, time-sharing or purchase required to pilot a technique or element that is indispensable to the project; and
- b. non-experimental equipment of proven capability in the proposed use; and
- c. procedures that are endorsed by a sufficient number of users having a potential traffic in demonstrably needed transactions to make the planned system economically self-supporting.

4. RMP investment in piloting projects that require major equipment investment will be confined to projects whose plans for disengagement of RMP support:

- a. Include commitment for procurement and appropriate amortization as well as operation of all necessary equipment in their plans for full-scale non-RMP operation; and
- b. Base their plans for post-RMP operation on realistic projection of need, without reliance upon promotion of non-functional utilization; and
- c. Provide that in the event of discontinuance, any equipment purchased with RMP funds will be liquidated with appropriate return to RMP or the government.

BACKGROUND

BROADENING THE QUESTION

The Council request addressed itself to projects that include significant elements of automation and research and development. This response is somewhat broader, because RMP investment in other kinds of equipment also appears to be precarious business.

The RMPS does not have detailed information on requests for an investment in major equipment. We have information about project titles and magnitudes that indicates the kinds of equipment that are most important. No field survey was made to improve our information at this point, for two reasons. First, we are developing a long range information system which has a higher claim on staff time at present than a one-time survey of selected project proposals. Secondly, it appears practicable to enunciate a workable guide for equipment acquisition without a detailed survey.

Several types of major equipment systems have figured importantly in RMP project proposals. They have not been confined to projects with major research and development components. Education, clinical reference, and clinical service demonstrations have involved major communication, mobile unit, and other equipment systems.

THE NATURE OF THE RISKS

From past Council discussions, site visits, common sense and day to day observations, RMPS has concluded that a high risk of loss may be present in any project proposal that involves major investment in hardware.

A gamut of risks, rather than a single hazard, must be evaluated or put to rest, whenever a major equipment investment is part of a proposal. Moreover, most of the risks attached to such projects are not inherent in the performance of the hardware itself. Some examples:

- ... A proposal to evaluate screening plans to use equipment of unknown performance characteristics to record tests whose norms for the subject population group are uncertain. This gives the project three evaluations to accomplish - the equipment, the test, and the screening of the population, of which only the latter may be a basic RMP mission.
- ... A continuing education proposal plans to employ television to present materials that require precise representation, to audiences whose attention or even attendance is difficult to hold. This also gives the project problems to overcome in four major fields - television, reproduction, audience motivation, and effectiveness in changing behavior, of which only the last named is RMP business.
- ... A telephoned heart sound or ECG project is proposed for a thinly populated area, to use equipment and diagnosticians whose performance characteristics are known to be satisfactory.

Sharp cost-benefit analysis is needed here, to determine how the unit cost for cases in which the system would make a significant difference to the patients would compare with the cost of bringing those patients and high performance

diagnosticians together. Thorough advance negotiation is also needed to obtain assurance of acceptance by first-line practitioners and their patients.

... A complex medical record system proposes to provide computerized data banking, retrieval and information transmission, using equipment whose performance characteristics and reliability are well established.

Such a proposal presents a complex problem in cost-benefit comparison of alternatives. It also presents problems of acceptance, not only for the function, but for details like compromises on specifications for data inclusions, terminology, and presentation of the information products. All of these studies and negotiations should be completed and shows positive results before money is tied up in equipment.

RMP INVESTMENT

A summary has been made of projects involving major equipment investments whose total project direct cost awards to date total \$200,000 or more. The costs of equipment acquisition, rental and time-sharing in these projects is not known. However, the summary provides some notion of the amount of RMP investment whose success depends upon the capabilities and performance of hardware, and on the quality of the judgments, planning and negotiation that were employed in its application.

The large projects in the table below have accounted for more than \$24 million in total direct cost awards for the 4-year period. Undoubtedly there has been a significant investment in smaller projects that hinged upon similar considerations during this period.

MAJOR ACTIVITIES INVOLVING AUTOMATED TECHNOLOGIES
AND OTHER LARGE EQUIPMENT INVESTMENTS

<u>Classes and Numbers of Projects</u>	<u>Total Direct Cost Obligations by Fiscal Years</u> (in \$ thousands)			
	<u>1967</u>	<u>1968</u>	<u>1969</u>	<u>1970</u>
A. Projects involving automated equipment investments of \$50,000 or more. 22 projects, aggregating \$14,609,000	2,441	3,451	4,883	3,834
B. Projects involving automated equipment of unknown costs. 12 projects, aggregating \$3,856,500		493	1,350	2,013
C. Mobile unit projects. 6 projects aggregating \$954,000		88	386	480
D. Communication networks for continuing education. 6 projects aggregating \$4,876,000	243	1,074	1,744	1,815

AUTOMATION - THE STATE OF THE ART

Viewed from a respectful distance the computer field presents a busy, but apparently orderly landscape. This because most basic computer production is in the hands of giants, who manage to maintain their own equilibrium. The field of automation, or application of computer thinking and technology, is very different. When seen at close range, it is characterized by disorganization, volatility and speculative turbulence.

Many factors have contributed to this situation. Among them are rapid technological change, high requirements for specialization in application, low requirements for entrepreneurial capital, lack of sophistication among the buyers, and widespread uncoordinated availability of grant and contract support for speculative development.

All of these factors are operating in the development of automation for medical purposes. Here the confusion is heightened because both suppliers and users of mechanization and instrumentation traditionally have been small, independent and in their own ways fiercely competitive units.

In medical automation, relatively isolated small or one-system achievements have fired the imaginations of popular writers, physicians, business men and the general public. We imagine the world to be populated with benevolent computers, showering blessings upon us.

In cold fact, automation has saved us from becoming mired in routine management, business and statistical data. It has made conceivable many

specialized diagnostic applications, such as ultrasonic and certain heat and radiation sensing procedures. Automation has made possible improved deployment (or utilization) of highly specialized techniques, such as computation of radiotherapy dosage. Between these extremes of mass production on the one hand and pin-pointed specialization on the other, is a large area in which success has been highly elusive.

It is technologically possible today to automate any operation we specify. Parenthetically, we must note that for social, economic or other reasons, many operations we can specify should not be automated. In medical care, application of automation capability has been retarded by difficulties in specification. The program for automation of the medical laboratory of the National Institute of General Medical Sciences has found this to be true. In an examination of the problem in preparation for a forthcoming 1970 publication, they have found six key aspects of laboratory automation that remain undeveloped:

1. Computer control of output quality,
2. Positive patient identification for samples,
3. Development of better methods for existing tests as well as new tests for chemical and biologic substances as yet unknown or unmeasured,
4. Development of a reasonable approach to the problem of mass screening,
5. Development of methods for reporting test results which will enable the physician to obtain a knowledge of the patient's condition at a glance. (Especially true in clinical chemistry.)

6. Establishment of normal values for all chemical parameters by age, sex, geographic location and race.

These problems represent inability to specify what is wanted and lack of agreement on specification of how results are to be presented. The systems in which these problems occur present technological problems also in both automation and basic process. Solutions for these problems are predictable, but there is little reason to attack them while the larger difficulties of specification remain unresolved.

The medical laboratory already has experienced somewhat similar frustrations at a lower level of productivity development. Typified by the continuous flow analyzers, this phase has been one of mechanization rather than full automation.

Characterized by NIGMS as "not very good, not very bad analytical instruments," these devices now act as an economic brake on automation, in addition to facing specification problems of their own.

About 90% of hospital laboratories have invested in this family of devices. To these small businesses such investments are large. As a result they tend to be locked into mediocrity until the investments are amortized, and indeed until operational pressures force directors and staff to consider re-tooling themselves to cope with new technology. This in turn tends to narrow the discernible immediate market for true automation, and to discourage potential producers from investing in major developmental efforts.

The same problems that have dimmed the shining vision of laboratory automation affect the automation of many other medical service operations. Under contract with the National Center for Health Services Research and Development, a Washington, D. C. firm, Herner and Company, reported on October 1, 1968 on their survey of computer use in 1,251 hospitals that responded to a questionnaire mailed to 2,431 institutions.

Among the respondents, use and non-use of computers were reported as follows:

<u>Facility size</u>	<u>Users</u>		<u>Non-users</u>		<u>Total No.</u>
	<u>No.</u>	<u>Pct.</u>	<u>No.</u>	<u>Pct.</u>	
Over 200 beds	511	49.8	515	50.2	1,026
*Under 200 beds	32	14.2	193	85.8	225

*Only a 10 percent random sample of smaller hospitals was addressed.

In broad terms the computer using institutions reported that medical and research functions were performed by less than 15% of their computer applications.

<u>Class of Functions</u>	<u>Application</u>	
	<u>No.</u>	<u>Pct.</u>
Administrative and financial	1,689	66.7
Operational procedures	467	18.4
*Medical and research	378	14.9

*274 of these were in medical record maintenance, statistics and indexing.

Many reasons may be adduced for this minimizing of automation in medical care and research functions of the reporting institutions. It is certain that the difficulty in specifying computer services that are useful in current medical practice is one of the major obstacles to the development of automation in medical care and research.

In plain words, automation of medical care remains in an early stage of its research and development phase. Two arms of the Public Health Service have specific responsibility and ongoing programs for research and development that includes automation. These organizations are the National Center for Health Services Research and Development, and the National Institute of General Medical Sciences. Regional Medical Programs should leave to these programs research and development in medical automation.

From all of these facts, it appears that research and development involving automation occupies a very narrow band in the Regional Medical Program spectrum.

Oct. 22, 1970/HD/jh

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

Date: October 22, 1970

Reply to
Attn of:

Subject: Projects That Provide Medical Services, Including Coronary
and Other Intensive Care

To: National Advisory Council to the Regional Medical Programs

1. Minutes of the last two meetings of the Council record interest in developing guides for use of RMP funds in two kinds of medical service.
 - a. Item IX, A, 1, page 7, Minutes, March 31 - April 1, 1970 ... establishment and continued demonstration of intensive care units...
 - b. Item X, A, 3, page 11, Minutes, July 28-29, 1970 ... projects ... for demonstration ... outraining ... (which) ... become ... service to patients.
2. Essentially, these are two aspects of the same question:

To what extent, for how long, and for what purposes may RMP funds be used to initiate and provide medical services?
3. Examples of services to patients which have been proposed for RMP initiation or support include among others:
 - a. Intensive care, including coronary care units;
 - b. Stroke centers;
 - c. Multi-phasic or other screening services; and
 - d. Mobile emergency services.
4. Every mission or project activated by a Regional Medical Program should be a step, logical in direction, format and priority, toward improving the capability of the Region's medical resources to match the needs of its people on a self-sustaining basis. As the Council has noted, further specification of these principles could be helpful in keeping service projects within their bounds.
5. The following document, Medical Care Services in a Regional Medical Program is presented in two sections. The first, Guide to Project Review, is intended for issuance to Regional Medical Programs as a part of our forthcoming guidance system. The second, headed Background sums up for Council members the staff reasoning which produced the Guide.

MEDICAL CARE SERVICES
IN A
REGIONAL MEDICAL PROGRAM

GUIDE TO PROJECT REVIEW

An effective Regional Medical Program bases its solicitation, selection and scheduling of grant, contract and core staff activities upon the needs of its service population revealed by continuing objective appraisal of the medical services available in its region. Unsolicited requests for RMP grants or contracts, like those invited or originated by the Regional Medical Program organization, are subjected to the rigorous tests of the system analysis and the planning process before they are subjected to formal initial, continuation, or renewal review.

Both voluntary and RMP initiated proposals that provide services to persons or groups are subject to all the tests of necessity and timeliness that apply to RMP support of other activities. Service projects frequently exhibit escalation of expenditures, stimulate public assumption of vested interest in subsidization and create distorted public impressions of disease-categorical needs. Direct medical care services also are important concerns of other grant-in-aid programs. Therefore, certain tests of approvability and timeliness are especially important to projects in which RMP support makes possible direct medical care services.

1. Objective comparison of RMP support of a medical service with other conceivable alternative modes of progressing toward the stated demonstration training or research objective, in terms of cost, time, effectiveness and other measures;

2. Objective assurance that the proposed medical services:
 - a. If of predictable potential value, will be performed under conditions capable of producing the predicted value; or
 - b. If of uncertain value, will be performed so as to measure the values achieved and identify the conditions that affect results.
3. Evidence that all other granting agencies concerned with the proposed services have been consulted and will:
 - a. Assist the service segment of the project in coordination with RMP assistance;
 - b. Assume responsibility for assisting in development of any residual subsidization that may be needed after the scheduled termination of RMP support; or
 - c. Will not participate in grant or contract support of the service functions of the project.
4. Objective appraisal of the probability that successful services provided by the project will be integrated into the medical care system of the region, within the schedule planned for disengagement of RMP support, including:
 - a. The extent to which such integration will be more attractive than continued RMP support in the views of the project leadership and the community;
 - b. The project plan's provision for public education on the temporary role of RMP support and its dedication to stimulation, training or development; and

- c. Where the patient care services are highly specialized and costly, the credibility of long-range plans for their efficient deployment and utilization as they are integrated into the medical service system of the community and region.
5. Evidence that the project will recover revenue appropriate to the services rendered and the economic status of the persons or groups served, and will utilize and account for that revenue in compliance with applicable grant law and regulation
6. Evidence that the proposed service, selection of clientele, and mode of operation are compatible with the objectives of the Comprehensive Health Planning agencies of the area, and with national objectives.

BACKGROUND

At the March-April, 1970 meeting, the Council expressed a need for guidelines to the funding of intensive care units and stroke centers. In July the Council expressed a need for guidelines to RMP support of patient care in demonstration and training projects. The draft of a guide presented above is intended to respond to both needs.

At present, RMP's have funded over 100 ICU projects, a large majority of which are coronary care units. Many are requesting RMP support beyond the periods originally scheduled for disengagement of RMP funds, and beyond the periods considered necessary to demonstrate their success or failure in improving regional deployment of medical resources.

A CCU staffed with personnel well qualified to perform or learn its special functions, and to maintain the necessary discipline has a high possibility of developing capability to improve both morbidity and mortality secondary to infarction. An appropriately placed and accepted CCU can improve deployment and regionalization of services in its area. The location of small ICU's in outlying hospitals with strong teaching ties to a large central institution also has proven merit. Such services also are potentially self-supporting and once established should readily integrate themselves into the medical care systems of their communities and regions.

Units set up in hospitals that cannot provide trained personnel and disciplined performance will not provide successful patient care. Units located so that they may compete for patients in a given area or operate at low levels of service are likely to dilute both the regionalization and effectiveness of patient care in their areas. They are also likely to prove incapable of integrating themselves on a self-supporting basis into the medical system.

All of these characteristics are found in other costly, specialized services that require high levels of training and operational discipline as well as major start-up investments in equipment.

In any clinical class of such projects, it is likely to be the failures that press for extension of grant assistance beyond the periods of their original plans.

To a greater extent than is often realized, success or failure of such projects is predictable. The greatest potential for success is

achieved by identifying potential locations systematically from a thorough knowledge of the needs and resources of the area, before any applications are entertained, and then requesting competing applications from suitable facilities.

The same technique is advisable in correcting a system of limping projects that resulted from one-by-one consideration of unsolicited requests for support. Fully detailed knowledge of need, resources and potential in the entire area, as well as in the applicant institutions, is the most reliable guide to recognition of viability. Recent short-term performance is important, but it is sensitive to many factors that need not significantly affect long-term expectations.

Stroke centers are typical of projects that provide patient services of highly speculative clinical value. Sixteen such centers supported by the National Institute of Neurological Disease and Stroke and eighteen acute stroke units supported by RMPS are evaluating specific modalities of stroke therapy. Until we know the potential values of these modalities and the conditions under which specific levels of success can be achieved, their contributions to regionalization will remain doubtful.

Revised 10/29/70/HD/nmh