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Project SOAP:

A Systems Approach to Biomedical Research Program Management

A Case Study

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Project SOAP: A Systems Approach to Biomedical Research Program Management • A Case Study

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Project SOAP: A Systems Approach to
Biomedical Research Program Management
A Case Study

SYNOPSIS

This report documents a case study in the field of management science in which a systems approach resulted in the implementation of a discipline for managing biomedical research programs within a Federal research support agency. As such, it has value for practitioners of the systems approach in itself, and also as a potential guide for Science Administrators and Budget Analysts elsewhere in Government. It describes a method for allocating funds to basic/applied research activities, particularly the planning and evaluation of publicly-funded project grant programs.

Project SOAP (an acronym for Systems/Operations Analysis of Programs) was the name given a joint task group established under an interagency agreement between the Technical Analysis Division (TAD) of the National Bureau of Standards (NBS) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH).

This case study describes the methodology and substantive information developed during Project SOAP's two-year assignment (from July 1969 to June 1971), which resulted in the introduction of a discipline for program management for improving the administration of basic/applied research project grants supported by NIAID. Although application of the quantitative methods of operations research was

not possible during this effort, the basic logic of the classical resource allocation model was used as a framework for guiding management decisions.

The task group was created to explore the applications of systems analysis and operations research to management issues within the National Institute of Allergy and Infectious Diseases, particularly to the problem of resource allocation in its Extramural grants program. Together, the task group investigated the methods and criteria the Institute used for selecting projects within its various research programs.

Initially, it was found that the Institute's traditional administrative practices for budget allocation did not provide an adequate basis for managerial decision-making, since attempts to establish program priorities were ineffective. The agency was not able to justify to higher authority its desired choices when arbitrary budget cuts imposed by external circumstances seriously impaired important programs. The task group concluded that the best solution was the adoption of an explicit discipline for management: a discipline which would permit more effective control over what had become a major cause of friction and confusion within the Federal-Science environment. This "dissonance" stemmed from the presence of two value systems: the "scientific merit" criteria (an emphasis of the Scientific Community), on the one hand, and the notions of public

interest (here "health relevance" criteria, as conceived by the National Advisory Council), on the other.

The benefits which accrue to this Institute's Science Administrators from the full implementation of such an approach include not only greater assurance of "optimum" resource allocation but also a basic pattern of reasoning useful for guiding discussions with members of the Scientific Community, representatives of other Federal health research agencies, and the Office of Budget and Management.

Moreover, it has become evident in recent years that the single "peer review" procedure for selecting grant payment priorities cannot be expected to be responsive to changing National priorities unless stronger incentives are provided by Science Administrators for focusing research investigators' attention on nationally important health research problems. The DAPA (Dollar Allocation by Program Area) research investment procedure recommended by the task group is simply a more deliberate mechanism through which the Science Administrator and his Advisory Council can use the advice of experts from the Scientific Community jointly with other considerations in the process of establishing grant payment priorities for the Institute.

The author favors the establishment of more clear-cut and explicit planning and evaluation procedures for the management of research programs within the Federal Government.

Present efforts at decentralizing the management of NIH's biomedical research activities, with their emphasis on Institute determination of priorities aimed at particular National health problems, are a start in this direction.

The author also believes the approach described in this report can be used to provide Science Administrators elsewhere in Government with an approach for explicitly planning for and evaluating the performance of their basic/applied research programs, in order to balance the dollar costs with the expected benefits of particular research project proposals.

Within the National Institute of Allergy and Infectious Diseases, the Extramural Program science administrators are currently in the process of adopting the DAPA procedure to perform this function.

ACKNOWLEDGMENTS

A project of this nature depends upon the cooperation and assistance of many people, both from within and outside our respective organizations. We acknowledge our grateful appreciation to many individuals for their helpful contribution to various activities of this joint task group.

Our special gratitude is extended to Dr. Alfred M. Webb, whose guidance and forebearance were principal ingredients in the conduct of this project, and to Dr. C. West Churchman, Professor of Business Administration, University of California, and member of the NIAID Advisory Council, who originally suggested the Institute explore the use of systems analysis as a means for improving its allocation of resources.

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This case study describes the activities of an interagency task group that applied systems analysis to improve management controls within a biomedical research agency of the federal government. The results were the formulation and implementation of a discipline for program management which explicitly makes use of multiple criteria in arriving at resource allocation decisions.

The text details the necessary preliminary analysis describing operational activities, information flows, and key decision points within the organization. It goes on to identify the techniques employed and the difficulties encountered while attempting to improve the decision-making process for selecting research projects, under conditions of reduced funding. In particular, a comparison is made between: (1) the agency's traditional single-criterion "peer review" judgment for determining budget priorities, and (2) the multiple-criteria judgments required to effect more positive management control. The systematic use of separate "scientific merit" and "health relevance" ratings is compared with the organization's actual experience. The criteria used by various participants in the decision process are analyzed, and a dollar allocation "investment" procedure based on these findings is developed.

A procedure which organizes relevant information for research program planning and evaluation is presented, and extension of this recommended procedure to wider use by science administrators elsewhere in government is discussed.

Keywords: Biomedical research; "health relevance"; program planning and budgeting; R&D management; systems analysis; systems approach.

1. INTRODUCTION

The National Institute of Allergy and Infectious Diseases (NIAID) is one of the ten National Institutes of Health. It supports a broad range of biomedical research on the causes of allergy and the prevention and treatment of

diseases associated with such infectious agents as bacteria, viruses, fungi, and parasites.

The budget for the National Institute of Allergy and Infectious Diseases in recent years has been approximately $100 million a year. Half of this--some $50 million--is appropriated by the Congress for Extramural research and training grants which support biomedical research investigators at academic institutions throughout the United States and in some foreign countries. Of the approximately 1,700 grant applications received each year by NIAID, nearly one-half are non-competitive continuations; i.e., they are long-term commitments made by the Institute in previous years and are based on prior review and National Advisory Council* approvals.

Of the remaining 800 to 900 applications, about 70 percent are judged by a peer review procedure to have sufficient scientific merit. However, after the prior year's commitments have been paid from the allotted $50M, only some

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*The National Allergy and Infectious Diseases Council consists of a group of 13 to 15 prominent biomedical scientists, public health officials, and laymen appointed by the Secretary of the Department of Health, Education and Welfare for a term of four years. This Council was created to advise the Director of NIH on policy matters. Moreover, it has the statutory responsibility of approving recommendations for research project grants (through the Director of NIH) to the Surgeon General of the United States. Only with the Council's express approval can awards for Extramural project grants be paid by the Institute. Formal meetings of the Advisory Council are scheduled three times during each fiscal year, in November, March and June. Those Extramural grant applications initially accepted by a peer review group and favorably evaluated by the Institute Staff and the appropriate Council subcommittee are finally recommended for payment.

two-thirds of those remaining grant applications recommended for award can be paid.

As early as 1963, when the previous large increases in NIH appropriations first began to level off, there was much discussion among the NIAID Staff and Advisory Council members about the desirability of giving special priority to certain areas of research for support by Extramural Grants. It was recognized that such areas of research needed more support than other fields because they dealt with problems of particular importance, or held promise, or had been neglected in the past.

In 1964, when the NIAID Extramural Grants budget was actually restricted, a new and serious problem confronted the Institute: how to assure the means for support for those research activities which the Institute considered most relevant to its categorical mission of improving public health through the support of basic science and the performance of targeted research. The problem was not so much deciding how to determine the most scientifically meritorious projects from among those screened by the initial review groups (Study Sections) and referred to NIAID for financial support but, rather, deciding how to determine the preferred order of payment of those research project proposals approved--particularly as research budgets declined--and how to make this kind of decision on a more rational and systematic basis.

Finally, in 1967, faced with the practical problem of preserving support for important biomedical research projects while at the same time faced with an actual cut in budget for Extramural Grants, NIAID responded by designating, from among the many possible biomedical research areas, ten Special Emphasis Research Programs* (SERPs) as the ones to receive priority. Grants associated with these areas would be given a "two-decile"** advantage in payment priority over grants associated with other areas of research.

This procedure became the subject of much discussion within the NIAID management. It was called "decile-diddling" by some, and there were increasing demands for justifying the allocations resulting from such informal procedures. In essence, the rationality of the allocation process itself became an important issue.

The result of all this was that, in 1968, NIAID agreed to take a more sophisticated look at various methods for determining grant payment priorities in the

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*The initial NIAID Special Emphasis Research Programs were: Drug Resistance and Microbial Diseases; Streptococcal Infections and Sequelae; Congenital Defects caused by Microbial Agents; Antiviral Substances; Chronic and Degenerative Diseases; Infectious Hepatitis; Emphysema and Chronic Lung Disease; Transplantation Immunology; Clinical Allergy and Immunology; and Malaria. NIAID Staff Paper (June 5, 1967).

**For explanation, see pp. 22, 27-29.

Extramural program, a decision largely the result of the appointment of Dr. C. West Churchman* as a lay member to the NIAID Advisory Council.

1.1 The Necessity for Change

When the change in Federal budget priority for supporting NIH Extramural research resulted in the uniform cutbacks of 1969,** it became obvious to many within the Institute that NIAID's external environment was changing and that perhaps their basic decision criteria ought to be examined in a different light.

At the same time, after several Advisory Council meetings it became clear that different interpretations were being made by different Council members of the Study Sections' (peer review) ratings of grant requests. That this ambiguity resulted in the difficulty when these priority scores were considered by the Council was apparent, in particular, from the way final payment priorities for certain grants differed from those intended in ratings of the Study Sections. Some members of the Advisory Council felt that the use of Study Sections' priority scores together with the decile adjustments

*Dr. C. West Churchman, Professor of Business Administration, University of California, Berkeley, and a leading exponent of the "systems approach."

**In July 1969, NIH instituted an across-the-board 20 percent cut in research grants up for renewal. Later, because of vociferous reaction by the biomedical research community, DHEW reduced the budget cuts to 5-10 percent.

recommended by the Institute Staff did not result in their notion of a balanced research program, or at least did not result in a program the rationality of which was evident.

In seeking a change for the better, the Institute began to address itself to developing more explicit goals and criteria for evaluating the performance of its programs. The existing ones were found to be too vague and inappropriate for planning and guiding its decision-making process in relation to its public responsibility of improving the nation's health through research.

Dr. Dorland J. Davis, the Director of NIAID, best summed up the problem when he asked: "What actions should the Institute take to assure the most effective and responsible use of these funds entrusted to its stewardship?" Further, he posed, "How can we be assured five years from now--with present budget allocations--that some of our best [research] programs won't be starving, and our worst programs flourishing? Our goal ought to be to improve the management of our programs, not to perpetuate the controls we now exercise."*

In an attempt to provide this desired improvement, Project SOAP was thus established as a joint task group under an interagency agreement between the Technical Analysis Division (TAD) of the National Bureau of

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*Initial meeting with Project SOAP, August 8, 1969.

Standards (NBS) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH).

The objective of SOAP (an acronym for Systems/Operations Analysis of Programs) was to explore the application of systems analysis and operations research to significant management problems of NIAID, particularly to those of its Extramural Research Grants Program.

The title of the report prepared for the sponsor at the conclusion of the assignment, "Toward a Discipline for Program Management,"* epitomized the basic discipline used by the Project SOAP task group. This discipline introduced to research scientists and science administrators at NIAID a more consistent and rationally-based framework for resource allocation. The "Program Management Discipline" relates operational decision-making information to higher-level considerations of health research and public policy. It is strategic in nature; it attempts continually to reexamine goals as well as to determine the appropriate means for achieving the desired degree of managerial control.

Today, in practically every agency of the Federal Government there are operations researchers, management scientists, system scientists--all attempting to look at

*Cutler, R. S. and Martino, V. A., "Toward a Discipline for Program Management" (A Summary of Project SOAP Activities, FY 70-71), National Bureau of Standards Report No. 10-626 (January 31, 1972).

the problems of Government from the so-called "systems viewpoint." As scientists by profession, they are interested in characterizing the nature of operational systems in such a way that the decision-making function can be performed in a logical and coherent fashion. Furthermore, by applying scientific discipline and substantive knowledge to a particular field of activity, they expect to be able to develop measures which will give as adequate information as possible about the performance of these systems.

This report documents one such systems analysis study. No claim for a final successful solution is made. Rather, the following text describes both some specific "subsystem" analyses and the steps taken toward delineating a management decision-making structure within which the Institute itself later began to undertake more comprehensive and definitive programs. An abstract of the Official Minutes of the June 1971 Council meeting describing the "first step in implementation of the Dollar Allocation Procedure" is shown in the Conclusion on page 55.

1.2 Task Group's Approach

The Institute's interest in this systems analysis project was centered in the top echelon of the organization. The Institute Director assigned two men* from his staff to

*Dr. Alfred M. Webb, Chief, Office of Program Planning and Projections (NIAID); and Charles Myers, Management Analyst (NIAID), later reassigned.

join on a half-time basis the two full-time systems analysts from TAD.* This joint task group and their subsequent activities became known as Project SOAP.

The SOAP group received support and encouragement from NIAID's Director, Dr. Dorland J. Davis, who arranged the necessary introductions and scheduled meetings with professional staff operations personnel. Thus, the group's entree to the operational levels of the organization was assured.

1.3 Project SOAP Orientation

Initially, there were orientation problems to resolve. Because the scope of the assignment and the objectives of the study were not clearly definable in advance, NIAID's management personnel were uncertain about what to expect in terms of project results. A portion of the problem lay with the Institute's unfamiliarity with systems analysis and operations research terms and techniques. Similarly, the systems analysis people from TAD were unfamiliar with biomedical research. Thus, there were mutually recognized difficulties in achieving useful results within the allotted time. Fortunately, however, there was also a sincere resolve on both sides to make a meaningful and productive start.

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*Robert S. Cutler, Project Leader, and Vincent A. Martino, Operations Research Analyst, Technical Analysis Division, National Bureau of Standards.

In the beginning, the SOAP task group spent much of its time interacting with various key members of the NIAID organization. The discussions were quite candid, and one charge, frequently reiterated, emerged: that the TAD people were lacking in biomedical knowledge. Acknowledging this, the TAD analysts pointed out in response that the real issues of concern were in the area of management control and that expertise and "discipline" in this field was what they brought to the project.

1.4 Purpose and Scope

The primary aim of this TAD/NIAID study was to explore the application of systems analysis and operations research to the principal management problems of the National Institute of Allergy and Infectious Diseases, particularly to its problem of allocation of resources.

The scope of the assignment included two operational divisions within the Institute: the Collaborative Program and the Extramural Program. (The third division, the Intramural Program, was not included in the Project SOAP study because it was undergoing a reorganization at the time.) Major attention was to be given to the Extramural Program, which is responsible for awarding research project grants.

It was expected that this assignment would also create within the organization the broader perspective required to coordinate the management of some of the Institute's other biomedical research activities.

Specifically, the joint task group was organized to:

1. Review the process for awarding Extramural Project Grants and study the impact of the existing allocation procedure;
2. Develop improved selection criteria and management methods for use by the Institute's Staff, its management, and its Advisory Council.

It was anticipated that systems analysis techniques--such as PERT (Program Evaluation/Review Technique)* for network planning of Collaborative research, and quantitative methods for measuring research accomplishments--would lead to more effective management procedures. These, in turn, would provide a basis for integrating, within NIAID, closely associated research activities into Institute-wide programs--an approach already under serious consideration by the NIAID Director at that time. It was further expected that if the tools provided by management science proved effective in handling the NIAID Extramural grants program they might, similarly, prove effective for other NIH Institutes, and perhaps even for NIH as a whole.

*A basic tool of management science used for detailed planning and control of complex program elements.

The initial work assignment for the Technical Analysis Division began with a one and one-half man-year effort. As the project became operational, additional support was added. The level of effort in the first year was $93,000. The project was continued in June 1970 for the second year at $130,000, to which an additional $33,000 was added during the last quarter of the fiscal period. In all, approximately seven man-years and a total of $263,500 were expended during this two-year assignment.

1.5 The Initial Task

The first task to be tackled by Project SOAP, before any meaningful systems analysis could be performed, was the development of a primary information base. They had to find out what functions the various operational programs were currently performing; what kinds of information key decisions depended upon; and, in some sort of logical fashion, to describe what this "present system" consisted of. Each part of the "system" did not exist in isolation but, rather, within a context, or environment, that had to be explicated. Elements of "environment" were originally classified as "internal" (the NIAID context), "external" (the NIH context), or "Institutional" (the real world context), a term which ultimately describes the relationship of both NIAID and NIH to the "outside world."

In setting up this systems framework, organizing the work tasks, and isolating the kinds of problems amenable to solution, the task group found that flowcharts, such as that illustrated in figure 1 (following page), were useful for providing effective communication. They provided a visual means for describing the process under investigation and for identifying the loci of specific problems.

The management problems identified in the NIAID organization could be isolated thus: 1) "operating problems," i.e., problems dealing with routine internal operating situations (such as the processing of approved grants); 2) "strategic problems," i.e., problems relating to the anticipated changes in the external environment (such as program planning and evaluation); and 3) "policy problems," i.e., problems concerning long-term trends in the NIH institutional (outside world) context (such as health research priorities).

As previously stated, the primary aim of Project SOAP was the application of the techniques of systems analysis to the appropriate "problems," once the problems themselves were identified. Where necessary information about the operational effectiveness of particular programs was obscure or even lacking, the introduction of a qualitative, organizing framework was often all that could be immediately provided; but even such first steps proved far from worthless.

PROJECT SOAP: SYSTEMS/OPERATIONS ANALYSIS OF PROGRAMS

National Institute of Allergy and Infectious Diseases

(Biomedical Research & Development Programs)

OBJECTIVES: to define:

THE CONTEXT	Externol/Internol/Institutionol
THE PROBLEMS	Operotionol/Strotegic/Policy
THE APPROACH	Systems Anolysis/O. R. Applicotions

APPROACH:

I. CLIENT--ORIENTATION

Present System Description (Tosk Group) → Desired System Systems Anolysis → Recommended Action / Systems Plonning

II. PROBLEM--ORIENTATION

Problem Definitions
- Objectives
- Constroints
- Voriobles
- Criterio

→ Requirements Plonning
- Gools
- Approoch
- Meosures of Performonce

→ Problem Solving Tosks Defined & Assigned

III. O. R. TECHNIQUES APPLIED

Problem Solving → Results Tested → Solution Evoluoted

TASK GROUP NIAID/TAD

EXPECTED RESULTS:

1. A Management System with increased responsiveness to changing National priorities.
   a. Criteria b. Controls
2. A Pattern of Reasoning useful for guiding discussions: within NIAID; with Study Sections/Advisory Council; with NIH and Bureau of the Budget.
3. Special Analytical Studies pertinent to Operational and Strategic problems of NIAID.

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2/5/70

Figure 1

The "cost/effectiveness" part of systems analysis was necessarily deferred in favor of laying a foundation for determining more precise objectives and criteria, and for obtaining better bases for more policy-relevant data. In the case of the Extramural program, this kind of detailed examination served to focus the Institute's attention on particular information gaps in its primary decision process.

1.6 Systems Description

The primary accomplishment of the initial three-month exploratory phase was what might be termed an "input-output-effect" analysis of two organization divisions of NIAID: the Collaborative Program and the Extramural Program. The results obtained were functional descriptions of the "existing systems," which formed the basis for identifying "problems" and formulating requirements for the "desired systems." Also prepared were descriptive outlines which clarified the meanings of words used by the people making the operational decisions in each program and which documented, in operational terms, the basic activities actually performed. Included were carefully worded brief statements of program goals, objectives, inputs/outputs, and associated performance measures. The attempt here was not as yet to seek to make improvements, only to gather the kinds of information required for "Program Management," in order to accurately describe the decision process.

For example, a decision-oriented information flowchart (see figure 2, following page) was prepared to describe the existing operations of the Extramural Program. The level of detail reflected the understanding of the Institute's Associate Director for that program of what kinds of operational functions were both necessary and sufficient to define his principal decision processes and to relate the "inputs" and "outputs" of the Extramural Program to other organizational components. (A detailed description of these operations, including flowcharts, is contained in Project SOAP Notes No. 3 and 4.*)

1.7 The Desired System

As the current operations became more clearly understood by both the NIAID managers and the SOAP task group, the next question to be answered was: What ought to be the "desired system"? Not unexpectedly, the task group ran into difficulties. By focusing attention on the problem of "What should the system be accomplishing"? the group automatically raised the next question: "What are the criteria for measurement of performance?" In other words, they wanted to know WHAT the organization was attempting to achieve and HOW it actually evaluated its degree of success.

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*"Present System Description, Collaborative Research Program," Project SOAP Notes No. 3, December 15, 1969.

"Extramural Program: Research Grants Award System Description," Project SOAP Notes No. 4, January 30, 1970.

NIAID EXTRAMURAL RESEARCH GRANT AWARDS SYSTEM

TYPICAL FUNCTIONS AND KEY DECISION POINTS

(APPLICATION TYPES 1, 2, 3)

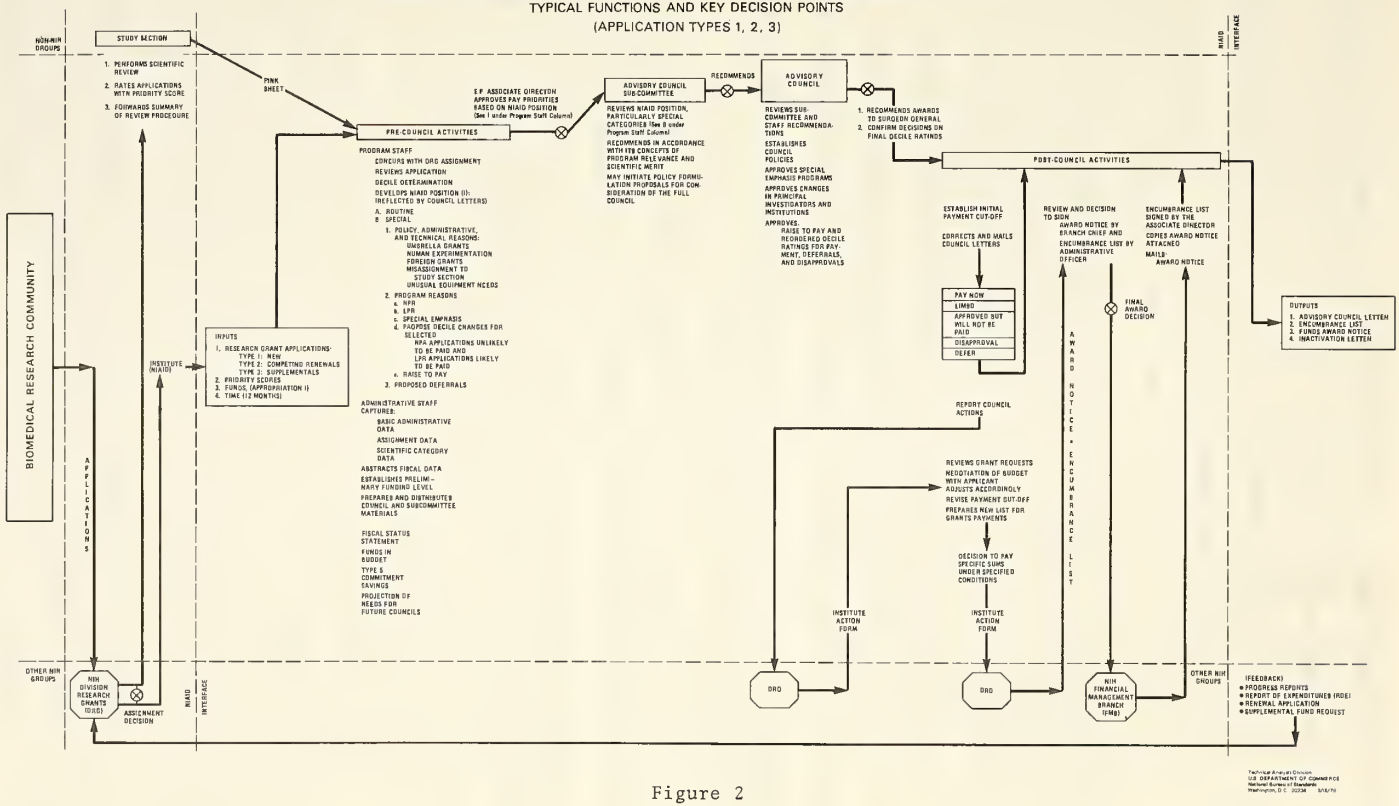

Figure 2

And these questions raised additional questions about WHOM the Institute serves and WHAT are the consequences of its actions?--all important concerns to a management responsible for a $100 million-a-year enterprise.

In this way, the SOAP task group began to lay the framework for an Institute-wide program management system (the "desired system"). This approach, it was hoped, would also eliminate many of the existing internal communications barriers between the Intramural, Extramural and Collaborative divisions by integrating some of their separate efforts toward a common goal: the development of biomedical research programs designed to be more responsive to national health research needs.

The attainment of this paramount goal, it was realized, would require considerable effort. The Institute's basic management functions--planning, organizing, and evaluating--would have to be strengthened, and formal methods and techniques to assist decision-making at various levels would have to be developed.

More specifically, the fundamental management problem confronting NIAID was "allocation of resources." The Institute was searching for a quantitative method for assessing the relevance of both its major research programs and its individual project proposals in terms of its explicit public health mission. During the initial task group orientation, for example, the following memorandum,

by the Assistant Scientific Director for Collaborative Research to his staff, described the type of management system desired by the Institute for evaluating its Collaborative Research Programs in terms of NIAID objectives:

a) Collaborative programs should be extensions of Intramural Research at NIH, to assure the availability of competent Project Officers.
b) Collaborative programs should be coordinated with the Extramural and Intramural Programs of NIAID, with other NIH Institutes and Government agencies, and with any similar research activity in the private sector. Where major technological advances are sought, the interests of prospective user organizations should be an important consideration.
c) Full use of Government, industry, and academic scientists should be made in obtaining advice and assistance in defining the scientific base, goals, and feasibility of new research programs.
d) Programs must have major Institute review and evaluation at intervals not to exceed five years.
e) Contract Review Committees are charged with assessment of technical proposals, contractor's competence and facilities, and reasonableness of budgetary cost and time estimates.*

Furthermore, because of the large number of research proposals which come to NIAID in the form of Extramural Grant applications, or Collaborative contract proposals, or through the research interests of senior scientists on its Intramural Staff, NIAID desired a more systematic means for

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*Memorandum, Dr. John R. Seal to Dr. Dorland J. Davis, Director NIAID, "Role of Scientific Director, Advisory Committees, Branch Chiefs in Collaborative Research," February 9, 1970.

judging what it termed "program relevance": the importance to the Institute of supporting a particular project proposal. It believed that a quantitative method for evaluating program performance in general would offer the potential for improving its current process for selecting research projects and establishing priorities. The sheer volume and complexity of this type of decision-making defied intuitive attempts to arrive at an optimum solution. Nevertheless, definite choices and hard trade-offs were being made--albeit, under tacit assumptions about what was and was not "relevant."

Therefore, the Project SOAP task group set forth to create an awareness of what a systems analysis capability within the NIAID Institute could do for facilitating the development of improved management techniques while, at the same time, promoting the wider acceptance of such new procedures throughout the Institute. While there were some signs after the first year (June 1971) that significant changes in NIAID's management philosophy had taken place, the ultimate effectiveness of the recommended DAPA procedure* developed by the SOAP task group has yet to be realized. The Institute has recently (March 1972) begun to emphasize the planning and evaluation of overall programs (rather than the mere review of the details of individual projects), and it

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*DAPA: Dollar Allocation by Program Area--to be fully explained in the following pages.

has apparently gained confidence in entering more actively into the proposed Dollar Allocation method for guiding investment in socially relevant areas of health research.

To come as far as it did, Project SOAP used an approach which involved three major phases--an Exploratory Phase, a Diagnostic Phase, and a Prescriptive Phase--which are described in the following sections of this report.

2. THE EXPLORATORY PHASE

The Project SOAP task group commenced its assignment with a review of the Collaborative Program. This operational program consists chiefly of target-oriented research projects funded by contracts; it also involves some selected Intramural laboratory activities. It was believed that the techniques of systems analysis--for instance, Program Evaluation and Review Technique (PERT) and Critical Path Method (CPM) Network Planning techniques for organizing time-dependent and information-dependent activities, and the development of briefing charts for progress display purposes--would result in a more effective program management procedure.

The second undertaking involved the Extramural Program. It included the development of an operational flowchart (see previously mentioned figure 2) and studies of the implications of the "Decile System"* and of the current allocation procedure for awarding research project grants, including an investigation of criteria for selecting Special Emphasis projects. The objective was more explicit criteria, leading in turn to improved operating procedures.

A brief management overview of the NIAID Institute and its operating activities and procedures is given next, as background for the subsequent accounts of the two specific tasks sketched above.

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*A ranking method for equalizing the distribution of project grant priorities recommended by the various Study Sections.

2.1 The Institute's Organization

The operations of NIAID are divided into three major divisions: the Intramural Program, which includes the research conducted by the in-house laboratories; the Extramural Program, which is concerned primarily with research and training grants awarded to individual outside investigators; and the Collaborative Program, which directs, under contract, research with industry and other institutions. To put it another way, the operations are divided into three major organizational activities: General Laboratories and Clinics (Intramural), Research and Training Grants (Extramural), and Nationally Organized Research Programs (Collaborative). Below are more fully expanded functional descriptions of the Collaborative and Extramural programs as they existed when the SOAP Task Group was first introduced to them in October 1969.

2.1.1 Collaborative Research Program Operations

The Collaborative Research (and development) Program is one of the three major operational units of the Institute. It differs from the others in that its operations are conducted primarily through contracts with outside companies and research laboratories. Its role is to direct, coordinate, and provide support for developmental research on specific biomedical products and related scientific information.

The Collaborative program's major purpose is the translation of the findings of basic research (biomedical knowledge) into methods or products for the treatment and control of allergic and infectious diseases. Specific objectives are: the development and testing of specific vaccines against viral and bacterial agents; the production, control and distribution of biomedical research reference reagents; and the development of methods and knowledge about various types of human tissues and their compatibility with other tissues for use in transplantation of human organs. In addition, the members of the staff provide support and scientific management for two international programs: a cooperative medical program with Japan, and a domestic research and training program with an international component.

These collaborative efforts are conducted via the mechanism of research contracts with industry, universities, federal agencies, and other biomedical organizations. They are directed by members of the NIAID scientific and administrative staff, with advice and counsel obtained from various ad hoc advisory groups.

The Contract Review Group (CRG)*, composed of the top management team, review each contract proposed for the development of specific outputs, such as new experimental vaccines. They examine the basic data and contractors' proposals for development and production, and then approve those proposals which they find best meet the Institute's needs in that area, such as the development of a new vaccine.

2.1.2 Extramural Research Program Operations

The Extramural Research Program provides support, through the mechanism of research grants, to public and other non-profit institutions and investigators to establish, expand, and improve research activities in the health sciences and related fields.

The existing process for the award of Extramural research grants begins when applications are received by NIH from prospective research investigators. Each application is assigned by the NIH Division of Research Grants (DRG) to a categorical Institute

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*Contract Review Group. Its members are the Institute Director, the Scientific Director, the Assistant Scientific Director, the Associate Director for Collaborative Research, the Associate Director for Extramural Programs, the Special Assistant to the Director, the Executive Officer, and the Chief of Program Planning.

(such as NIAID) whose mission most closely involves the proposed research activities, and to one of 55 Study Sections (discipline-oriented Peer Review Groups) for review and assessment. This process for selecting recipients for project grants from NIH is widely known and accepted by many segments of the scientific community. It is similar in principle to that used by other Government agencies supporting basic research, like the Atomic Energy Commission and the National Science Foundation.

(As previously stated, the Project SOAP task group did not examine the activities of the Intramural Program because it was undergoing a reorganization at the time.)

The number of programs within these three organizational divisions--the Intramural, the Collaborative, and the Extramural--could total anywhere from ten to about fifty, depending on the enumerator's choice among various meanings of the word "program." Activities wholly within the Collaborative Research Program, such as the Vaccine Development Program, or the Pneumococcal Vaccine Program, or the Research Reference Reagents Program, etc., were frequently spoken of simply as "programs." In the Extramural organization there were research activities supported by grants in loosely defined areas called Special Emphasis Research Programs, such as Transplantation Immunology, Infectious Hepatitis and Antiviral Substances. The fact was that a kind of vagueness about many of the terms

used by members of the Institute--terms such as "program"--accounted for the serious semantic difficulties the SOAP group encountered while attempting to formalize precise "systems descriptions."

2.2 Grant Allocation Procedure

The allocation of resources to Extramural project grants had been a major concern of the NIAID Institute for a number of years. Since 1962, the "decile system" has been used by the Institute as the basis for allocating grants. It employs a decile-ranking method for equalizing the distribution of priorities recommended by some ten to twenty different Study Sections. Following is a more detailed description of the system as employed by NIAID.

THE DECILE SYSTEM OF THE NIAID

Since 1962, the National Institute of Allergy and Infectious Diseases has used a "decile" system to equalize the differing levels of priorities on research grant applications recommended by different Study Sections. The details of this system and some of its effects are described below.

In accordance with the policy of the National Institutes of Health, every Study Section provides a priority score for each application recommended for approval by the majority of its participating members (for grants assigned to NIAID for payment). This priority score is derived in the following manner:

1. Each participating Study Section member rates every approved application on the basis of order of payment from 1 (first order) to 5 (last order). Criteria used in making this judgment include scientific merit, study design, originality, competence of investigator, and adequacy of working environment.

2. After the meeting, scores for each application are averaged and the result multiplied by 100 to provide a 3-digit rating.

3. The resulting priority score is recorded on a confidential "resume" of actions of the Study Section and is distributed to the awarding Institutes/Divisions.

When such a "resume" is received by the NIAID, all priority scores for that Study Section are listed in numerical order, regardless of the Institute to which assigned. The list is then divided into 10 equal parts known as "deciles," with the first decile representing the most favorable priority. If an application ties with another or falls between deciles, it receives the more favorable rating. The decile number is then marked on each summary sheet sent to the Council. Applications falling in the 10th decile are not paid unless the priority is raised by specific vote of Council.

Throughout a fiscal year, awards are made on grants which fall in the most favorable deciles to the financial level that can be maintained throughout the year. Renewal grants in the least favorable deciles are brought to a termination and those in the intermediate deciles are extended with the expectation that they will be renewed later in the year if sufficient funds become available. After the March NAAIDC meeting, applications in less favorable deciles from this and prior Council meetings are awarded in order as long as funds are available. Unless an applicant withdraws a pending application, it remains in competition for available funds until the end of the fiscal year.*

Various methods for managing the allocation of grants had been proposed, and the one in use partially reordered the Study Section-imposed priority ranks of approved applications in accordance with Institute preference criteria, termed "program relevance." This method had not proven entirely satisfactory to all members of the Advisory Council.

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*See also footnote (*), p. 34.

Selected grant proposals in Special Emphasis Research categories were given an "HPR"* rating, resulting in an arbitrary two-decile escalation and often raising them to payment status. This practice (facetiously described as "decile-diddling") effectively introduced the Institute Staff's program preferences but did not provide the Advisory Council with the kinds of information that several members felt were needed "to make responsible recommendations."**

2.3 Program Relevance Concept

It was primarily this dilemma--whether to use Study Section priority scores "as is" or to modify them by the Institute's program relevance ratings in order to determine payment priorities--that led the Institute Director to appoint a special subcommittee of the Advisory Council to look into the matter. Specifically, the Criteria Subcommittee was to develop an acceptable concept of "relevance"

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*HPR: A rating given a particular project considered by the Institute to be of "High Program Relevance." The use of preferential payment designations "HPR," "LPR," and "NPR" evolved over several Council meetings between the years 1965 and 1969. As the effects of such reordering of Study Sections' priority recommendations (two decile levels, up or down) were felt by the scientific community, and reacted to by the Advisory Council, steps toward modification of this procedure were taken. Finally, at the March 1970 Council meeting, a motion was carried to discontinue the LPR and NPR ratings until the basic questions concerning the staff's preferential payment criteria could be clarified and an improved operating procedure adopted.

**Dr. Churchman, November 1970 Council Meeting.

and establish explicit criteria for use in judging factors associated with "relevance." In addition, they were to consider an improved relevance rating procedure.

The plain fact of the matter was that the Study Section members themselves realized that all their time and effort spent on reviewing a particular grant in a research area might come to naught; regardless of its scientific merit, a particular aspect of research might not get funded if it were not deemed "relevant" to some mission. Similarly, they realized, nationally recognized scientists might not receive support for work they considered extremely important to a particular area because their work was judged "non-relevant," while inferior scientists might receive support because their work was judged "more relevant."

3. THE DIAGNOSTIC PHASE

The purpose of this phase was the diagnosis of key issues requiring policy-level resolution before an analysis of possible operational changes could be made.

The following is a brief outline of Project SOAP's identification of three principal factors associated with the management of the Extramural Program:

- Study Section Priority Scores
- Program Relevance Criteria
- Preferential Payment Procedure

3.1 The Preferential Payment Issue

In 1966, when the NIAID originally presented its plan for stimulating and supporting, preferentially through grants, more original investigations bearing on disease problems deemed of special importance, its advisory committees (particularly its Advisory Council) gave consideration to ways in which such a programmatic structure could be achieved within the Extramural Program.

The following year, the Institute's staff, with the help of its Advisory Council, identified several areas of "high program relevance" which they began to call Special Emphasis Research Programs. They felt these fields of biomedical research were deserving of special emphasis within the context of the Extramural Program. At that time, these areas comprised about 35 percent of grant projects and

funds. They were judged to be of greater importance to the health needs of the nation than other areas. The intention clearly was not to limit or to direct original scientific research supported by NIAID grants but, rather, to give scope to individual investigators in pursuing their preferred lines of research in a way which would foster advancement on disease problems of greatest national importance.*

The challenge was clear, but the mechanism was not, especially during the subsequent fiscal retrenchment which, for the next several years, resulted in making payment priority decisions difficult for the Institute.

In the opinion of several outspoken members of the Advisory Council, the review of any publicly-funded program requires, at the outset, clarification and agreement on a statement of program goals and priorities. These individuals have pointed out that such a requirement is of particular importance when budgets are limited and apparently worthy efforts must go unfunded.

A substantial number of Study Section participants in the NIAID Extramural grants award process felt, however, that considerations other than intrinsic scientific quality ought not to influence research grant payment. This was confirmed

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*Dorland J. Davis, "Remarks on Special Emphasis Programs of the National Institute of Allergy and Infectious Diseases," The Journal of Infectious Diseases, University of Chicago, Vol. 121, No. 2, February 1970, p. 231.

by the study of rating criteria in Exercise II.* One of the basic difficulties appeared to lie in an uncertainty about desired "ends," a dilemma which is associated with the current debate between applied research vs. basic research. Questions raised by this situation can perhaps be phrased thusly: Is the Advisory Council expected to develop planning criteria, provide judgment on program balance, and evaluate program implementation, or is it merely to reassure the Institute's Director that the Extramural program is moving along the right track?

3.1.1 Study Section Priority Scores

It became a matter of concern to members of NIAID's National Advisory Council that different interpretations were being given by different Study Sections to their "scientific merit" judgments and resulting priority

*Exercise II, "Biomedical Research Relevance Criteria," Project SOAP, National Bureau of Standards Report No. 10-423, June 30, 1971. This Exercise will be explained in the following pages.

scores.* Study Sections were never required to provide explicit advice on order of payment, but practical considerations in some NIH Institutes made such rating scores useful for payment priority purposes.

The priority scores were ostensibly based on considerations of "scientific merit," but, in reality, the scores reflected the Study Section members' personal notions of the extent or degree to which the proposal should be supported by extramural funds. (An earlier study of NIH grant application procedures by Saunders and Gordon** concluded that Study Section priority scores had become "a haphazard mixture of two separable considerations"

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*A priority score was traditionally derived in the following manner:

1. Each participating Study Section member rated every "approved" grant application on the basis of "scientific merit" from 1.0 (highest) to 4.5 (lowest) in 0.5 increments.
2. These two-digit ratings for each application were averaged and the result multiplied by 100 to provide a three-digit numerical score.
3. The resulting "priority score" was recorded on a confidential resume of action by the Study Section and distributed to the previously designated NIH Institute for funding.

An example: Each of six Study Sections assigns "scientific merit" scores 1.5, 2.5, 2.0, 1.5, 2.0, 2.5.

$$\text{Priority Score} = \frac{1}{6}(1.5 + 2.5 + 2.0 + 1.5 + 2.0 + 2.5) \times 100 = \frac{12.0}{6} \times 100 = 200.$$

**Saunders, J. Palmer and Gordon, Mordecai, H., "NIH Study Section Ratings: Scientific Merit or Order of Payment," National Cancer Institute (1965).

referring respectively to the evaluation of research grant proposals for scientific "quality" and for "order of payment." Their hypothesis of separability was inferred statistically from the scores of four Study Sections who reviewed 225 individual Extramural research grant applications assigned to the National Cancer Institute in 1965.)

The fact of the matter was that the components of the concept of "scientific merit" as applied by the Study Sections were not explicitly known. The resulting confusion raised the question of the appropriateness of certain other criteria in this decision process and thus the desirability of using multiple criteria judgments as the basis for determining grant payment priority.

3.1.2 "Program Relevance" Criteria

During the March 1970 Advisory Council Meeting, several members voiced concern about how decisions were made on matters pertaining to "program relevance." They wanted to know, specifically, what "criteria" were used for determining HIGH, LOW, or NO "program relevance." A motion was made and carried by the majority that the "Council not consider Low Program Relevance (LPR) or NO Program Relevance (NPR) ratings in evaluating payment of grants."* This meant that the Council would no longer consider these special cases until further informa-

*Minutes of March 1970 meeting, NIAID Council, March 18, 1970.

tion was provided about the criteria used. "HPR" was allowed, however, in order to provide in the interim some expression of Institute payment preference.

3.1.3 Preferential Payment Procedure

Normally, the NIH Extramural grant review procedure is explicitly concerned with the "scientific merit" of the proposals, with other aspects represented only implicitly. However, biomedical research supported by NIAID and the other Institutes of NIH affects ultimately the health and well-being of the entire American people. Realization of this fact has underscored legislation concerning NIH for over 25 years, with confirmation of benefits from several viewpoints: physical, social and economic.* Both fundamental and applied research produce new knowledge which can make immediate or long-range contributions toward the effective control of certain diseases and associated health problems.

Grant proposals selected for the Special Emphasis Research categories were given an "HPR" rating, resulting in an arbitrary two-decile escalation, which often raised them to payment status. This practice introduced the Institute's preferences ("program relevance") but did not provide the Advisory Council with the kind of information it felt was needed before it could make responsible

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*See Stephen P. Strickland, "Policy Making in Biomedical Research: A Perspective on Relevance," Project SOAP Notes No. 16, March 15, 1971.

recommendations. For example, the Council wanted to know the effect of such re-ranking action on the other competing grants, the relative "importance" to the Nation's health of each Special Emphasis area, and the rationale or plan behind each selection of such an area. The task group set out to satisfy these needs.

3.2 Preliminary Study of "Health Relevance" Assessment (Exercise I)

In June 1970, Project SOAP conducted a limited investigation among the three members of the Advisory Council Criteria Subcommittee: Drs. C. West Churchman, Irwin C. Gunsalus, and Maxwell I. Wintrobe. They agreed to try to assess "health relevance" as a concept distinct from "scientific merit." Twenty applications were sent by mail to each of the three Criteria Subcommittee members. Their review was made without knowledge of the "scientific merit" priority scores, and without any discussion or communication between the three members.

The results of this study, based on a cursory analysis of the twenty "relevance" rating scores, indicated that it was possible for Advisory Council members to attach a "health relevance" category to proposals, and that there appeared to be some interesting relationships between the scores of this Ad Hoc Group and the NIH Study Sections' priority scores. For example, comparison of these

relevance scores with the priority scores for the same proposals showed that eight out of 11 judged "high" for "scientific merit" scored "high" for "health relevance," and four out of six judged "low" for "scientific merit" scored "low" for "health relevance." The consensus of the group was that, in spite of the lack of specified criteria, there appeared to be some commonly held basis for assessing "relevance."

These findings were presented by the chairman of the Criteria Subcommittee to the NIAID Advisory Council at its June 1970 meeting. This led to the Council's recommending an expansion of the study of relevance criteria (Exercise II), with instructions to include a more representative sample of research grant applications and a wider participation by other qualified reviewers.

3.3 Biomedical Research Relevance Criteria (Exercise II)

This more comprehensive exploratory investigation was made in September 1970 in an attempt to improve the general understanding of the decision process for awarding Extramural research project grants at NIAID. Exercise II involved a dual review, the rating of research proposals separately, first, for "scientific merit" and, second, for "health relevance;" and it attempted to identify the various decision criteria used by different groups within the NIH Extramural grants award system.

A total of 120 professionals, most of whom were directly involved in the system of awarding grants, were grouped into six "juries" for this exercise. Each participant rated a sample of 24 research applications (or subsample of that 24) on dimensions of "scientific merit" and/or "health relevance." These ratings were analyzed to determine if there existed a meaningful and consistent concept underlying these dimensions and, if so, what the characteristics of this concept were. Corollary evidence was obtained from statements of criteria elicited from some of the participants.

Analyses of jury mean scores (using nonparametric correlation techniques) indicated that there were statistically significant similarities among juries in scores associated with "health relevance" for the sample applications rated. One jury, composed of six Study Sections, both reported and exhibited its inability to distinguish clearly between assessments for "health relevance" and those for "scientific merit." The general consistency among the "health relevance" ratings and their agreement with the "scientific merit" ranking suggested that the Study Sections' judgments about priorities were generally related to their concept of "scientific merit," at least on these test applications. Characteristics of the criteria stated by individual jurors as their bases for judgment, moreover, documented the existence of review considerations other than scientific quality.

The results of this exercise were not definitive. However, certain characteristics were indicated. There was general although not unanimous agreement among reviewers about their concepts of "health relevance." (The lack of unanimity was not surprising, since the concept of "health relevance" is a complex one requiring greater specificity to assure a common understanding.) The concept underlying "scientific merit" as interpreted by Study Sections included more than simple scientific quality considerations. This additional dimension was closely related to their concept of "order of payment."

4. THE PRESCRIPTIVE PHASE

The accomplishment of this phase was the formulation of specific guidelines and recommendations leading to an improved Program Management discipline for NIAID. Several mutually related actions pertaining to resource allocation and NIAID Program Management were recommended.

4.1 The Program Management Concept

The system recommended for managing the various programs, projects, and activities within the Institute was shown in comparison to the then-present mode of operation (see figure 3, following page). The principal attributes of the existing system were characterized as being detailed, retrospective, and custodial in nature. By comparison, the proposed management system provided a broader perspective and depended upon anticipatory planning and the use of explicit measures of performance. This was considered to be a desirable improvement by many Council members and Institute Staff.

Under the existing system, the cost/effectiveness relationships were highly subjective. Moreover, the payment priority advice was received from many individual Study Sections that might not have had appreciation of the Institute's major health research programs. The basic improvement in resource allocation desired by the Institute required a means for maintaining some proper balance between its two primary mission goals: the support of basic science,

PROJECT SOAP RECOMMENDATIONS

DECISION LEVEL	PRESENT SYSTEM	PROPOSED SYSTEM	DESIRED IMPROVEMENTS
COUNCIL POLICY	• Detailed • Supervisory • Retrospective	• Overview • Advisory • Anticipatory	Explicit policy goals: • Science Support • Health Research • Research Investment Plan
MANAGEMENT STRATEGY	• Input-Oriented • Discipline Custodian • Distribution	• Output-Oriented • Program Manager • Investment	• Program Planning & Evaluation (Coupling Means/Ends) • Measures of performance: • Research Effectiveness • Social/Economic Indicators • Balanced Costs
OPERATIONAL PROCEDURE	DECILE	DAPA	Institute Determination of Priorities Communicate "Reasoning"

Project SOAP
Technical Analysis Division
National Bureau of Standards

Figure 3

and the achievement of targeted research. In addition, there was need for a consistent method for communicating the Institute's programs, plans, and performance to others (inside and outside), while also providing a more rational basis for decision-making, particularly for the Extramural Grants Program.

Furthermore, to remedy the Institute's problem in determining a preferred order of payment for grants, Project SOAP recommended a management concept for coordinating the planning, budgeting, and resource allocation decisions in a way that would provide the Institute greater control over its program performance.

The resource allocation problem was reduced to three sets of decisions within the Institute: 1) the program planning decision, 2) the "scientific merit" rank decision, and 3) the program category assignment decision. The effect was to delegate to the operational level the authority to judge the relevance or contribution of a particular research project proposal and to assign it to a proper program category. These categories were the ones associated with a prior Council commitment of funds to a Special Emphasis Research area in which the ultimate solution of a particular disease problem was being sought.

Progress toward such health-oriented goals could be assessed by the estimated reduction in time and resources remaining to reach a level of scientific knowledge which, in the opinion of experts, is sufficient to transfer the project to the Intramural/Collaborative Program (supported by other funds). In the event such progress lagged, a decision could be made to abandon the particular approach by phasing out investment in it. In either case, the appropriate funding (transfer or abandonment) would call for Council/Staff/Institute interaction.

While this summation is a simplification of the Institute's program management role, it clearly indicates a resolution of the major portion of the dissonance in the current "dual-review" system which stemmed from the failure to define and delegate clear functions to each level in the decision-making hierarchy.

4.2 Recommended Criteria for Extramural Program Management

As a result of analysis of the criteria statements received during the research relevance exercises (Exercise I and II, mentioned above) and subsequent discussions with members of the Institute's Staff and Advisory Council, Project SOAP recommended the following four criteria* for evaluating Extramural research projects for quality, importance, and cost:

*For a more comprehensive explanation, see "Recommended Criteria for Extramural Program Management," Project SOAP Notes No. 17, March 15, 1971.

I. Quality of Research ("Scientific Merit")

II. Importance (Relevance) to Health Research Programs

III. Distribution of Funds Between Programs (Short-Term Balance)

IV. Investment in Science (Long-Range Forecast)

It is expected that these "Guideline Criteria" will develop for the Institute a more explicit pattern of reasoning for guiding the decision-making process between the Council, the Staff, the Study Sections, and the Division of Research Grants of NIH. Later, these guidelines can be used to establish a basis for assessing and revising the Institute's Special Emphasis Research Programs. Thus, they can become the medium for communicating Extramural Program priorities to NIH, the Office of Management and Budget, the Congress, and the scientific community at large.

4.3 Research Investment Procedure: Dollar Allocation by Program Area (DAPA)

After exploring several possible approaches to solving NIAID's priority management problems, Project SOAP concluded its study with a proposal for a new procedure. The "Dollar Allocation by Program Area: An Investment Procedure" was presented to and accepted by the NIAID Advisory Council at its March 18, 1971, meeting.

DAPA is an alternative to decile manipulation as a device for allocating funds to Extramural research activities.* It is based on the concept of capital investment to areas of socially important health research, within the context of projects supported by NIAID Extramural grants. The procedure is designed to replace the present "program relevance-decile adjustment" system, while also preserving the existing practice of ordinal ranking for "scientific merit" by the Study Sections.

This procedure is analogous to a two-part securities investment portfolio, such as that for common stocks and bonds. Figure 4 (following page) shows how research funds had previously been allocated and served to indicate to the Advisory Council and NIAID staff certain funding imbalances in their existing program structure. This illustrates a feature of using DAPA. The first part of the portfolio reflects selected investments in specified Special Emphasis Program areas (SERP's) of particular importance to the mission of the Institute. The purpose of these SERP's is to increase the probability of yielding "health relevant" results from grant-supported research. The second part concerns investments of Extramural funds in support of free-ranging investigator-inspired research. Grant applications are paid in order of peer-recommended "scientific merit" priority scores.

*For a detailed description, see "DAPA Research Investment Procedure," Project SOAP Notes No. 19, June 15, 1971.

NIAID Extramural Research Project Grants
DAPA Research Investment Portfolio
(March 1971)

Program Category	Number of Grants	$ Million Amount	Percent Extramural Budget
I. Special Emphasis Research Programs			
A. Clinical Allergy	58	3.2	6.3%
B. Transplantation Immunology	71	3.7	7.3%
C. Strep. Disease & Sequelae	25	0.9	1.8%
D. Drug Resistance	210	7.1	13.9%
E. Infectious Hepatitis	5	0.3	0.6%
F. Chronic & Degenerative Diseases	45	1.5	2.9%
G. Antiviral Substances (Interferon)	116	5.3	10.4%
H. Biological Regulation of Vectors	40	1.4	2.8%
I. Immunity to Animal Parasites	44	1.4	2.8%
SERP Total	614	24.8	48.8%
II. Investigator Inspired Research Projects	565	23.7	46.5%
III. Other Research Projects	66	2.4	4.7%
TOTAL	1,245	$50.9	100.0%

Figure 4

4.3.1 The DAPA Procedure

At least once a year, the Advisory Council meets to advise the Institute on Extramural Program investment policy. The Institute staff provides a review of present SERP activities, with summaries of the distribution of funds to grantees in each support area. Staff also submits a proposed investment plan for Council approval, which includes necessary historical perspectives of specific programs.. Recommendations for new SERP's or terminations of present ones would require support documentation. Incremental adjustments within previously approved guideline ranges need only be proposed to the Council for approval.

After Staff's presentation, the Council may deliberate the merits and implications of the plan as well as call upon outside experts for additional information. The Council then resolves the issue by "approving" a modification of the Institute's investment proposal. This includes the total dollars and percentage range to be allocated for: 1) free-ranging research projects, and 2) each Special Emphasis Research Program category. Also to be approved (perhaps with modifications) are statements describing each SERP's area (Program Definition Statements), including its specific goals, scope, research characteristics and a brief state-of-the-art summary.

Special Subcommittees of the Advisory Council ad hoc advisors, and Institute Staff would be appointed and

specifically assigned Extramural program planning and evaluation functions. These working groups would meet during periods between scheduled Council meetings to determine the nature and magnitude of each approved SERP category, including major revisions if warranted. Specialized information and competent advice from other advisory groups (like Study Sections, consultant experts, and contract studies) would be available to them.

Pertinent health statistics on disease/disease problems, populations, specific disease mortality and morbidity rates, hospitalization costs, epidemiology, and related health information will be included. The use of these data suitably combined in an appropriate model would provide a quantitative basis for establishing the programmatic "health relevance" for each SERP category.

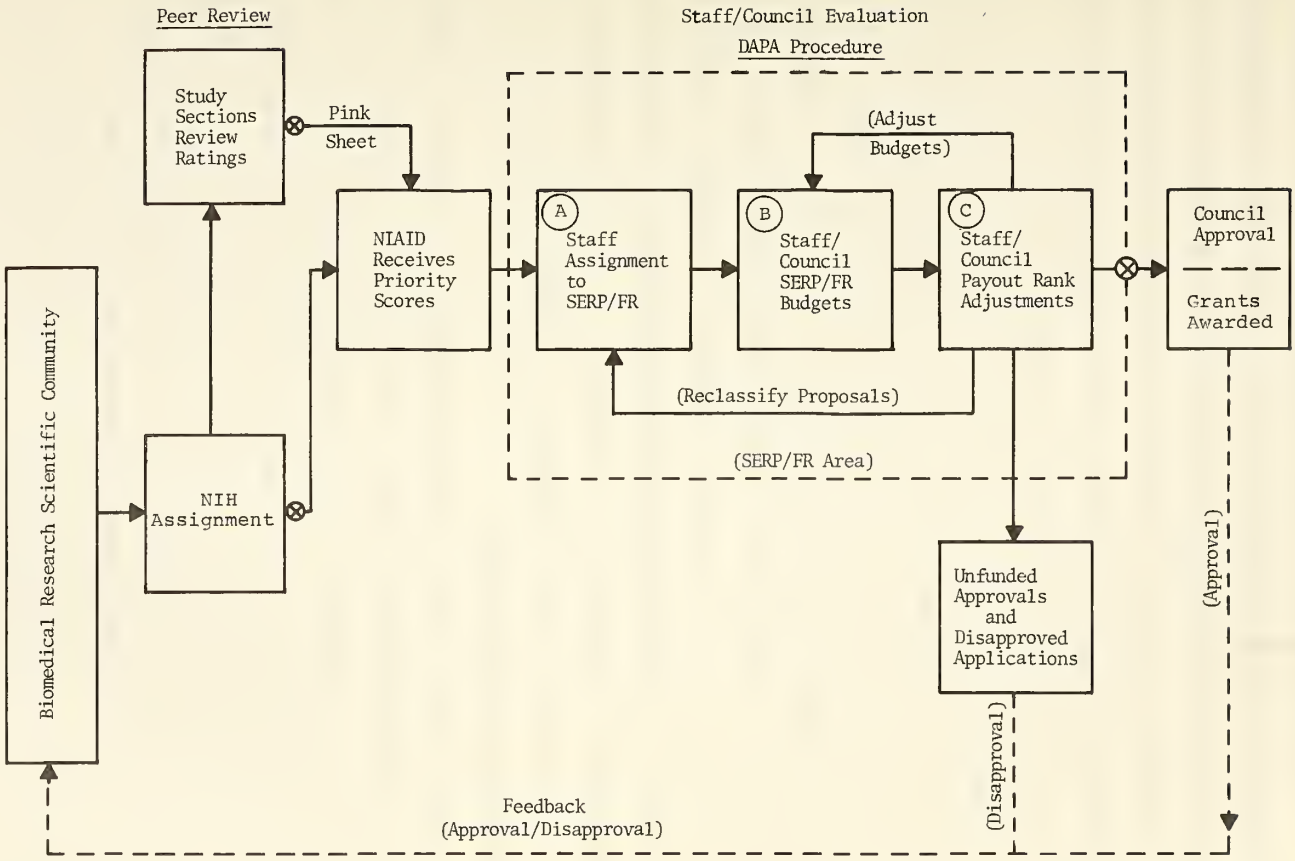
The qualitative judgments of the Staff/Council Subcommittee would, of course, require such data as a basis for proposing appropriate levels of investment and establishing SERP payment priorities.

In brief, the DAPA procedure is part of a program management discipline for distributing limited research funds. It provides a reasonable method for Staff/Council interaction in balancing budget allocations between desired ends (health research "needs") and available means (biomedical research opportunities), while at the same time relieving the Advisory Council of the task of reviewing

each individual grant proposal recommended by the Study Sections for payment approval. (A flow chart of the DAPA Procedure is shown in figure 5, following page.)

Grants supporting free-ranging (FR) research investigators would continue to be awarded on the basis of Study Section priority scores. Those proposals which further qualify for support under one of the Institute's Special Emphasis Research Programs would be paid, on the basis of similar order of priority scores, to the limit of designated program funds allocated to each prior approved category.

The application of the results of this systematic planning and evaluating process would become the responsibility of each SERP Program Manager appointed by the Director, subject to the advice and continued review of his subcommittee. When a particular SERP category has reached maturity (attained that "critical mass" of fundamental knowledge required for applied research--as the category of hepatitis did a few years ago), the decision to "transfer" support and scientific review to a more appropriate Intramural or Collaborative research activity within the Institute could be made. This ultimately would lead to more direct health research applications in one of the NIAID Institute's national clinical centers.



Project SOAP
Technical Analysis Division
National Bureau of Standards

Figure 5 DAPA RESEARCH INVESTMENT PROCEDURE

Program areas and their budgets would be reviewed regularly by Staff and modified by Council/Staff agreement, as new and more current information is obtained. Progress or stagnation could thereby be more clearly discerned, with greater assurance of the Council's making timely assessments as well as fully-based initial decisions.

Implicit in the DAPA approach is the necessity of professional judgment and reliable information upon which to base these decisions. Under existing conditions of great uncertainty regarding the technological, economic, and social feasibility of emphasizing a particular field of research, this procedure provides increased flexibility for guiding the Extramural program planning and evaluation activities. Moreover, it offers an operational method for potentially doing a better job with the skills and resources available.

The Project SOAP task group believes that the use of the dollar allocation method (DAPA) could become an important management tool for science administrators elsewhere within NIH for negotiating the "health relevance" of biomedical research programs with the Office of Management and Budget. Further testing and evaluation of the DAPA Research Investment Procedure was, therefore, recommended. As noted earlier, initial steps have been indicated in this direction.

Because of its potential importance for long range program planning, the Task Group also investigated the possibility of developing a Biomedical Research Utility Model to aid in planning and evaluating the social/economic impacts of major health research programs. This part of the study, which is contained in Project SOAP Notes No. 14, was not implemented due to initial reluctance on the part of NIAID Staff to embrace so sophisticated a modeling method without a greater understanding of and confidence in the validity of its results. The model basically employed statistical data from epidemiological sources to evaluate the National importance of a particular disease.

It attempted to estimate the "economic cost" to the Nation in terms of medical expenses, hospitalization costs, lost work time, and a factor for human discomfort. The approach is similar to that for estimating insurance risk, but does not have the advantage of clear empirical data. For this reason, it was felt the actual application of a Biomedical Research Utility Model was premature.

(Developing such models is, of course, a difficult and demanding task, but an inescapable one in arriving at an appropriate quantitative basis for the inherently quantitative decisions of resource allocation.)

5. CONCLUSION

Summing up: this case study documents the methodology and substantive information developed by the Project SOAP task group during its two-year assignment to perform analytical studies for the National Institute of Allergy and Infectious Diseases of the National Institutes of Health between 1969 and 1971.

Project SOAP created for NIAID a clearer understanding and a more focused awareness of the nature of its resource allocation problems, particularly those of the Extramural Grant Program. This first step was reflected in the action taken by the NIAID Advisory Council at its meeting, June 21, 1971. (See following page, which was abstracted from the official minutes of the June 1971 Council.)

It would be unreasonable to expect that any task group could attain so profound an insight into the myriad problems of a complex organization that it could actually identify any one problem as the crux of matter and determine how it should be solved. There are certain problems far too complicated for systems analysis as yet to comprehend. Nevertheless, given its limited scope of understanding in approaching the management situation it faced, the Project SOAP task group stimulated NIAID to perceive its new role in a changing environment: that of managing its resources explicitly. With this new awareness, NIAID was then in a far better position to accept and adopt the use of recommended management methods for improving its decision-making processes.

Report of NIAID Advisory Council Meeting

(Abstracted from Official Minutes of the June 1971 Council
National Institute of Allergy and Infectious Diseases/NIH)

Allocation of Extramural Resources
(Informational)

The first step in implementation of the "Dollar Allocation Program" is taken.

In taking the first step in the implementation of the "Dollar Allocation Program" which has evolved from the Institute-sponsored SOAP study, Council reviewed the Special Emphasis programs of the Institute, including the definitions of these programs, and the funds which might be allocated to them. Rather than following the past procedure of raising selected research grant applications to payable priority scores they concluded that during FY 72, funds should be allocated to specific programs to enable the payment of more applications assigned to these programs. The Council would review this allocation at each of its subsequent meetings and would not, with the present limit of funds, approve the payment of research grants beyond the upper 60% of approved applications in any of the programs receiving special allocation.

In the future, Council will be emphasizing review of programs rather than review of individual projects within these programs. The Council chose to continue the present discipline-oriented subcommittee system for the review of Institute programs as well as for the grants assigned to them.

Background:

In 1969 an Interagency Agreement between the Technical Analysis Division of the National Bureau of Standards and the NIAID was entered into for the purpose of developing criteria for the selection of grants and/or programs for preferential treatment to better meet the needs of the health problems of the country. The Criteria Subcommittee of Council was appointed to act as liaison between Project SOAP (Systems/ Operations Analysis of Programs), the working group of this agreement, and the Council in these efforts. After tentatively exploring a number of possible avenues, the Dollar Allocation for Program Areas was presented to and accepted by Council at the March 1971 meeting.

Council instructed staff to redefine, in a more concise manner, the Special Emphasis areas of the Institute for consideration by Council at the June meeting. It was agreed that the dollar allocation approach would be entered into gradually. Program definitions were reviewed carefully, revised by staff and were presented to this Council for consideration.

PARTICIPANTS

We acknowledge with gratitude the helpful contributions of the following persons to the various activities associated with this joint task group:

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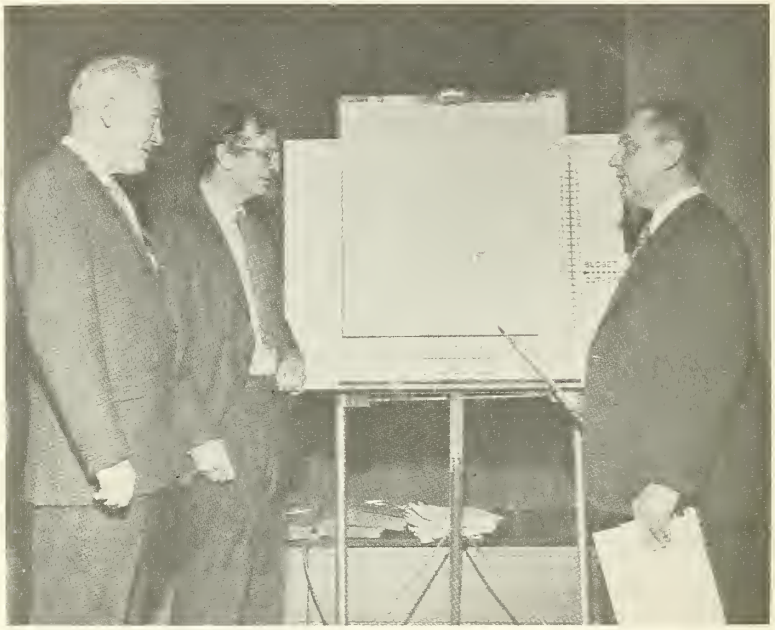
Deserving of special recognition are those individuals who gave invaluable help to Project SOAP. They are: Dr. Mary Ellen Golby, who edited the material that appears in this document, Drs. Alexander R. Craw and Alan J. Goldman, who critically reviewed the successive drafts of the manuscript, and Mr. Louis C. Santone, who provided encouragement and financial support for its documentation. Special acknowledgment is also due Mrs. Janette E. Taylor, without whose assistance this report would not have been possible.

Above, Dr. C. West Churchman, Professor of Business Administration, University of California and chairman of the Criteria Subcommittee, presents the results of this exercise to Dr. Dorland J. Davis, NIAID Director, at right of chart. Looking on are members of Project SOAP task group, left to right: Vincent A. Martino, TAD/NBS; Dr. Alfred M. Webb, Chief, Program Planning, NIAID; Dr. Davis; Robert S. Cutler, Project Leader, TAD/NBS; and Charles Myers, Management Analysis Officer, NIAID.

PROJECT SOAP ISSUES PRELIMINARY FINDINGS ON 'HEALTH RELEVANCE' RATING EXERCISE



A recent interagency agreement between IAT's Technical Analysis Division (TAD) and the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health, resulted in the creation of Project SOAP. Not a detergent, Project SOAP (System/Operations Analysis Programs) is concerned with developing quantitative methods for determining priorities in allocating NIAID's limited research funds. One issue considered was whether it would be feasible to give some weight to the "health relevance" of research projects in deciding whether to fund extramural research grant applications. Preliminary findings by TAD indicate that it is indeed practical and possible to consider the health relevance of a proposed research project as well as its "scientific merit" implications. Implicit in these findings is the need for development of "criteria" for health relevance, and work is currently in progress along those lines.

Above, far right, Dr. W. E. Cushen, Chief of TAD, presents the results of the health relevance analysis to (left) Dr. Dorland J. Davis, Director of NIAID, and Dr. C. West Churchman, Professor of Business Administration, University of California, and Chairman of the NIAID Advisory Council Subcommittee on Criteria.

Reprinted from the NBS Standard, Vol. XVI, No. 2 (February 1971).

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APPENDIX

(Sections A and B)

SECTION A - LIST OF NOTES AND WORKING PAPERS

PROJECT SOAP NOTES*

Notes No.	Author	Title	Date
1.	Robert S. Cutler	"Definition of Terms"	Aug. 29, 1969
2.	Robert S. Cutler	"Systems Concepts Re: Program Management"	Sept. 26, 1969
3.	Vincent A. Martino Robert S. Cutler	"Systems Description of Collaborative Research Program"	Dec. 15, 1969
4.	Robert S. Cutler Vincent A. Martino	"Extramural Program: Research Grants Award System Description"	Jan. 30, 1970
5.	Project SOAP	"Task Group Briefing to NIH"	Feb. 5, 1970
6.	Dr. Julius Lieblein	"Preliminary Analysis of Data, NIAID Decile System"	Mar. 15, 1970
7.	Edward G. Neigut	"Prospective Assistance Areas for NIAID Collaborative Programs"	Mar. 31, 1970
8.	Robert S. Cutler	"Criteria Subcommittee Meeting," Berkeley, California, April 25, 1970	May 29, 1970
9.	Vincent A. Martino	"Analysis of Issue: Relevance Criteria"	June 30, 1970
10.	Vincent A. Martino	"Preliminary Study of Group Assessment of Health Relevance, Exercise I"	Aug. 30, 1970
11.	Harold R. Millie	"In-Basket Survey of Public Inquiries Regarding NIAID Health Information"	Oct. 1, 1970
12.	Dr. Julius Lieblein	"Review of Report: Change in Method of Calculation of Deciles"	Oct. 29, 1970
13.	Robert S. Cutler	"Unbundling Criteria: Science Merit/Health Relevance"	Dec. 4, 1970
14.	Dr. Emmett Keeler	"Models of Disease Costs and Their Use in Medical Research Resource Allocations"	December 1970

*Copies of Notes are available from: Project SOAP, Technical Analysis Division, National Bureau of Standards, Washington, D.C. 20234

Notes No.	Author	Title	Date
15.	Stephen P. Strickland	"Policy Making in Biomedical Research: A Perspective on Relevance"	Mar. 15, 1971
16.	Robert S. Cutler Thomas A. Goldman	"Thoughts from Exercise II Pertaining to Social/Economic Impact Criteria"	Mar. 15, 1971
17.	Robert S. Cutler Vincent A. Martino	"Recommended Criteria for Extramural Program Management"	Mar. 15, 1971
18.	Robert S. Cutler	"Recommendations for Council"	Mar. 18, 1971
19.	Robert S. Cutler Vincent A. Martino	"DAPA Research Investment Procedure"	June 1, 1971
20.	Robert S. Cutler	Exercise II Report: "Biomedical Research Relevance Criteria"	June 30, 1971

WORKING PAPERS

Historical Perspective for Relevance Rating (P. Reeder)	Oct. 13, 1969
TAD/NIAID Progress Report (R. S. Cutler)	Dec. 15, 1969
Discussion of Issue: Program Relevance (R. S. Cutler)	Apr. 17, 1970
NIH Decision Making: Role of the Science Administrator (F. R. Abinanti)	May 12, 1970
Report on Criteria Subcommittee Exercise I Re: Health Relevance (V. A. Martino)	July 24, 1970
NIAID Goals for the 1970's: Preliminary Staff Paper (A. M. Webb)	Aug. 24, 1970
Exercise II Criteria Statements (V. A. Martino)	Dec. 23, 1970
Council Policy Guidelines (R. S. Cutler)	Dec. 23, 1970
Social/Economic Impacts--External Criteria (Dr. T. A. Goldman)	Jan. 29, 1971
Exercise II Summary: Research Relevance Rating and Criteria (R. S. Cutler and V. A. Martino)	Feb. 25, 1971
Project SOAP Progress Report, FY 71 (R. S. Cutler)	Mar. 4, 1971
Systems/Operations Analysis of Programs (An analysis of the studies performed by the Project SOAP Task Group) (R. S. Cutler)	Oct. 30, 1971

SECTION B - BACKGROUND DOCUMENTS

NIH Study Section Ratings: Scientific Merit or Order of Payment? (J. Palmer Saunders, and Mordecai H. Gordon, NCI Paper)	Apr. 10, 1965
NIAID Special Emphasis Research Programs (NIAID Staff)	June 5, 1967
Remarks on Special Emphasis Programs of NIAID (Dr. Dorland J. Davis)	Oct. 25, 1969
Transcript of November 1970 Council Meeting (G. Northcutt)	Nov. 16, 1970
Transcript of March 1971 Council Meeting (J. Taylor)	Mar. 18, 1971
Interagency Agreement File (Modifications 1-9)	Mar. 16, 1969 through Mar. 21, 1971
NAAIDC Criteria Subcommittee Recommendation	June 19, 1970
Council Resolution (March 1971)	Mar. 25, 1971
Report of June 1971 Council Meeting	June 21, 1971

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16. ABSTRACT (A 200-word or less factual summary of most significant information. If document includes a significant bibliography or literature survey, mention it here.)

This case study describes the activities of an interagency task group that applied systems analysis to improve management controls within a biomedical research agency of the federal government. The results were the formulation and implementation of a discipline for program management, which explicitly makes use of multiple criteria in arriving at resource allocation decisions.

The text details the necessary preliminary analysis describing operational activities, information flows, and key decision points within the organization. It goes on to identify the techniques employed and the difficulties encountered while attempting to improve the decision-making process for selecting research projects, under conditions of reduced funding. In particular, a comparison is made between: (1) the agency's traditional single-criterion "peer review" judgment for determining budget priorities, and (2) the multiple-criteria judgments required to effect more positive management control. The systematic use of separate "scientific merit" and "health relevance" ratings is compared with the organization's actual experience. The criteria used by various participants in the decision process are analyzed, and a dollar allocation "investment" procedure based on these findings, is developed.

A procedure which organizes relevant information for research program planning and evaluation is presented, and extension of this recommended procedure to wider use by science administrators elsewhere in government is discussed.

17. KEY WORDS (Alphabetical order, separated by semicolons)
Biomedical research; "health relevance"; program planning and budgeting; R&D management; systems analysis; systems approach.

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