# Development of Projects for Research and Demonstration in Health Services

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DURING THE 1930's and the period following World War II, the nation as a whole began to take interest in the everyday problems of the citizen and his family. Today, few public or private agencies remain unconcerned with improving the health, education, and general economic ability of the people. Those of us in health services today may have the opportunity of contributing more to public health than any previous generation, except perhaps the one that suppressed the major communicable diseases.

The technical nature of today's health problems is different: it revolves largely around the chronic diseases, environmental threats, and organization and economics of health services. Also, the present challenge is perhaps even greater than that raised by the germ theory. Advances in biomedicine have given us greater medical power to protect or restore the health of any randomly selected person. The challenge now is to advance the best health services from sample populations to the true population.

In the decades since the earlier emergence of public health, we have learned to place increasing reliance on the rational methods of science and logic. Therefore, the general approach which was so effective earlier should now be used with even greater intensity. That is, we should identify our problems as hypotheses for investigation, study to understand them precisely by experimentation, and, when we get workable results from our experiments, apply the results on a scale commensurate with the pertinent problem.

These are sensible rules for the acquisition and organization of information, which are appropriate to both wise administration and to experimental science. Unfortunately, we have allowed this fact to become obscured by the enormous growth of scientific specialization on the one hand and by undervaluation of public administration on the other. In the past few years, however, we have begun to give clearer recognition to the common principle. This principle is directly related to the development of "projects" for research and for demonstration and extension of public health services.

Generally, administrators and health service practitioners become alerted to problems or opportunities by the following process. First, a situation arises which presents an opportunity to improve standard practice, or perhaps standard practice is inadequate for the immediate purpose and there is no immediate solution for the deficiency. The questions then arise as to whether the particular situation occurs rarely or frequently and whether a possible improvement would be an important addition to practice. Often additional information, plus careful organization and evaluation, is needed to answer these questions. Finally, if the decision is to collect and evaluate additional data, a study or project must be designed and conducted.

This process is completely divorced from the mechanisms of finance or review procedures. Rather, it is an intellectual process of recognizing an unusual condition, deciding whether it is important enough to follow up, and, if so,

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organizing an effort which will be technically adequate to provide a reliable answer. Thus, this organized response becomes a project.

I use the terms "opportunity" and "problem" as if they had precise meaning. Of course, they do not; they are labels applied to situations which training and experience have prepared us to recognize as abnormal variances from expected standard courses of events, but for which they may not necessarily provide readymade answers. In fact, it is unlikely that standard practice will supply answers, because such situations exist at the borderlines of professions and disciplines. To put it more accurately, the subjects and issues in which we sense opportunities and problems are those in which our professions and disciplines are not yet fully developed. These are the areas in which research and demonstration play their proper roles.

No discussion of the design of research and demonstration can be adequate without consideration of the purposes and goals of the services to be studied or demonstrated. The analysis of purposes and goals provides the background against which the longer-range and emerging problems and potentials are delineated and selected for study and development. There is a necessary circular relation between the a priori philosophical objectives of a program and the detailed research or testing of the parts of that program.

One must have some thought-out plan or aim in order to see a problem or an opportunity and to circumscribe its specific investigation. In the long run, successful research and demonstration will provide new data and insights with which to reconstruct the general philosophical objectives. Thus, the formulation of goals is an essential part of any serious program-building effort.

### Setting Prospectives and Goals

Public health may be said to have its own maladies. Perhaps one of these is chronic underestimation of its own importance. As remedies, we need several measures of the significance of national health status and of the health services system.

*Measures of national and personal importance.* One measure of the health services system is its effect on the general economy. Health services today constitute the third largest U.S. industry in terms of the number of people employed. Only agriculture and construction are larger. At present about 4 million persons, approximately 5 percent of the civilian labor force, are engaged in producing and delivering health services. In 1964 about $36 billion were spent for health services, approximately 6 percent of the gross national product. Moreover, between 1950 and 1960 health services increased by 54 percent, in contrast to a decline of 38 percent in agriculture and only a 10 percent increase in construction.

The health industry will probably continue to expand. The expected increase in the national population is an obvious reason for growth. Increases in per capita disposable income from expected growth of the total economy should create additional effective demand for health services. Greater availability of more effective preventive and curative therapy owing to research will be another stimulus to demand for service, and hence for growth of the industry.

Health services have a still greater claim to importance, however, than the ability to create employment. The institutions and resources which promote good health may claim first-rank importance among the instruments of civilization. This is the basic reason for committing resources to health services; the production of employment opportunities is, happily, a secondary benefit. We are especially fortunate to be living in an era which, as a matter of policy, is giving more and more priority to raising the national health status, together with providing greater economic security and greater civic opportunity. This element of favorable national policy would seem to foster and encourage even more vigorous health services policies and programs in the States and communities.

*Nature of health services.* Perhaps certain technological features of the health services field hold great promise of future achievement of what we have heretofore only dreamed. In the past, technology and resources for promoting the general welfare were lacking. Only a few persons could be helped because supplies and logistics were inadequate. We may be near

the time when all the necessary resources and functional elements may be brought into better working balance.

The technology which organized health services should comprehend intellectually and command administratively is one of vast range and complexity. We are organizing and delivering medical care and other health services which are more and more the direct outcome of scientific progress. This is the result of the growth of biomedical science in the universities and specialized research organizations, supported by the National Institutes of Health, the National Science Foundation, and many other agencies. Collectively, certain components of these agencies constitute what we may call the biomedical research system. There is a definite relationship between the biomedical research system and the health services system. Medical knowledge and techniques developed by the biomedical research system are part of the raw materials for the construction of new and improved health services. Therefore, the development and administration of total health services require appreciation and understanding of the biomedical research system and especially of specific items of knowledge and technique which become ready for further test and development. These latter are the specific inputs which the health services system must evaluate and assimilate on a continuing basis.

The second major part of health services technology is that comprehended by what is called public health practice plus an increasing area of direct medical services. These combined areas include the whole function of State and local public health agencies, with all their medical, organizational, social, and economic dimensions. The scope of State health departments' interest in medical care has been set forth recently by the Association of State and Territorial Health Officers (*1*). From the standpoint of perceived researchable problems in community and public health, the scope of potential health services has been outlined rather comprehensively in a report submitted in December 1963 by the Bureau of State Services-Community Health, Public Health Service, to a committee of the Congress (*2*).

At present, the critical fact to be noticed about the total scope of technology is that while the biological nature of man can be altered at only a very slow rate, if at all, the organizational and economic aspects of the total health services system are manmade and may be altered in relatively short time periods. The full implications of the potential for change are not easy or simple matters to grasp. We do not have the necessary statistics and other data for estimating the characteristics of health systems, even in a small geographic area, let alone the theory for relating the components in a dynamic manner. However, these are subjects which will yield to certain types of research. The point is that we must recognize that the manmade parts of health services form a pattern which is susceptible not only to descriptive studies but eventually to planned experiments.

To carry the analysis of the health system one more step, for the sake of thoroughly recognizing its full extent, the system may be analyzed into several distinct elements: professional knowledge; manpower qualified by training and experience in the requisite professional knowledge; materials, supplies, and equipment requisite for professional practice and related activities; buildings for professional practice and administrative purposes; and various predetermined plans for organizing the knowledge, manpower, materials, equipment, and buildings into operational units deployed over the populations at risk or under treatment. These elements and their many combinations and subdivisions are the raw materials of that part of our technology which is manmade and therefore capable, theoretically, of improvement.

*Other social services.* All the areas in which the processes of change and innovation will require attention are not yet mapped out. The national concern for the individual, mentioned earlier, is also becoming a concern that people receive all the services they need at the right times and in the right combinations for maximum benefit. This means that, at least, health and certain welfare services may need to be delivered in a single package for certain populations. For older people, housing may have to be included in the package; for children, health and educational services may need to be combined more closely. This means that the public health administrator's plans for organizing the components of his program should consider

combined operations with other services for certain populations. The locus of service in the future may be the individual in the context of his family continuously over long periods of time. This contrasts to the locus of services in the operating centers of the separate agencies which depend upon the individual and the family to seek them out on random occasions.

*Leadership and executive responsibility.* The most important single factor in the definition of goals is the degree of leadership which health officials decide to exert in using or not using research and demonstration in their respective programs. The consequences of this decision cannot be avoided by inaction. For, if no leadership is given for improvement in health programs of any size, such as those of States or large cities, adverse effects will appear in end-product services. We cannot stand still. There is no status quo. Failure to espouse developmental operations leads surely to obsolescence.

The undertaking of developmental operations through research and demonstration requires additional staff and activities different from those in traditional services. These require additional, long-term capital investment. New activities, not immediately justified by service output, requiring long-term investment by the health organization, can be undertaken only through the decision and personal commitment of the responsible health executive. His policies on these points are absolutely crucial.

## Design of Developmental Efforts

I have discussed the high social importance of health services, their complexity when seen as a system, and the paramount role of leadership committed to development. The following is a general, perhaps superficial, overview of project design.

*Analysis of problems for study.* The complexity of phenomena in health services is probably the source of greatest difficulty in conducting effective research or demonstration. Because there can be many variable and relevant factors in the event systems to be studied or demonstrated, project designs most often err on the side of including more than can be scientifically managed. The general rule should be to include the absolute minimum number of factors which will answer the question or account for the observed results. But how do we know in advance what the minimum is?

We must start with the unevaluated insight, hunch, or plain curiosity of a person about the cause of some phenomenon and his desire to test the validity of his hunch. In the case of an intended demonstration, we presumably have some tested evidence that the application of certain precise operations will produce certain results which are known beforehand to be beneficial.

The next questions should then be: How many separate factors or elements seem to be involved in the subject? Do they seem to form a consistent, interacting whole or merely a cluster with vague limits around the edges? If the total system is fairly large, we know that we will need an equally complex and costly design to collect data and analyze the effects of individual factors and certain combinations. However, the large system may be susceptible to study one part at a time, beginning with the most interesting or the most important part. If we are doubtful about the existence and extent of an integral system, a descriptive study to locate and define the parts may be in order.

For a proposed demonstration, it may be desirable to set certain practical limits, such as total cost of the demonstration, unit costs of services, and kinds of personnel and equipment needed, in order to hold these factors within the normal resources of the average service unit. These limits then become additional criteria for evaluating the demonstration.

If our preliminary decision is that we seem to have identified a minimum relevant set of factors, and we are willing to handle a project of that magnitude, we proceed to the next stages. These are difficult but necessary stages if our results are to be reliable in any degree.

The original insight or hunch must be reformulated into a tentative hypothesis. This is a statement (or statements) which declares that a certain relationship exists between causes and effects or between one set of independent events and a second set of events which follows the first set. In the case of a demonstration, the hypothesis is that a certain set of services, when performed, will have certain results. The production of these results has presumably already been validated by some test, and the repetitive

performance of the demonstration activities should give the same or comparable results. In the case of a descriptive study, we still require a working statement to guide us in selecting the factors to be described and in gathering information which will contribute to such description.

The hypothesis, working statement, or functional parts of a demonstration, as the case may be, should be thought of and written in operational terms, if possible. That is, we should imagine how the factors will actually interact with each other, what changes will take place, what kinds of information can be collected from observing the interactions and changes, and what potential significance the interaction and changes may possess. In this stage, all available information which may throw light on the possible operation of the factors should be searched out and analyzed.

The preceding step should produce a plan which tentatively specifies (*a*) the factors to be studied, (*b*) the question or questions to be answered about each factor, (*c*) the data to be collected on each factor to answer each question, and (*d*) the methods for analyzing the data. By this time, the original problem and the motive for the study should be better understood. Perhaps the problem will even be revealed as purely verbal, of minor consequence, or insoluble with existing resources.

*Preparation of proposals.* To prepare proposals, expert assistance is needed from someone qualified to apply the instruments of modern statistics and preferably experienced and interested in the special techniques of experimental design. This applies whether the project is a description, a survey, or a multifactorial experiment. It also applies to many kinds of demonstration, especially those which include evaluation. From this point, the subject is beyond the scope of this paper and my ability.

Unfortunately, from the standpoint of those interested in developing a project, the formal literature on research and demonstration design is heavily weighted toward the needs of the trained statistician. Relatively less has been written for the nonstatistician as to the kinds of logical problems he should consider for most common kinds of projects. However, some general materials are available (*3–11*).

As to the preparation of proposals, assuming the design is otherwise well in hand, I can indicate the things that reviewers of applications look for and which careful design can provide.

It is extremely important that the objective and purpose of a project, whether experimental research or simple demonstration, be stated clearly and candidly in the proposal. If the purpose is to explore a problem and clarify methods for a later, more sophisticated project, it should be so stated. A simple and limited purpose is not cause for apprehension. The most frequently seen fault in proposals is overambition to solve everything at once.

In the course of assembling ideas with which to state the objective, it will have been necessary to decide whether one is dealing primarily with research or demonstration. In practice, the separation between research and demonstration is a matter of degree. This can be seen by considering the procedures necessary to carry out a proper evaluation of the results of demonstrating particular services: (*a*) application of the services to the particular population for which the demonstration had been originally designed (*12*) and observation of the results of the demonstrated services (both of these include consideration of sampling techniques); and (*b*) comparison of the theoretical results predicted by the demonstration design (its hypothesis) with the actual results on the demonstration population. This approaches the testing of an hypothesis by an experiment (*4a*).

In addition to a clear objective, reviewers will look for the methods and procedures to carry out the project. Attention should be lavished on the organization and form in which the entire project methodology is to be presented in the proposal. A complex, long-term project may go through several stages, from organization and planning to development and testing of instruments to data collection and analysis. In such cases, the presentation should be organized in terms of these stages.

If difficulties are anticipated in obtaining enough of the right subjects, enough instances for observation or data collection, or if there is any question as to the access of project workers to the subjects, it would be helpful to state how these difficulties will be met.

Each kind of information which will be col-

lected should be defined as precisely as possible. For example, age, sex, height, and weight are four distinct classes of information having different distributions in the population and requiring different collection techniques. Sex may be observed, age taken from birth records or oral reports, and height and weight must be measured by physical instruments. The project proposal therefore should specify how each class of information will be collected. When the project requires instruments complex enough to necessitate scientific development themselves, either appropriate existing instruments should be chosen or the project should include at an early stage the necessary resources and procedures for development and validation of new instruments. This should be done before the instruments are needed to collect data for the project.

The strength of a project as a whole is revealed in the methods for the organization and analysis of the information which the total effort has brought together. The effects of good or poor design are now apparent. Of course it is too late to develop a plan for the analysis of data collected without reference to any designed objective or to any planned analytical techniques. If these matters have been handled well in the project conception, it will not be difficult to present them fully in the proposal.

Of equal importance in the design and in the writeup of the proposal are the decisions and statements about staff, other resources, and budget for the project. Discussion of the qualifications of staff should take place after discussion of other design elements in order to focus attention on the merits of the design itself, regardless of the fame or lack thereof of the project director or principal investigator. If a good idea can be taken as the measure of a man, young or unknown workers will have their chance.

However, reviewers of research proposals must necessarily scrutinize the qualifications of the person or persons who have presumably constructed the design and prepared the application, and who will execute the project. This highlights the balance between the abilities of the principal investigator or project director and the consultants. If the consultants have been largely responsible for the design and writeup of the proposal, will the investigator or director truly be able to comprehend, direct, and complete the work? Obviously, the proposal should include a full account of the training and experience of the principal investigator in research and demonstration and in related administrative and program direction and developmental activities.

Responsibilities of each member of the professional and technical staff should be clearly defined, and, conversely, all major project tasks and elements should be covered adequately by proposed staff. The budget for other items should be generous enough to do the job well without excessive cost. Finally, the total requested time should be calculated on the basis of the estimated time needed to carry out each serial element of the design, including preparation of the final report.

### Future Potentials

I have discussed an extensive set of ideas concerning the use of the individual project as a technique of program development. These ideas, however, are by no means complete in coverage or final in form. But my account would be even less sufficient if I neglected oncoming innovations, which may change the whole technical environment in which future health services projects are conducted.

An increasing number of research proposals are applying automatic methods to the records and communications systems of various segments of hospital administration. These automatic methods will eventually cover patient-care activities as well as administrative and fiscal matters. To use records and communications stored and handled almost entirely by a mechanical system, man and machine must adapt to each other. The basis for adaptation is worked out by an analysis of the activities in which the records and communications are employed, and, hopefully, a new synthesis of human activity plus machine capacity is defined. The automated methods are then designed as a component of the new process.

It may be possible to apply these methods in all the major medical and administrative departments of hospitals. Several hospitals serving contiguous areas might possibly use a com-

mon computer facility and be linked together as one system for communication purposes. It also has been proposed to study a complete State health department with the object of developing similar processes to serve its particular needs. Perhaps even private practitioners will be able to communicate with hospitals by data telephones or similar devices.

During development of automated processes, conventional workways are re-examined, and a certain amount of simplification and standardization may result. The computer memory may eventually permit storage and random retrieval of longitudinal records on large numbers of patients and others receiving health services from a hospital or service unit which participates in the data handling system. Such a data bank would represent an enormous research potential in the service program.

Assuming that such networks become reality in the larger urban areas within the next 15 years, the terms "public health services" and "public health agency" will undergo redefinition. Provision of rapid and virtually simultaneous communication among practitioners and institutions, plus access to a common record system (properly safeguarded for essential confidentiality), may produce degrees of organization and coordination which are impossible with existing manual methods. We would then be able to acquire experience in a system extensive enough to produce a new perspective, and we might no longer be perplexed about the role of official agencies versus that of private agencies. Perhaps we could then recognize that a truly articulated system is "public" by definition, simply because it is extensive enough to serve all the people. Energy and resources could then be focused on needed improvements.

As the larger health service institutions move into this new technology, research and demonstration projects can be planned and carried out in a much more efficient environment. They will operate with a level of background information and communications unavailable now. They will be addressed to more sophisticated questions, which we cannot even formulate at present. Descriptive studies may decline in number and importance because the service data systems will routinely provide the information which we now collect through special studies. Longitudinal studies on large populations will be feasible. It will be increasingly possible to study experimentally the effects of economic, social, and administrative factors in health services.

In this stage of development, the background information and the higher levels of communication and coordination will permit delineation of health services and the related processes of rational development as one of two or three of the most important public institutions in our society. Only maintenance of employment and education may challenge its priority.

This is the potential objective for which we are primarily responsible.

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