CURRENT TOPICS

The National Heart, Lung, and Blood Institute Overview 1980

The Director's Report to the NHLBI Advisory Council

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THIS PRESENTATION deals with what Dr. Jeremiah Stamler called "Levy's arrow" (fig. 1), which depicts the involvement of the National Heart, Lung, and Blood Institute (NHLBI) in the biomedical research continuum. I shall discuss this continuum, together with the role of the NHLBI and its Advisory Council in making assessments, assigning priorities and making allocations. I shall also illustrate its pertinence to meeting society's needs with respect to health and related matters. By using a single Institute program as an example, I will try to show how biomedical research affects the community as a whole and has an impact on social issues and how, in turn, these issues influence biomedical research.

I will use the terms knowledge acquisition, knowledge validation and knowledge transfer. However, in the context of NHLBI activities, they are often synonymous with support of basic and clinical research, support of applied research and clinical trials, and support of demonstration and education programs (fig. 2).

The arrow may also be considered in terms of the process of innovation itself: idea generation, the communication of new ideas, idea utilization and development, and the diffusion of these ideas, once validated, into general practice.

A Broadened Spectrum of Activities

Traditionally, the major role of the NHLBI has been in knowledge acquisition through the support of basic and clinical research. However, over the last 10-15 years, both because of the increasing diversity of its research programs and because of demands and pressures for "relevancy," the Institute has become increasingly involved in knowledge validation exercises; that is, in clinical trials to verify research hypotheses and experimental results. At one time, a sixth of the Institute's budget — more than $50 million of extramural funds — was devoted to clinical trials. During the past few years, we have also gotten more involved in knowledge transfer, e.g., demonstration and education activities. However, though the NHLBI and the National Institutes of Health (NIH) are still the mainstays at the knowledge acquisition end of the arrow, more and more agencies, public and private, are involved in helping deliver the fruits of health research into the health care community.

A Broadened Congressional Mandate

With the passage of the National Heart, Blood Vessel, Lung, and Blood Act of 1972, Congress made it clear that they intended the Institute to be involved in basic research and in research validation and technology assessment, and in education activities for the public and the professional.

Thus, we may discuss three activities in which the Institute is involved: First, acquisition of new knowledge, because the current state of knowledge is incomplete; second, research results that require further testing and validation before they can be properly applied; third, dissemination of research results that have been appropriately validated and thus can be widely applied toward better prevention, detection and treatment of disease.

In terms of distribution of the Institute's funds, approximately 80% of the Institute's dollars are spent in knowledge acquisition, about 15% in knowledge validation, and about 5% in knowledge dissemination.

The Role of the Council

Though 80% of our funds go into knowledge acquisition, primarily through investigator-initiated research grants, the NHLBI Advisory Council spends much time discussing, assigning priorities to, and making funding decisions about activities in knowledge validation and knowledge dissemination. This is appropriate because activities in these areas are much easier to assess in terms of impact, likelihood of outcome, and needs. The results of basic and clinical
research are so unpredictable and so speculative that we rely primarily on the peer review system, on our many study sections — each composed of experts in a particular discipline — to make the funding recommendations about research grants. However, the actions that the Council takes also affect this basic area of knowledge acquisition. And the better it is at the translation end of the arrow, the more surely it helps guarantee the continued support of basic biomedical research.

To achieve Institute goals in knowledge acquisition, validation and transfer, we have a number of support mechanisms. Research grant applications may be submitted by any investigator at any time. Here, the research goal and the plan for achieving it originate with the investigator himself. Other research activities are shaped to some degree by the Institute, its Council, or its other advisory committees to fill in gaps or to take advantage of areas of opportunity. Sometimes this guidance may extend to drawing up fairly specific research blueprints for craftsmen outside to execute.

But the investigator-initiated research grant is the backbone of our support programs and, over the last 8 years, the proportion of the funds available for such research grants has remained remarkably stable at about 75% (fig. 3). The Council reviews these proposals before they are funded, relying on the recommendations of the primary review committees, but the Institute does not directly initiate these projects.

Only about one-fourth of the funds in the research grant line are used for Institute-solicited activities. For the most part, these support multidisciplinary specialized research centers and activities designed to study areas that are considered important, but in

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**Figure 1.** The National Heart, Lung, and Blood Institute continuum of research (Levy's arrow).

**Figure 2.** Biomedical research continuum. NHLBI = National Heart, Lung, and Blood Institute.
which there have been few investigator-initiated proposals.

Organization of the Institute

To administer these activities, the Institute has five different divisions. Of these, the Division of Heart and Vascular Diseases (DHVD), the Division of Lung Diseases, and the Division of Blood Diseases and Resources are involved in the support of extramural research. In these extramural program divisions, we have all of the grants and contracts in heart, lung and blood disease. Thus, each of the division directors can oversee a full program, direct attention to research areas that need coordination and identify areas of neglect or redundancy.

The Division of Extramural Affairs is not involved in the management of extramural programs, but serves as our interface with the other bodies of the NIH. It has another extremely important function: to review all applications that come in for research on heart, lung and blood diseases. Some of these applications may have been solicited by program divisions, but they become part of the heart, lung and blood portfolio only after independent review by the Division of Extramural Affairs.

The Division of Intramural Research is our separate research establishment. It is not involved in extramural funding decisions or in the management of extramural programs.

Programs of DHVD

It would be impossible to discuss all of the NHLBI programs in terms of the arrow and the continuum of research, so I will focus on one division, the DHVD. Ten program areas are in this division. Four deal with major etiologic processes: atherosclerosis, hypertension, congenital and rheumatic heart disease, and cardiomyopathy and infections of the heart. Three deal with the clinical sequelae of these processes: coronary heart disease, peripheral vascular disease and cerebrovascular disease. Two deal with the most serious clinical manifestations of these problems: arrhythmias, heart failure and shock. Finally, there is the Circulatory Assistance Program, formerly known as the Artificial Heart Program.

Arteriosclerosis, hypertension and coronary artery disease receive the majority of the research dollars and attention in the portfolio of the DHVD (fig. 4). This is appropriate because of the magnitude of the health problems posed by these diseases.

The DHVD Hypertension Program

The Hypertension Program is the second largest program of the DHVD. In fiscal year 1980, $68.7 million — 22% of that division’s budget — was spent on hypertension. We consider this an appropriate, if not austere, level of funding. I will discuss this program in terms of the biomedical research continuum — Levy’s arrow. It is a program that most clearly demonstrates the Institute’s commitments to and program activity in all three activity areas.

We support a tremendous amount of basic and clinical research — knowledge acquisition — in hypertension. An example of a knowledge validation activity in this program area is our recently completed Hypertension Detection and Follow-up Program (HDFP). In the knowledge transfer area, we have the National High Blood Pressure Education Program (NHBPEP), a program designed to disseminate to health professionals and the public what we can and should do for hypertension today.

In our hypertension program, the primary goal, as in most of our programs, is prevention. But the hypertension program is unique in that we have effective ways to control hypertension. Thus, our short-term goal in hypertension is to optimize the use of current therapeutic measures.

Hypertension: Humble Beginnings

Let us move the discussion of hypertension and the activity areas back to 1948, when the Institute came into being (table 1). Very little research activity was being done then and physicians could not offer their patients with hypertension very much. The few drugs available were either largely ineffective or had serious side effects. The main therapeutic alternative in 1948
was the rice diet, which was effective in some patients but unpalatable to many.

We were not sure if we were dealing with a disease, a symptom of a disease, or a possibly beneficial circulatory adaptation to the aging process. In fact, a theory in vogue until the middle 1950s — and given serious consideration in textbooks, like Harrison's *Textbook of Medicine* — held that hypertension was essential to maintaining critical perfusion pressures in areas like the brain, a concept that would suggest that we would be doing harm if we even attempted to lower blood pressure in persons who had hypertension.

Thus, in 1948, we had little basic knowledge; hence, little knowledge to validate, and certainly very little at all to disseminate to health professionals or the general public.

**Hypertension: Research Expansion**

Over the next 20 years, we learned about the tremendous complexity of hypertension. We learned about the involvement of the central and autonomic nervous systems in the control of blood pressure; the role of then-obscure hormones, such as kallikreins and kinins, prostaglandins, renin and angiotensin; the role of the vessel wall and its intrinsic reactivity; the role of the heart and kidneys; and the importance of nutrition and of salt and water balance. We got suggestions of the importance of psychologic and sociologic factors. But despite all we have learned about the complexities of hypertension, in more than 95% of the patients suffering from the disease, we still don't know its cause.

**Hypertension: An Expanding Arsenal of Weapons**

Even so, learning about all the different systems involved in hypertension has allowed development of drugs that reduce elevated blood pressure by a variety of mechanisms. They include diuretics like the thiazides, introduced in the 1950s, that help the body get rid of extra salt and water; drugs like α-methyldopa, which help to control blood pressure by acting on the central nervous system; drugs that directly dilate peripheral blood vessels; and β blockers, which reduce blood pressure primarily through their effects on heart rate and output. Properly used, this variety of proved agents makes it possible to control hypertension of all degrees of severity.

**Hypertension: Magnitude of the Problem**

In the last 30 years, we have learned about the magnitude of this disease and its impact on the nation. We know that 35 million Americans have hypertension, as defined by World Health Organization criterion (blood pressures over 160/95 mm Hg). We know that an additional 25 million Americans have so-called borderline hypertension (blood pressures of 140/90 to 160/95 mm Hg). Altogether, then, some 60 million Americans have hypertension.

From epidemiologic studies like those at Framingham, Tecumseh, and elsewhere, we have learned that hypertension is the most important factor contributing to some 500,000 strokes each year, about 170,000 of them fatal, making stroke the third leading cause of death in the United States.

We have also learned that hypertension is a major accelerating factor in the process of atherosclerosis, a disease responsible for 1.25 million heart attacks and some 650,000 heart attack deaths each year. We estimate conservatively that hypertension costs this country more than $8 billion annually in health care costs, lost wages and productivity, not to mention the costs of suffering attending the premature loss or disability of a loved one.

**Hypertension: A Demonstration of Therapeutic Benefits**

By 1972, we had one other extremely important piece of information: the results of the Veterans Administration (VA) Trials, begin in the 1960s and completed in the early 1970s (table 1). These studies showed conclusively, in the VA population, that the treatment of moderate and severe hypertension — i.e.,

![Figure 4](http://circ.ahajournals.org/figure/FIGURE_4.png)

**Figure 4.** Heart and blood vessel diseases extramural research programs: fiscal year 1980, obligations of $309.2 million.
blood pressure levels above 105 mm Hg diastolic — was cost-effective, by virtue of reducing mortality from stroke, heart failure and renal failure.

Because of the promising results of this trial and because of the knowledge of the magnitude of the hypertension problem, the availability of effective drugs at that time, and of the realization that these drugs could prevent much disability and death, two programs — both enthusiastically supported and recommended by the NHLBI Advisory Council — were begun in 1972. One was the NHBPEP, which was designed to disseminate knowledge to the public about what can and should be done about hypertension, based on existing knowledge about high blood pressure and its treatment. The other was the HDFP, a clinical trial with 14 participating centers designed to acquire new knowledge.

The National High Blood Pressure Education Program

In 1972, all too many were not alert to what could and should be done for hypertension. The majority of Americans who had hypertension were unaware of it. Most persons did not relate hypertension to its sequelae, such as stroke and heart failure. Many people confused hypertension with nervous tension.

Nor did all physicians know as much as they needed to know about hypertension and its treatment in 1972. Many physicians still accepted the tenet that perhaps elevated blood pressure should not be treated, lest critical organ perfusion pressures be compromised. Too few physicians were aware that they had to work closely with their patients to achieve and maintain good blood pressure control. They not only had to tell the patient that he had high blood pressure, but they had to describe in some detail what the problem was and what could and should be done about it. Too few physicians really took the time to think about or deal with problems of long-term adherence to prescribed therapy, e.g., persuading patients to take medicine when they felt well and getting them to continue taking medicine despite side effects that might make them not feel well. Too few physicians took on the task or were effective in the task of making patients understand that although medications could control the disease, they could not cure it, so lifetime treatment would probably be necessary.

NHBPEP: the Approach

Thus, the NHBPEP, from its inception, was based on some simple premises. To the health care professional, we emphasized the high prevalence of hypertension, the fact that it was asymptomatic, that it was easy to detect, that effective therapy was available, but that adherence was essential.

To the general public, we emphasized the very high prevalence of hypertension; that many who have it may not know it, because one can’t feel it; that it is easy to detect, requiring only a simple, painless blood pressure check; that it can be controlled; and that, with long-term treatment, the risk of heart disease, stroke and renal failure can be reduced.

NHBPEP: Coordination of Efforts

The NHLBI was charged by Eliot Richardson, then Secretary of Health, Education, and Welfare, with coordinating the program. The program is unique in that it involves a federal agency coordinating activities in both private and federal sectors, taking advantage of what each sector has to offer. Coordination in the private sector is effected through a High Blood Pressure Coordinating Committee, made up of representatives of private organizations concerned with or directly involved in research or health care delivery in hypertension. These include the American Heart Association, the American College of Cardiology, the National Kidney Foundation, the American Medical Association, the National Medical Association, and many others.

An Interagency Technical Committee coordinates all program activities in the federal sector. To deal with problems and issues that come up, we have established working groups and task forces. These have dealt with such matters as extending hypertension control activities to minority groups, questions of
treatment in the pediatric age range, the role of pharmacists or nurses, and hypertension control in the work setting.

By 1976, the NHBPEP was one of our most exciting ongoing activities and the most visible part of our hypertension program. It had moved from making physicians and the public aware of hypertension to emphasizing maintenance of adequate blood pressure control.

**NHBPEP: Some Promising Results**

Within the first 2–3 years of the program, we had evidence that, whereas initially about 50% of those with hypertension had been unaware of their disease, this had dropped to only 30% in the communities surveyed. Initially, it was estimated that, among Americans aware of their hypertension, only about 16% had their blood pressure under adequate control. After the program was initiated, a survey in the communities where the 14 HDFP participating centers were located indicated that 30% were receiving adequate treatment.

Spot surveys done in Westchester in 1975, Milwaukee in 1976 and Chicago in 1977 also confirmed that the number of hypertensives who were unaware of their disease was rapidly decreasing and that an increasing number of hypertensives — 50% or more — were being treated, and indicated that 50% or more of these were under good control. Other survey data indicated that patient visits to their doctors for hypertension increased by almost 50% in the first 3–4 years of the program, while visits for all other causes had increased hardly at all.

It may be fortuitous, but we have also noted a temporal association between the NHBPEP and a precipitous fall in stroke deaths (table 2). Stroke deaths had been declining at a rate of about 1.5% per year in the 1960s. Since the inception of the program in 1972, stroke deaths have declined at the remarkable rate of over 5% a year, so that during the 1970s, the mortality rate has fallen by 40%.

**TABLE 2. Decline in Stroke Death Rate, 1963–1978**

<table>
<thead>
<tr>
<th>Year</th>
<th>Death rate* per 100,000 population</th>
<th>Decline since 1963 (%)</th>
<th>Decline since 1970 (%)</th>
<th>Decline since 1972 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1963</td>
<td>76.4</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>1970</td>
<td>66.3</td>
<td>13.2</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>1971</td>
<td>65.2</td>
<td>14.7</td>
<td>1.7</td>
<td>—</td>
</tr>
<tr>
<td>1972</td>
<td>65.0</td>
<td>14.9</td>
<td>2.0</td>
<td>—</td>
</tr>
<tr>
<td>1973</td>
<td>63.7</td>
<td>16.6</td>
<td>3.9</td>
<td>2.0</td>
</tr>
<tr>
<td>1974</td>
<td>59.9</td>
<td>21.6</td>
<td>9.7</td>
<td>7.8</td>
</tr>
<tr>
<td>1975</td>
<td>54.5</td>
<td>28.7</td>
<td>17.8</td>
<td>16.2</td>
</tr>
<tr>
<td>1976</td>
<td>51.4</td>
<td>32.7</td>
<td>22.5</td>
<td>20.9</td>
</tr>
<tr>
<td>1977 est.</td>
<td>48.4</td>
<td>36.6</td>
<td>27.0</td>
<td>25.5</td>
</tr>
<tr>
<td>1978 est.</td>
<td>45.3</td>
<td>40.7</td>
<td>31.7</td>
<td>30.3</td>
</tr>
</tbody>
</table>

*Age-adjusted.

Based on National Center for Health Statistics Data.

**NHBPEP: Some Interesting Fallout**

NHBPEP has had striking effects in other parts of the biomedical research continuum. From 1970–1978, without any real effort from the Institute other than the NHBPEP, there was a remarkable increase in the interest of our research investigators in hypertension and in publication of basic and clinical studies in this research area (fig. 5). The output of publications peaked in 1975, but since then, has still remained much higher than it was earlier. This provides a dramatic example of how activities at one end of the continuum can affect the others.

NHBPEP helped stimulate biomedical interest in hypertension. This led, in turn, to a demand in 1976 that the Institute look into new opportunities in hypertension research, particularly with respect to causation, because until we know the causes of hypertension, we are unlikely to find a means of prevention.

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**FIGURE 5. Number of hypertension research publications by year.**

* U.S. publications plus selected foreign publications.
† End of 1978 (estimated).
The NHBLI Advisory Council established a task force that delivered to us, in late 1978, a nine-volume report outlining opportunities and strategies for hypertension research into the 1980s.

By stimulating professional and public awareness of hypertension in the community and emphasizing the health benefits of early detection and adequate treatment, the NHBPEP also helped stimulate a 1976 demand by many members in the community that the Institute undertake a clinical trial to assess the health benefits, if any, resulting from the treatment of mild hypertension.

The Trial that Never Was
The push for the Mild Hypertension Trial was based on the fact that we had clear evidence from the aforementioned VA study that treatment of moderate and severe hypertension reduced morbidity and mortality from hypertension-associated disorders, but we did not know if such benefits attended the treatment of those with diastolic blood pressures between 90 and 104 mm Hg. About two-thirds of the hypertensives in the United States population have blood pressures in this range.

A Council subcommittee appointed to consider such a trial concluded that it would require some 5000–10,000 subjects; would have to go on for 6 years; and, if done as a controlled, double-blind trial, would cost the Institute almost $100 million.

The estimated cost was a major concern, but there were others. The proposed double-blind trial would require a placebo-treated control group, and the consensus in the medical community was that persons with hypertension should not be denied treatment. Moreover, it was anticipated that the dropout rate among patients in the control group might be unacceptably high.

But the Mild Hypertension Trial was finally rejected by the Council because of a strong feeling that the HDFP, already in progress, would probably provide us with the needed information, since about 70% of its participants had mild hypertension. In fact, it did give answers.

The Hypertension Detection and Follow-up Program
This study, concluded in 1979, demonstrated that a 17% decline in mortality is possible through a systematic, aggressive approach to hypertension in community clinics. Even more dramatically, it demonstrated a 20% decline in mortality among aggressively treated patients with diastolic pressures of 90–104 mm Hg.

The Study also demonstrated that we could get blood pressure down and keep it down, whatever the subject’s initial blood pressure level, and that the ensuing health benefits applied about equally whether the subjects are male or female, young or old, black or white. This study should put an end to any myth that hypertension among blacks is especially resistant or difficult to treat. Thus, we can expect gratifying reductions in morbidity and mortality from hypertension-associated diseases among blacks if we can increase blood-pressure control activities in the black community, where the prevalence of hypertension is almost twice that among whites.

HDFP: Newer Data
The HDFP will be generating much more information over the next 2–4 years. Already, however, recently reported morbidity data accord well with the mortality data from the study and emphasize the health benefits of adequate control of mild, moderate and severe hypertension.

These data showed that morbidity from hypertension-associated conditions decreases with the aggressive treatment of hypertension. Among patients so treated, the number who develop left ventricular hypertrophy decreases. Moreover, among patients with left ventricular hypertrophy at entry, many experience regression of the condition with vigorous treatment of their hypertension.

Even more exciting, not only did stroke mortality decrease among aggressively treated patients, but stroke morbidity fell dramatically as well. Among those who had no end-organ disease and had not been on antihypertensive therapy at the start of the study, those in the aggressively treated group had 50% fewer strokes than those who received routine treatment. These data clearly indicate that illness, disability and death from hypertension-associated conditions are all decreased by aggressive treatment of mild hypertension.

The HDFP has given us some exciting answers, but it has also raised new questions and given increased urgency to some old questions that had been previously identified. It has pointed up additional opportunities throughout the biomedical research continuum (table 1).

The Quest for Causes
Clearly, lifelong treatment of hypertension can control its dreadful sequelae in as many as 60 million Americans; but developing effective means of prevention would offer an even more cost-effective approach. The results of the HDFP give increased importance to seeking answers about the basic cause or causes of hypertension.

Over the next several years, we will explore more aggressively the possible roles of disturbances of central and autonomic nervous system, endogenous hormone imbalances, adverse genetic influences, and sociologic and psychologic factors in the genesis of hypertension. We must also get a better understanding of factors that affect blood vessel tone, salt and water balance, and heart and kidney function. Some moves in this direction are already under way, such as the recent efforts to encourage research into the effect of hypertension on the microcirculation and on the effect of salt on hypertensive persons.

As many as 40 million Americans have diastolic pressures between 90–104 mm Hg. Although the HDFP studied the mild hypertensive, it was a drug trial and thus gave little indication of what we might
expect from nonpharmacologic treatment of mild hypertension.

Are Drugs All There Is?

Despite the effectiveness of conventional modes of therapy, few would take comfort in consigning 40 million or more Americans to a lifetime of drug therapy if something better is available. Thus, we should look to nonpharmacologic means that may achieve adequate blood pressure control in some mild hypertensives or reduce drug requirements in others.

First, we have to establish the effectiveness of nonpharmacologic therapy. With respect to blood pressure control, how much can be achieved with salt restriction, weight reduction or regular exercise? What can we really expect from biofeedback, meditation and related nonpharmacologic therapies? Can we validate these forms of therapy?

To answer these questions, the Council has approved several investigator-initiated clinical trials to determine the role of salt restriction and weight reduction in hypertension.

Other questions should be answered. How can we identify those who, despite mildly elevated blood pressure, may not be at increased risk of cardiovascular disease and so may not need antihypertensive therapy immediately? Or can we learn to identify in advance those mild hypertensives who probably would respond to nonpharmacologic therapy, and so begin with such approaches? Can we define salt-sensitive and salt-resistant hypertensives in order to identify those who would respond dramatically to dietary salt restriction?

Is “Normal” Blood Pressure “Safe”?

The HDFP showed that treatment of persons with diastolic blood pressures of 90 mm Hg or higher was clearly beneficial. But what about those with diastolic blood pressures around 85 mm Hg? They are clearly at a higher risk of arteriosclerosis and its complications than are those with levels lower than 80 mm Hg. Could we expect health benefits to follow treatment of pressures in the upper portion of the normal blood pressure range and, if so, what blood pressure level should be set as a therapeutic goal? The HDFP had a very aggressive stance: In those whose blood pressures were 90–99 mm Hg, the aim was to lower it by at least 10 mm Hg. This meant that many persons had their blood pressure lowered into the low 80s and some had their blood pressures reduced below 80 mm Hg. Is this practical? Is this cost-effective for America as a whole? We may need to redefine what truly constitutes normal blood pressure.

We have other research validation questions. What are the long-term benefits of treating mild hypertension in the young? What are the long-term effects of using drugs in hypertensive persons who are only at slightly increased risk for cardiovascular disease during the first 3–4 decades of life? What should we do about the 10% of the elderly population with pure systolic hypertension? Although there is little doubt from Framingham and other epidemiologic studies that these people are at increased risk from cardiovascular disease, will aggressive treatment of pure systolic hypertension cause more side effects than benefits? Will aggressive treatment of systolic hypertension reduce mortality, or will it increase the risk of dementia? The Council has recommended the funding of a pilot project to get us additional information about the treatment of systolic hypertension in the elderly.

Hypertension and the Health Care Delivery System

Health care questions must be answered. To what extent can concepts used in the HDFP stepped-care clinics be applied to community care? The clinics were set up to meet the needs of the HDFP, a clinical trial, and many dollars were spent to ensure close patient monitoring and to encourage compliance with prescribed therapy. How much would it cost to reproduce such clinics as health care delivery units in the community? Should they be coupled with other care units?

Why did these clinics consistently outperform the usual community resources? Adherence to therapy was remarkable. Was it because the patients were tracked and reminded to come in, with their visits scheduled at convenient times, or because they were specially motivated in clinics that focused on treatment? What aspects of the stepped-care treatment program are applicable and can be transferred to the care of the hypertensive patient by the individual practitioner?

There are still other questions in the health care area. What kind of demand would doing all that we know right now about hypertension put on our whole health care delivery system? Can our physicians handle all this alone, or to what extent might nurse-practitioners, pharmacists, or paramedical personnel be mobilized toward the goal of getting hypertensive patients under therapy and encouraging compliance? If we are going to deliver hypertension care now to 60 million Americans, costs will increase. However, benefits will increase and morbidity and mortality from hypertension-related disorders will decrease.

Treatment: Returns on Investment

About 5 years ago, when we knew only that it was beneficial to treat moderate and severe hypertension, we derived a cost-benefit analysis. We concluded that, among those below age 65 years in the working class, for every dollar spent we would save $1.25 because of decreased morbidity and mortality. If we were to add the 40 million or so mild hypertensives into this treatment program, would the cost-benefit ratio still be $1.25 or would it diminish? Might we end up spending more than we save? Should we provide free therapy to indigent hypertensives who cannot afford high blood pressure drugs? Should reimbursements be provided by insurance companies to hypertensives who go on treatment and stay on treatment?

Still other questions must be answered. But let me desist long enough to say that the HDFP has been very successful. It has answered the questions that we
asked; we shouldn’t be too unhappy that we have been provided with a new set of questions.

The Institute plans to hold a workshop this year to focus on the implications of HDFP for health research and health care, to assign priorities to some of these issues, and to investigate the feasibility of participation by other federal agencies in areas outside the usual domain of this Institute.

The HDFP went on during a period when we were already seeing a dramatic increase in attention to hypertension and a dramatic fall in stroke mortality. Nevertheless, the results of this study indicate that full application of what we already know about the treatment of hypertension, including mild hypertension, could save an additional 80,000–100,000 lives each year.

**Conclusion**

I have spent some time discussing Levy’s arrow, using just one program as an example. I attempted to avoid belaboring you with statistics, number of projects supported in hypertension, budget allocations and funding mechanisms in order to focus on program needs and opportunities. We have needs in almost all the other program areas as well as opportunities just as exciting as those in hypertension. We are not opportunity-limited, but resource-limited. The key to the future of NHLBI and NIH, in seeking both the support of the Congress and the support of the general public, hinges on presenting the story of the NIH in terms of program achievements, opportunities and needs.

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**Coronary Bypass Surgery for Chronic Angina — 1981**

**A Perspective**

**Shahbudin H. Rahimtoola, M.D., F.R.C.P.**

*Life is short, and the art long; the occasion fleeting; experience fallacious and judgment difficult.*

—Hippocrates, *Aphorisms*

**CORONARY** artery bypass graft surgery (CABG), available for the last 14 years, has been a most important advance in the management of symptomatic patients with coronary artery disease (CAD). Medical and surgical therapy are complementary; patients treated surgically should also receive appropriate medical therapy.

**Potential Problems in Evaluation of Data**

**Medical Studies**

The prognosis of patients with CAD treated by medical therapy has been studied often, but there have been no controlled studies of medical therapy. It is difficult to identify medically treated patients who could be compared with surgically treated patients because of differences in their conditions. Many of the medically treated patients were evaluated before 1970, and characterization of risk factors, ventricular function and even operability is often incomplete.1-4 Moreover, medical therapy for angina in the 1970s is likely to be superior to that available in the 1950s and 1960s because of an increasing awareness of the need to control risk factors such as smoking and hypertension, and the availability of various forms of nitrates and of β-blockade therapy.

**Surgical Studies**

Nonrandomized studies of surgical therapy of angina have produced valuable information about operative mortality, perioperative myocardial infarction, relief of pain, vein graft occlusion, recurrence of angina and survival after CABG.5 However, survival data from these studies cannot readily be compared with historical controls treated with medical therapy because of the likelihood that the medically treated patients are not comparable to those who undergo CABG.

**Matched Control Studies**

Recent medical studies5-12 usually allocate patients to medical therapy in an uncontrolled manner and probably contain many patients considered less likely to benefit from CABG. Therefore, the medically treated group probably contains inoperable patients and also high-risk patients; these higher-risk patients may be unidentifiable at present. When used in matched control studies,13-15 these patients may not be an appropriate group to compare with current surgically treated patients, at least as far as survival is concerned.

**“Normal” or U.S. Population**

Comparison of CABG patients to the U.S. population16 may be of limited value. The U.S. population contains not only normal people but also people with malignancy, renal and pulmonary failure, inoperable CAD, emotional disorders, and other diseases that put

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