WITH THE PATIENT IN MIND
The Task Ahead - Regional Medical Programs 1969-1974

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INTRODUCTION

Regional Medical Programs have been launched at a critical time in American Medicine. The initial reception by the Nation has been far more enthusiastic than many supporters believed possible. Initial financing has been adequate. The program is now undergoing a process of analysis to determine whether the premises on which it was based are still valid; whether the initial implementation has been effective; and whether experience suggests that changes should be made for the years ahead. The fact that this audience is here to participate in these considerations and decisions emphasizes the fact that this program is indeed founded on local concern for the needs of those patients with heart disease, cancer, stroke, and related diseases.

Much of this paper and most of the meeting will be focused on the Report to the President and Congress required by the enabling law. Such a Report comes at a very early stage in the development of the

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program. Nonetheless, this Report will constitute the basic document on which the program for the period from 1969-1974 will be built.

In his issue paper on evaluation, Dr. Sanazaro has defined the several stages that characterize any new health program. He notes that in the first stage, available data is limited and decisions must be made almost entirely on the basis of the best judgments of responsible persons. This is where we have been during much of the past year. The focus has been on establishing mechanisms and approaches which promise better utilization of existing information and the collection of additional data which will form the basis for more confident decisions in the future.

In considering proposals for extending the legislation, Congress faces the same difficulties that we have faced. Congress will value, as we shall, the best judgment of those who have acquired wide experience in the health fields and who have assumed responsibility for launching the individual Regional Medical Programs throughout the country. To reinforce the limited hard data that is available, the President and Congress will expect evidence of firmer commitments, clear purposes, and crisper definitions. These examples must be developed by you who are involved at the Regional level on the basis of your actual experience and future plans. Since the very nature of Regional Medical Programs involves opportunities at the regional level to probe for workable solutions to complex problems, we in Washington cannot conjure the required realistic examples which indicate modifications are needed. Only your efforts and experiences can provide such evidence.
A major problem is related to the scope of the program. Gene Burdick's most pleasant book is one called the BLUE OF CAPRICORN. In a short story entitled "The Far Limits" he writes:

"The Pacific is enormous, plural, contradictory. One aches for limitations, for boundaries that reduce the sensation of awe. For each person the limits are different. For some people the Pacific is no larger than a tiny village, a strip of white sand, a reef. For a tiny group, that inquisitive body of oceanographers, the Pacific is illimitable. So great is their curiosity that their Pacific runs from the Bering Straits to the glittering ice cliffs of Antarctica."

The scope of Regional Medical Programs will certainly lie somewhere between Burdick's tiny village and the entire Pacific.

As the Nation begins an innovative and ambitious venture in improving the quality of health care for patients with heart disease, cancer, stroke, and related diseases, it is being watched intently by its neighbor nations. LANCET in a recent editorial refers to the Regional Medical Programs as "An American Catalyst." A description of the Connecticut program by Dr. Henry Clark at a Boerhaave Conference in Leiden, Holland, was of great interest to health leaders from Holland, Belgium, England, Sweden, and Turkey.

At one time I was chairman of the NIH Postdoctoral Foreign Fellowship Committee which brought young scientists from 40 countries
for research fellowships in the United States. These young physicians and scientists uniformly praised our unique ability to bring together for the purpose of the problem under study, the skills of those from many disciplines. Our foreign colleagues who have observed this inter-disciplinary achievement in research will be greatly interested to observe whether we can parallel this performance in the field of medical care. To bring this about, the primary focus must be not on the needs of medical schools, the needs of hospitals, the needs of health departments, or even the needs of physicians and other health workers. Rather, the primary focus must be on the needs of patients.

This Conference is framed against a series of difficult decisions facing American Medicine. We must decide how we shall provide health manpower for ever increasing needs and demands. We must decide how we shall provide particularly for those receiving the poorest care of all—the poor, the minorities, the isolated—both in the country and in the heart of cities. Severe economic pressures are being exerted on the entire field of health, particularly on America's hospitals. Urgency exists with respect to how we shall organize to best use the many new technologies that promise potential benefits if wisely and effectively used.

These problems and trends are powerful in their impact. They require that instruments of great durability and equally great sensitivity be structured so that medicine may be favorably influenced to provide the greatest service to those in need. We believe that Regional Medical Programs, with their emphasis on local initiative and local control, was created as such an instrument to help solve these problems and cope
with these trends. To this end, we are now in the process of testing
the progress and capabilities of Regional Medical Programs.

**STATUS REPORT**

Secretary Cohen, last night, presented a splendid review of
the historical development of the broad policy and philosophy that led
to the establishment of Regional Medical Programs. The copy of a recent
paper of mine forwarded to you in advance of this meeting summarized
progress from October 1965 to October 1966. A few illustrated facts should
suffice to up-date that data:

The National Advisory Council has met six times. At four of
these meetings applications for planning grants were reviewed.

(SLIDE #1) As a result of decisions reached at the April 1966 meeting,
seven grants were awarded.

(SLIDE #2) At the June 1966 meeting, three additional applications were
approved.

(SLIDE #3) At the August 1966 meeting, eight more applications were approved
and...

(SLIDE #4) Most recently at the November 1966 meeting, the Council approved
16 applications, bringing the total of funded programs to
34.

(SLIDE #5) In addition, 14 planning applications which will bring the
total population covered by planning activities to some 90
percent of the nation are expected to be presented to the
February Council Meeting. The first four applications for
operational phases will also be presented at that time.
There has been widespread involvement of individuals and groups in the development of all of these applications for Regional Medical Programs. Deans and faculty members of all of the Nation's existing medical schools and most of the schools under development have participated in this activity along with most of their teaching and affiliated hospitals. Representatives of state and local medical societies and health departments have been part of the discussions in almost every instance. In addition, area-wide hospital planning agencies and state and local hospital associations representing the Nation's community hospitals almost always have been represented. Members and staffs of cancer societies and heart associations have participated along with other public and private health agencies and representatives of the public such as elected officials, businessmen, labor leaders, and leaders of religious and ethnic groups.

A study of the backgrounds of the individuals who are assuming responsibilities as full-time coordinators and staff directors of Regional Medical Programs, indicates that about half of these individuals come directly from the field of medical education. Another substantial number were formerly involved in key positions in hospital administration. The remaining came from leadership roles in voluntary health agencies, State government, and the private practice of medicine. The high caliber of people being sought and employed for these positions is impressive.
A study of the make-up of regional advisory groups indicates that on an overall basis...

- 21% are practicing physicians
- 18% are associated with medical schools and affiliated hospitals
- 13% are from Cancer Societies, Heart Associations, and other voluntary health agencies
- 12% are administrators from hospitals
- 8% are nurses and other health workers
- 8% are from public health departments
- 14% represent the public at large

HIGHLIGHTS OF ISSUE PAPERS

Let us now focus attention on the issues that are emerging. These have been described in a series of Issue Papers sent to you as background material for discussion at this Conference.

The first of these papers entitled, "The Development of Cooperative Arrangements" includes a fine statement by Dr. Charles Hudson which was prepared four years ago and expressed his views on the desirability of developing cooperative arrangements. We have been told that Regional Medical Programs have made considerable progress in developing genuine cooperative arrangements throughout the Nation. Groups in virtually every region have been probing to establish a workable basis for starting the planning process. However, the initial approaches concerning the size and shape of regions for planning purposes must be re-examined critically from time to time, especially when the region moves from planning into the establishment of an operational program. Let me be quite specific, questions have been raised and will continue to be asked whether these arrangements developed for the purpose of starting to plan for a regional
medical program will be the most effective arrangements for specific operational activities in heart disease, cancer, stroke, and related diseases.

Another issue suggested for discussion in the paper on cooperative arrangements is the nature of the local decision-making mechanism. The law requires that all operational grant requests must be approved by regional advisory groups. The question arises whether this approval shall be merely a proforma endorsement based on confidence in the applicant organizations and institutions, or whether it shall represent a careful evaluation of regional priorities based upon sound knowledge of needs and capabilities. This issue is closely related to the problems of the review and approval process for operational grants to be discussed later.

In the second Issue Paper entitled, "Continuing Education and Regional Medical Programs," it is noted that continuing education has been accepted as an article of faith by the medical profession. Although it is regarded as an essential activity for the scientific and clinical renewal of the physician, the Issue Paper points out that this vital educational experience has often been characterized by lack of continuity. There are two key issues. First, how can programs be designed that effectively reach the physician and others in the health field; and secondly, how can self-monitoring aspects be incorporated into these program to determine which of them are favorably effecting the care patients have received, and to what degree.

I have often referred to the clinical pathological conference as a unique feature of medicine. It is here that even the most senior clinicians
their clinical judgment for all to see. It is a method for
correcting error and thereby improving care. It and other established
methods such as the autopsy, the use of a case conference, and the
use of consultants has firmly established medicine's commitment
to constant scrutiny and critical evaluation of its judgment and techniques.

We are now entering a phase of medical care which requires that
we do for populations of patients and populations of physicians what
we have done so long and so effectively for the individual case and the
individual practitioner. The techniques of epidemiology, medical care
research, of community medicine must be adapted to personal health, as well
as public health. To this end, we asked Dr. Paul Sanazaro to prepare the
Issue Paper "Evaluation of Medical Care Under P.L. 89-239" and Dr. Vernon
Wilson to discuss the problems in a subsequent talk. The issue is how
rapidly the still-developing techniques for evaluation can be employed so
that our effort to improve care will be logically rather than
empirically determined.

THE REPORT OF THE SURGEON GENERAL TO THE PRESIDENT AND CONGRESS

The fourth and last Issue Paper is concerned with the primary
focus of this meeting and grows out of the fact that the Surgeon General
of the Public Health Service is required by the law which established
Regional Medical Programs to make a Report to the President and Congress on
or before June 30, 1967. A subcommittee of the National Advisory Council
on Regional Medical Programs and the Surgeon General concurred in our view
that, in addition to the steps already taken toward the development of
information for this Report, representative groups from the entire country should be convened. As a result, regional coordinators, representatives of regional advisory groups, and others identified as key people in the development of approved and pending grant proposals have been invited to this Conference. Major health organizations who have expressed an interest in this program were also invited to send representatives. Appropriate representatives of other government agencies including the National Institutes of Health, other bureaus of the Public Health Service, the Bureau of the Budget, and Congress were invited to attend. Also included are the 65 individuals who have served as consultants to the Division in helping define policy and philosophy. Specifically, these include members of the Initial Review Committee, members of the ad hoc Committee for the Report to Congress, members of the National Advisory Council, and liaison representatives of other National Advisory Councils with related interests.

All of the members of the President’s Commission on Heart Disease, Cancer, and Stroke have also been invited. We are particularly interested in having them now refocus not only on the program as it exists today but on possible future modifications. Their background of competence and the experience they gained in producing the document which served to initiate the legislation establishing Regional Medical Programs will prove to be invaluable.

Public Law 89-239 specifies three things that the Report must accomplish.
It must appraise the activities assisted by grants in the light of their effectiveness, and...

(SLIDE #7) It must deal with two issues...

- The relationships between Federal financing and financing from other sources of the activities undertaken on behalf of the Regional Programs.
- The extension and modification of the law.

We must give serious attention to the relationship of Federal and non-federal financing. Congress will examine this issue carefully. For instance, activities once started are not easily curtailed. Yet the essential purpose of this program is to help bridge the gap between the advancing frontier of new scientific knowledge and the broad application to patient care. All funds cannot remain tied up in continuing programs to support of yesterday's advances. A significant amount must be available to encourage new programs at the cutting edge of science.

Although not required by the law, experience has indicated that the Report must also speak to at least four other questions:

(SLIDE #8) In specific terms, the type of construction authority needed to achieve the goals of the program and the urgency of this need must be made clear to the President and the Congress. Any request for such authority must be substantiated by firm, objective evidence of need, particularly if favorable matching requirements are needed.
Since the earliest days of the program, questions have been raised repeatedly concerning the need to clarify certain provisions of the law. We shall have an opportunity in the Report to identify these areas and provide interpretation.

The law authorizes grants only for the planning and establishment of individual Regional Medical Programs. It has been suggested that the goals of the program might be achieved more readily by expanding this authority to allow grants for activities involving multiple regions that will support the work of individual Regional Medical Programs.

A fourth major question has been how rigidly or freely one may interpret the emphasis on the disease categories of heart, cancer, and stroke. I invite your attention to two paragraphs from the Issue Paper concerned with the Report. "During the planning phase, the major activities undertaken by Regional Medical Programs have involved the establishment of a planning staff, the initiation of studies to obtain the basic data concerning pertinent health needs and resources, and the development of cooperative relationships among major health resources in the region. These activities are generally generic by nature and consequently have not significantly involved problems of categorical definition. In most cases in order to plan effectively for heart disease, cancer, and stroke it has been found necessary
to consider at times the entire spectrum of resources available for personal health services. However, the emergence of the operational phase of the program will put a more intensive focus on its categorical purposes. Only projects which can be shown to have direct significance for combating heart disease, cancer, stroke and related diseases can be assisted with Regional Medical Program grant funds." The implications of this issue requires careful consideration as you discuss the future of these programs.

It should be emphasized that this Report to the President and Congress will be the basic document on which recommendations for future legislation extending and modifying Public Law 89-239 will be based. In addition to your participation in the discussions at this meeting, I invite each of you personally to send me any written suggestions which you think will be helpful in the preparation of this important document. We anticipate the preparation of a draft of the Report shortly after this meeting. Thus, your comments can be most effective if they are forwarded to me promptly.

Operational Grants

I come now to a very important section of this paper. The planning phases of Regional Medical Programs are well on the way to covering the entire Nation. We are now in the process of reviewing the first applications for operational grants.

The initiation of operational activities is the most vital element of our mutual task ahead. It is the operational activities to be approved, funded and implemented under the current legislation that must constitute the central focus for recommendations for extension of the program. Based on
experience to date which includes staff analysis, site visits, deliberations by the Review Committee and the National Advisory Council, and discussions with other Public Health Service programs, we have identified some of the important issues which must be considered in the review of applications for operational grants.

At the risk of generalizing from relatively few examples, I should like to review with you the characteristics of the operational proposals as we have seen them in the initial applications. It is important that we consider together the initial operational activities. Your actions in developing operational proposals, and the actions of our Review Committee and Advisory Council in approving these proposals, will express far more effectively the nature of Regional Medical Programs than general policy statements and will reveal most clearly the importance of these Programs to society.

The review of the first operational proposals has raised sharply the question of what methods should be used to evaluate such applications. Each is characterized by a number of specific activities within the overall proposal. However, a Regional Medical Program must be more than a collection of projects. The review process, therefore, must focus on three general characteristics of the total proposal which separately and yet collectively determine its nature as a comprehensive and potentially effective Regional Medical Program.

(SLIDE #8) The first focus must be on those elements of the proposal which identify it as truly representing the concept of a Regional Medical Program. Our review groups have determined that it is not fruitful to consider specific aspects of the proposal unless this first essential determination concerning the core of the Program is positive. In making this determination the reviewers have asked such questions as: "Is there a
unifying conceptual strategy which will be the basis for initial priorities of action, evaluation, and future decision-making?" Is there an administrative and coordinating mechanism involving the health resources of the regions which can make effective decisions, relate those decisions to regional needs, and stimulate the essential cooperative effort among the major health interests?" "Will the key leadership of the overall Regional Medical Program provide the necessary guidance and coordination for the development of the program?" "What is the relationship of the planning already undertaken and the ongoing planning process to the initial operational proposal?"

(Slide #9) After having made a positive determination about this core activity, the next step widens the focus to include both the nature and the effectiveness of the proposed cooperative arrangements. In evaluating the effectiveness of these arrangements attention is given to the degree of involvement and commitment of the major health resources, the role of the Regional Advisory Group, and the effectiveness of the proposed activities in strengthening cooperation. Only after the determination has been made that the proposal reflects a Regional Medical Program concept and that it will stimulate and strengthen cooperative efforts, will a more detailed evaluation of the specific operational
activities be made.

(SLIDE #10) If both of the two previous evaluations are favorable, the operational activities can then be reviewed, individually and collectively. Each activity will be judged for its own intrinsic merit, for its contribution to the cooperative arrangements, and for the degree to which it includes the core concept of the Regional Medical Programs. It should also fit as an integral part of the total operational activities, and contribute to the overall objectives of the Regional Medical Programs.

This is not a conventional review process. The total process for reviewing complex operational applications will often require up to six months or in some cases even more. The applications already in hand are providing us with a learning opportunity to develop the most appropriate review processes. Our experiences indicates that the interplay of an initial site visit will be necessary to determine whether the essential criteria for a Regional Medical Program have been met. Nevertheless, the written proposal should include an exposition of the guiding philosophy and administrative processes which have gone into the development of the proposal, and should explain how the specific activities proposed relate to these overall objectives. A justification of each separate project, however worthwhile, cannot provide a sufficient basis for making the essential determinations. Consideration of other characteristics of the initial operational proposals and their review also reveal the essential nature
of a developing Regional Medical Program. They provide concrete examples of most of the issues to be discussed at this Conference. For instance, these proposals clearly lead from the strengths contained within the region. This is understandable and justifiable and may be the most effective way to implement the first phase of the regional medical program. Leading from strength may develop some activities which can serve as models for other regions or a resource which can be utilized by adjacent regions through effective interregional cooperation.

Fortunately, there are examples in the initial applications which give evidence of interregional cooperation in capitalizing on the particular strengths within an adjacent region. I would like to add a cautionary note, however, that the full development of a regional medical program must show equal concern for strengthening the weaknesses of that region.

Our reviewers question repeatedly how weaker institutions, the minorities, the poor will be helped by the proposal. Not only are the reviewers concerned that the focus of the program is out towards the periphery, but that the applications themselves reflect this concern on the regional level.

Activities which have been chosen seek to reinforce cooperation and mutual interaction between the academic community and the community practice of medicine. Such linkages will be among the most important contributions of the program. If the specific activities proposed in an application fail to strengthen cooperative arrangements or even interfere with such cooperation, the entire Regional Medical Program
would be threatened. The maintenance and nurturing of the cooperation established in the planning phase of the program will surely pose a major challenge to all Regional Programs, especially those with more complex institutional relationships than are represented in the first applications. Thus, the review process must be concerned initially with the applicant's concept of a Regional Medical Program and his total proposal rather than with specific activities.

We also see evidence in these applications of the design of initial operational phases of the program that can serve through continued planning and evaluation as the basis for further evolution of Regional Medical Programs. We cannot emphasize too strongly the necessity of incorporating in the Regional Medical Programs the methods of evaluating and modifying the program so that it becomes to a considerable degree a self-monitoring system which will supply those participants at all levels with the information and the motivation and the flexibility to direct future efforts towards those fulcrums of action that accomplish best the objectives of the program. For this reason it is important to avoid freezing the program towards permanent support of all initial activities undertaken. Some of the activities should be self-limiting with the transfer of effort to other priorities as the programs evolve. If these programs become just another source of funds to finance specific activities, we shall have lost the opportunity to develop a uniquely effective mechanism in bringing the advances of medical knowledge to bear on the health problems of the people of the regions.
The development of the self-monitoring characteristic of the Regional Medical Programs is also a presumption of the review sequence described, for the future relationships between our review process and a regional medical program are to be based more on an evaluation of the effective results of the overall regional program and achieving its goals rather than on a detailed review of specific activities proposed.

As anticipated, categorical questions do arise. The initial proposals are directed toward the problems of heart disease, cancer, and stroke. Some broader activities do involve the more effective functioning of the total health-care system as essential requirements for improvements in the diagnosis and treatment of these diseases. The initial proposals show the unique opportunity provided by Regional Medical Programs to consider both the specific and broader approaches for meeting identified health needs in the region. While the many types of activities proposed in the applications complicate the process of review, they show evidence of a serious effort to match resources with needs and to bridge the gaps among science, education, and service.

Regional Medical Programs represent a new relationship between the Federal review mechanism and the regional framework for decision-making. Neither the traditional methods of project grant support, or formula grant support can be applied. We intend to work closely with you in developing the potential of this new relationship. Yet, there is a potential contradiction between the need to evaluate proposals at the national level and the intent that the Regional Medical Program
represent a new framework for decision at the regional level. If specific approval actions in Washington were entirely on a project-by-project basis, this would tend to move the major decision-making responsibility for determining the nature of each Regional Medical Program to the national level. Under these circumstances regional decision-making would be confined largely to the choice of which activities to propose for national approval, and we will have failed to achieve a major objective of the Regional Medical Programs.

Our whole review process is concerned with strengthening responsible regional decision-making. In order to provide the Regional Medical Program with an explicit and concrete mechanism for playing a meaningful role in the continued development of the overall Regional Medical Program after the award of grant support, we are considering the possibility of including in the grant award for operational activities a proportion of the funds to be used for carrying out the purposes of the RMP at the discretion of the RMP with the approval of the Regional Advisory Group. This approach would lend substance to the intent that the Regional Medical Program be more than the sum of its parts.

**SUMMARY**

The purpose of this paper is the purpose of this Conference:

1. To help set the stage for a fruitful discussion of the Report to the President and Congress; and

2. by free exchange of information, to be able to implement the next stages of the program in the best ways possible.
I have focused first on the issues described, the Report to the President and Congress, and finally on the applications for operational grants and their review, as the basic tools for you to begin defining the Regional Medical Programs to serve patients in 1969-1974.

Talented and distinguished speakers and panelists will assist you from time to time. There are high hopes for this Conference and even higher expectations for Regional Medical Programs - so high indeed that we must face realistically the possibility that the many challenges may exceed our combined ability to meet all of them as we would like to. There has never been a greater opportunity to link science, education and service but the difficulties are also great.

But "no ashes, no Phoenix". Mythology offers no tale more dramatic than that of Phoenix. With his flashing gold and scarlet plumage he descends to the altar of the sun and is consumed to ashes. With the rising of the sun he is reborn more glorious than before to signify for another 500 years eternal hope arising from disappointment.

Like the soaring Phoenix, Regional Medical Programs have arisen from previous hopes, expectations and disappointments. They offer new hopes and opportunities for new achievements in American medicine.