Chapter 7

# Technology Transfer at the National Heart, Lung, and Blood Institute

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Chapter 7

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## INTRODUCTION

Diseases of the cardiovascular and respiratory systems account for 5 of the 10 leading causes of death in the United States. Four of these are chronic diseases under study by the National Heart, Lung, and Blood Institute (NHLBI)–heart disease (ranked first), cerebrovascular disease (third), chronic obstructive lung disease (fifth), and arteriosclerosis (ninth) (see table 26). Moreover, hypertension and heart conditions are among the 10 leading chronic causes of morbidity (see table 27); and cardiovascular diseases account for nearly 5 million hospitalizations, with an average length of stay of over 10 days (table 28), and over 55 million physician office visits (table 29).

Although cardiovascular diseases remain the number one cause of mortality, there has been a continuing decline in age-adjusted mortality rates since the 1960's, including a 25-percent decline between 1968 and 1978 (see figs. 7, 8, and 9). This decrease in mortality from cardiovascular diseases has been attributed to advances in diagnosis and treatment, preventive measures, and changes in lifestyle. The decline has not been confined to the United States, but

**Table 27.—Morbidity From Selected Chronic Conditions, United States, 1979 (thousands)**

| | Condition | Prevalence |
|---|---|---|
| | Chronic sinusitis | 28,054 |
| 1. | Arthritis | 25,868 |
| 3. | Hypertension | 23,745 |
| 4. | Absence of extremities (or parts), deformities, orthopedic impairments | 20,213 |
| 5. | Hearing impairments | 16,663 |
| 6. | Heart conditions | 16,428 |
| | Hay fever (without asthma) | 15,620 |
| 8. | Digestive conditions ... , | 14,692 |
| 9. | Hemorrhoids | 8,813 |
| 10. | Eczema, dermatitis, urticaria | 7,754 |
| 11. | Chronic bronchitis | 7,474 |
| 12. | Corns, callosities, bunion | 6,584 |
| 13. | Acne | 6,450 |
| 14. | Asthma (with or without hay fever) | 6,402 |
| 15. | Varicose veins | 6,030 |
| 16. | Diseases of the urinary system | 5,602 |
| 17. | Migraine | 5,348 |
| 18. | Diabetes | 5,236 |
| 19. | Synovitis, bursitis, tenosynovitis | 4,637 |
| 20. | Diseases of nail | 4,302 |

SOURCE: National Institutes of Health, derived from unpublished data from the National Center for Health Statistics.

**Table 26.—Mortality From the Ten Leading Causes of Death, United States, 1979[a]**

| | Cause of death | Number | Rate per 100,000 population | Percent |
|---|---|---|---|---|
| | Total | 1,895,380 | 866.2 | 100.0 |
| 1. | Heart disease | 723,100 | 330.4 | 38.2 |
| 2. | Malignant neoplasms | 401,450 | 183.5 | 21.2 |
| 3. | Cerebrovascular diseases | 167,320 | 76.5 | 8.8 |
| 4. | Accidents | 102,740 | 47.0 | 5.4 |
| 5. | Chronic obstructive pulmonary disease | 49,580 | 22.7 | 2.6 |
| 6. | Influenza and pneumonia | 43,770 | 20.0 | 2.3 |
| 7. | Diabetes | 32,780 | 15.0 | 1.7 |
| 8. | Cirrhosis of the liver | 29,620 | 13.5 | 1.6 |
| 9. | Atherosclerosis | 28,410 | 13.0 | 1.5 |
| 10. | Suicides | 25,710 | 11.7 | 1.4 |
| | All other causes | 290,900 | 132.9 | 15.3 |

aBased o$_{n a}$ lo.$_{percen}$t sample of death certificates for the 12 months of 1979. Causes of death were coded to the Ninth Revision of the International Classification of Diseases.

SOURCE: National Center for Health Statistics, *Monthly Vital Statistics Report* 29:1, Apr. 9, 1980.

**Table 28.—Number of Hospital Discharges and Days for Patients With Cardiovascular Diseases, United States, 1978**

| First-listed diagnosis and ICDA code | Number of discharges (thousands) | Length of stay (days) | Number of days (thousands) |
|---|---|---|---|
| Total cardiovascular 390-458,746,747 | 4,828 | 10.2 | 49,163 |
| Rheumatic fever and rheumatic heart disease 390-398 | 114 | 10.8 | 1,235 |
| Acutemyocardial infarction 410 | 425 | 12.5 | 5,320 |
| Other coronary heart disease 411-413 | 1,529 | 9.1 | 13,989 |
| Hypertensive disease 400-404 | 317 | 6.8 | 2,168 |
| Cerebrovascular disease 430-438 | 648 | 13.4 | 8,700 |
| Congenital heart disease746, 747 | 62 | 7.7 | 479 |
| Other cardiovascular diseases 420-429,440-458 | 1,733 | 10.0 | 17,268 |

SOURCE: National Heart, Lung, and Blood Institute, based on unpublished data from the Hospital Discharge Survey, National Center for Health Statistics.

**Table 29.—Number and Percent Distribution of Physicians'Office Visits for Diseases of the Circulatory System and for Selected Principal Diagnoses, United States, 1978**

| Diagnosis and ICDA code | Numberofvisits (thousands) | |
|---|---|---|
| Total circulatory 390-458 | 55,167 | |
| Rheumatic fever and rheumatic heart disease 390-398 | 1,000 | |
| Hypertensive disease 400-404 | 24,968[a] | |
| Essential benign hypertension 401 | | 24,068 |
| Ischemic heart disease 410-413 | 14,578 | |
| Acutemyocardial infarction and other acute IHD 41O-411 | | 1,610 |
| Chronic IHD412 | | 11,295 |
| Angina pectoris413 | | 1,674 |
| Other forms of heart disease 420-429 | 4,378 | |
| Symptomatic heart disease 427 | | 3,314 |
| Cerebrovascular disease430-438 | 2,270 | |
| Diseases of arteries, arterioles, capillaries 440-448 | 2,190 | |
| Arteriosclerosis 440 | | 740 |
| Diseases of veins and other circulatory 450-458 | 5,764 | |
| Phlebitis and thrombophlebitis 451 | | 1,221 |
| Varicose veins of lower extremities 454 | | 988 |
| Hemorrhoids 455 | | 1.855 |

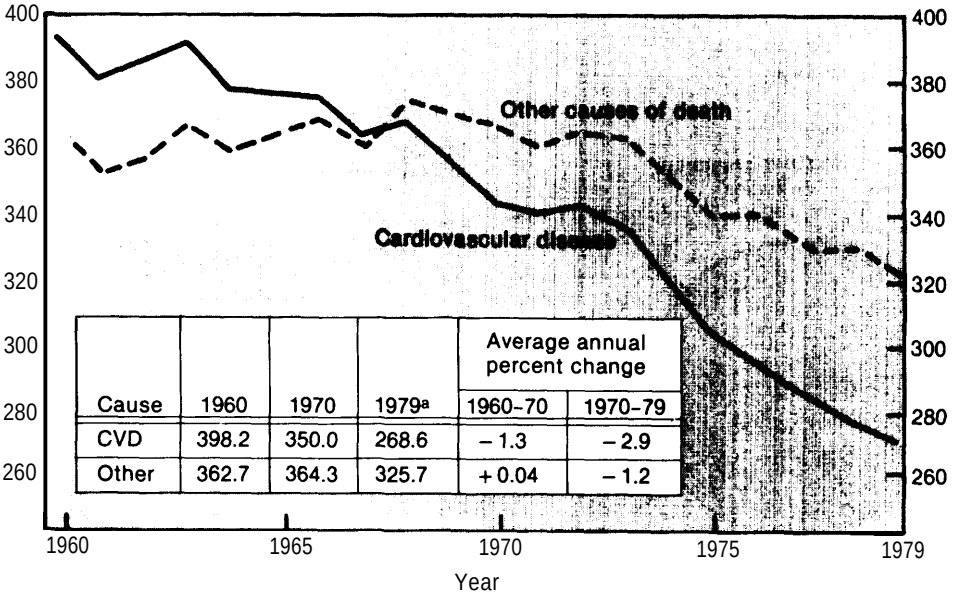
aAn estimate of 51 million Is given by the National Disease and Therapeutic Index, which includes visits in all locations (Office, hospital, etc.) and by telephone.

SOURCE: National Heart, Lung, and Blood Institute, based on unpublished data from the National Ambulatory Medical Care Survey, National Center for Health Statistics.

has also occurred in Canada, Australia, and Finland, countries that also have high coronary artery disease death rates. In England, however, where preventive care in nutrition and hypertension treatment have not been vigorously pursued, mortality from heart disease has remained constant. In 1968, a middle-aged male American had a 40-percent higher risk of death than an Englishman; by 1976 the American's risk had fallen below the Englishman's (37,40).

Improvements in rates of mortality and morbidity are not only desirable from a human well-being standpoint. There are also large economic implications. The economic cost in the United States of death due to circulatory, respiratory, and blood diseases was estimated at close to $40 billion, in terms of lost earnings (43). In fact, diseases of the circulatory system rank first among all diseases in economic costs of death (accidents are first overall). These diseases also rank first in total amount of disability (measured in number of days) caused by disease, in total economic cost of morbidity (productivity losses), and in overall totals of the economic "burden" of diseases, including the above meas-

**Figure 7.—Death Rates for Cardiovascular Diseases and Other Causes of Death, United States, 1960-79**



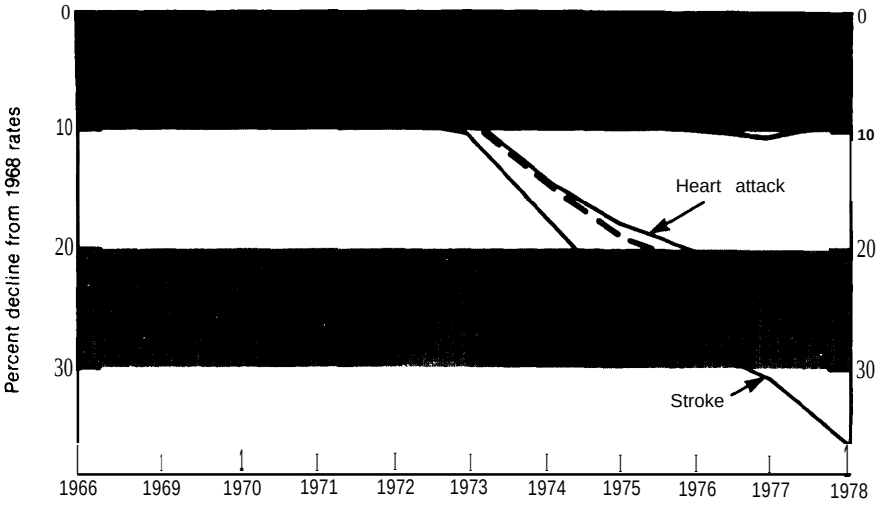

| Cause | 1960 | 1970 | 1979[a] | Average annual percent change 1960–70 | Average annual percent change 1970–79 |
|---|---|---|---|---|---|
| CVD | 398.2 | 350.0 | 268.6 | – 1.3 | – 2.9 |
| Other | 362.7 | 364.3 | 325.7 | + 0.04 | – 1.2 |

NOTE: Age-adjusted to U.S. population, 1940.

[a]Estimated by NHLBI.

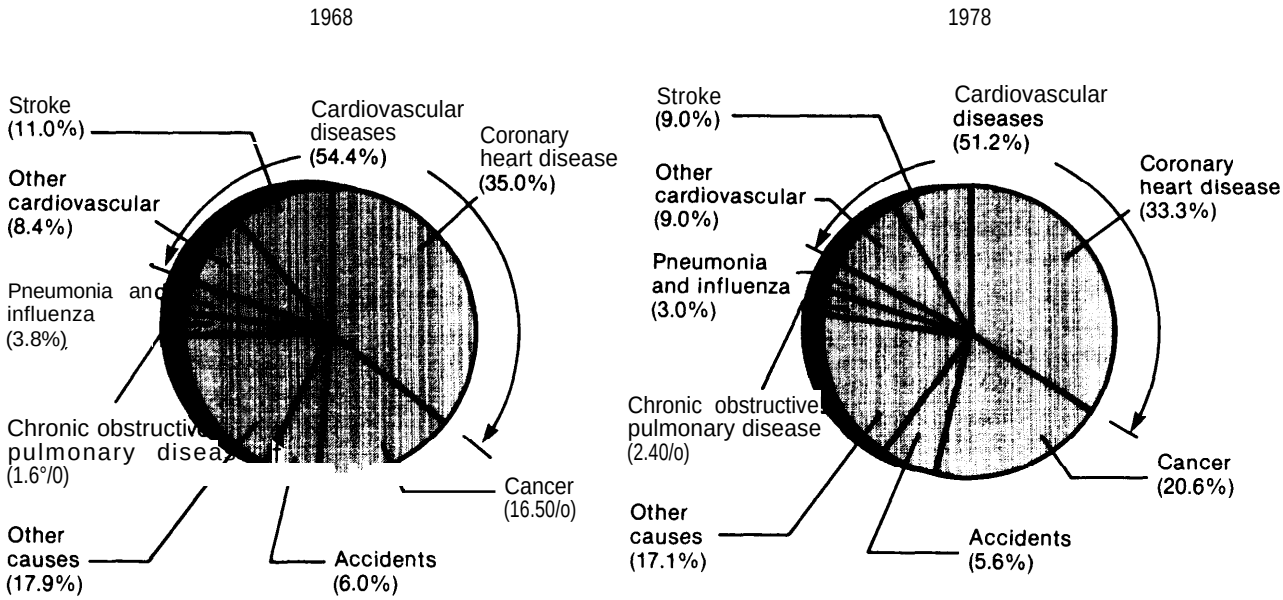
**SOURCE: Prepared by the National Heart, Lung, and Blood Institute.** Data from the National Center for Health Statistics.

**Figure 8.—Trends in Cardiovascular Disease and Noncardiovascular Disease: Decline by Age-Adjusted Death Rates, 1968-78**




SOURCE: National Heart, Lung, and Blood Institute,

**Figure 9.–Deaths by Cause and Percentage of Total Deaths, 1968 and 1978**




SOURCE. National Heart, Lung, and Blood Institute,

ures and others such as health care expenditures (43).

Improvement in treated cases through the combined impact of medical and surgical interventions (e. g., coronary bypass surgery, coronary care units, emergency medical services) cannot account for the 25-percent decline in age-adjusted mortality rates in the 1970's. The suggestion, therefore, is that the incidence and severity of the disease have decreased. Among the factors cited are greater awareness of overnutrition, increased physical activity, decreased smoking, and treatment of hypertension. On the latter factor *(37):*

> The proportion of hypertensive persons under treatment has doubled in recent years . . . More effective use of antihypertensive agents could be responsible for perhaps a third of the reduction in cardiovascular mortality . . . Evidence that hypertension control is an important contributor to the decline is especially strong because hypertension is one of the major risk factors for stroke, cardiac failure, and coronary disease; hypertension-related deaths have shown the steepest decline; and declines in stroke incidence are seen in women who have shown the greatest improvement in hypertension awareness and treatment (references omitted).

A review of the history and development of NHLBI would show a concurrent expansion in its functions and funding at the same time these decreases in cardiovascular disease mortality rates were occurring. Determination of a cause-and-effect relationship between the rise of NHLBI and improvement in cardiovascular mortality is not possible. However, as the leading research organization against cardiovascular disease, NHLBI influences the direction of research, development, and application of the instruments against cardiovascular disease, and for the past 10 years, it has operated under explicit legislative mandates in technology transfer. Thus, this summary of how NHLBI carries out its technology transfer responsibilities focuses on: 1) the administrative structure that

NHLBI has developed for technology transfer, and 2) the kinds of technology transfer activities it has supported to identify whether these activities have been in concert with the factors that are known to have helped to lower cardiovascular disease mortality rates.

## HISTORY AND DEVELOPMENT OF TECHNOLOGY TRANSFER AT NHLBI

The National Heart Institute was established in 1948 under the National Heart Act (Public Law 80-755). In 1969, it was designated the National Heart and Lung Institute to reflect its expanded responsibilities in diseases of the lung. And in 1976, its research responsibilities were recognized to include "the use of blood and blood products and the management of blood resources," and the institute was redesignated the National Heart, Lung, and Blood Institute.

Apart from these laws, which recognized NHLBI's role in heart, lung, and blood diseases, the National Heart, Blood Vessel, Lung, and Blood Act of *1972* (Public Law *92-423)* has most influenced NHLBI's current role. First, the 1972 legislation established separate funding and renewal periods for NHLB1, as had been established for the National Cancer Institute (NCI) in the previous year (1971). In contrast, the other institutes of the National Institutes of Health (NIH) fall under the general research authority of the Public Health Service Act, which places no specific disease category allocations nor time limits on their authorization. Second, the 1972 act specified the following responsibilities for NHLBI:

- research into the epidemiology, etiology, and prevention of heart, blood vessel, lung, and blood diseases, including the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences;
- research in the basic biological processes and mechanisms of the heart, blood vessel, lung, and blood;
- development and evaluation of the techniques, drugs, and devices used in the diagnosis and treatment of these diseases;
- programs to develop technological devices to assist, replace, or monitor vital organs;
- programs for field studies and large-scale testing, evaluation, and demonstration of approaches to these diseases;
- research in blood diseases and the use of blood resources;
- education and training of scientists, clinicians, and educators in these fields;
- public and professional education in these diseases;
- programs for research of these diseases in children; and
- programs for research, development, demonstration, and evaluation in emergency medical services.

The 1972 act also specified that:

- an Assistant Director for Health Information Programs be appointed to provide the public and health professionals with information on these diseases. Special emphasis was to be placed on disseminating information regarding diet, exercise, stress, hypertension, cigarette smoking, weight control, and other factors related to prevention;
- prevention and control programs be established with other governmental and private health agencies;
- national research and demonstration centers be established in these diseases;
- an interagency technical committee be established to coordinate Federal health programs and activities in these diseases; and
- no less than 15 percent of appropriated funds be used for programs in lung diseases, and 15 percent in programs for blood diseases and blood resources.

Finally, the 1972 act required annual reports summarizing that year's accomplishments and plans for the next 5 years from the director of the institute and from NHLBI's National Advisory Council.

In 1974, NHLBI divided its activities into program efforts in: 1) research, and 2) prevention, control, and education (72):

> The Research programs deal largely with the development of new knowledge and the testing and evaluation of existing knowledge. The Prevention, Control, and Education programs deal with the application and dissemination of knowledge already developed and evaluated through research, but not yet effectively applied toward the prevention, control, and treatment of disease. These Prevention, Control, and Education programs are an essential link between biomedical research and health care. Their purpose is not to deliver health services but rather to improve and expedite the transmission of fundamental research advances to the public and to medical practitioners and thereby help to promote the health of our citizens.

The research and prevention, control, and education activities were to be coordinated within a broad program strategy by (72):

- initiating an ordered sequence of coordinated program activities ranging from the acquisition of new knowledge to demonstration and control programs in the health care setting of the community;
- providing adequate program evaluation before the application of existing knowledge to health care delivery systems; and
- evaluating the impact of implemented programs on the health of the American people.

This program strategy was to be applied to subcategories or elements of heart and vascular diseases, lung diseases, and blood diseases and blood resources. The initial elements have remained the same for the Division of Heart and Vascular Diseases and undergone minor modifications in the Divisions of Lung Diseases and of Blood Diseases and Resources. Current NHLBI program elements by division are summarized in table 30.

The organizational structure of NHLBI is summarized in figure 10, and total appropriations are summarized in table 31, Fiscal year 1982 marks the second time that NHLBI appropriations have not increased in actual dollars.

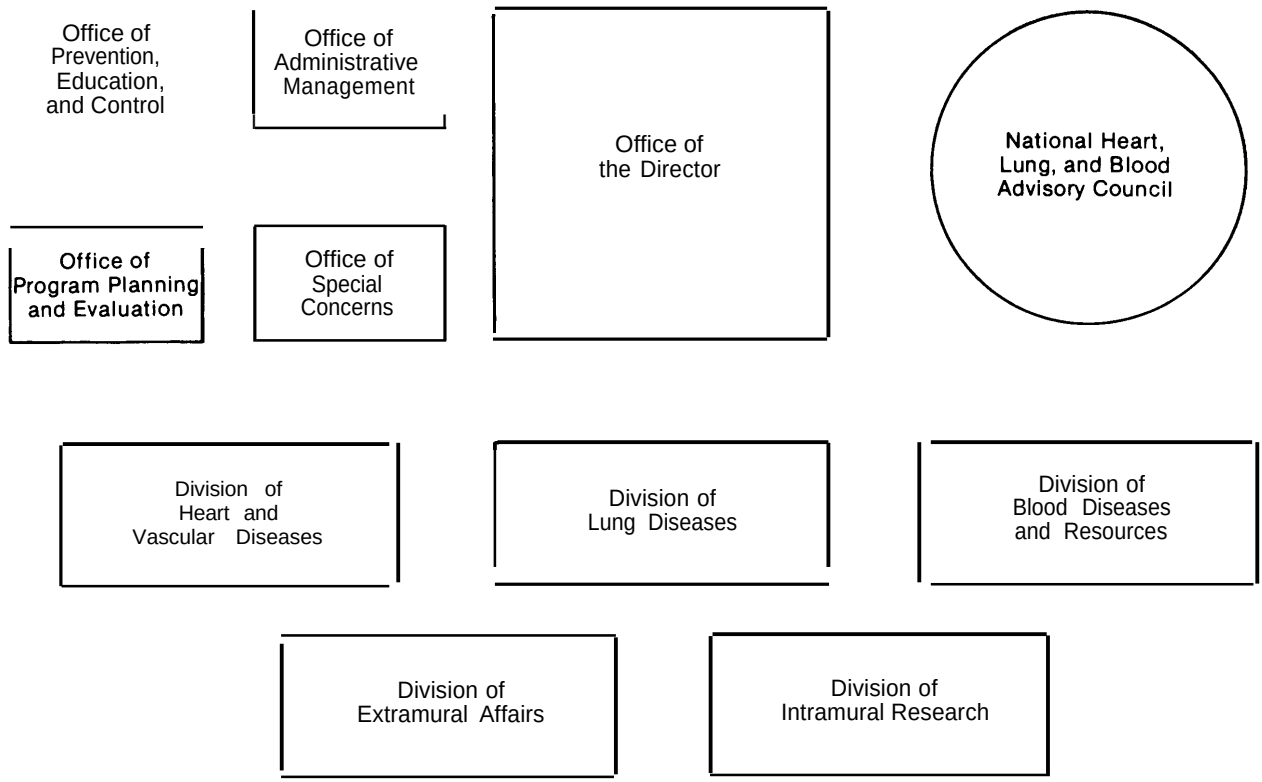
Because of overlapping responsibilities between the organizational components shown in figure 10 (e.g., extramural and intramural research takes place in all three of the categorized disease divisions), allocation of these funds among NHLBI's various activities can be expressed in various parameters, For example, table 32 summarizes 1980 funds as allocated among: 1) extramural research in heart and vascular diseases, lung diseases, and blood diseases

**Table 30.—NHLBI Program Elements by Division**

| Division of Heart and Vascular Diseases | Division of Lung Diseases | Division of Blood Diseases and Resources |
|---|---|---|
| Arteriosclerosis | Structure and function of the lung | Bleeding and clotting disorders |
| Hypertension | | Red blood cell disorders |
| Cerebrovascular disease | Chronic obstructive lung diseases | Sickle cell disease |
| Coronary heart disease | Pediatric pulmonary disease | Blood resources |
| Peripheral vascular disease | Fibrotic and immunologic interstitial lung diseases | |
| Arrhythmias | Respiratory failure | |
| Heart failure and shock | Pulmonary vascular diseases | |
| Congenital and rheumatic heart disease | | |
| Cardiomyopathies and infections of the heart | | |
| Circulatory assistance | | |

SOURCE: National Heart, Lung, and Blood Institute.

**Figure 1O.—NHLBI Organizational Structure**




SOURCE. National Heart, Lung, and Blood Institute

**Table 31.– NHLBI Appropriations, Fiscal Years 1972=82 (dollars in thousands)**

| | |
|---|---|
| 1972 ... ... ... .. . | $224,302 |
| 1973 . ..... | 290,784 |
| 1974 . ..... | 289,550 |
| 1975 . ..... | 324,630 |
| 1976 . ..... | 370,013 |
| 1977 . ..... | 396,661 |
| 1978 . ..... | 447,909 |
| 1979 , , . ..... | 510,134 |
| 1980 . ..... | 527,488 |
| 1981 . ..... | 560,264 |
| 1982 . ..... | 559,637 |

SOURCE: National Institutes of Health.

and resources; 2) intramural research; 3) direct operations; and 4) program management. Table 33 summarizes 1982 funds in similar fashion, but with extramural research categorized by research grants (see the table for further subclassification), research and development contracts, and training.

NHLBI uses yet another method of categorizing its funding in the 5-year planning requirements of its annual reports. Extramural research is subclassified into: 1) heart and vascular diseases; 2) lung diseases; 3) blood diseases and resources; 4) national research and demonstration centers; 5) prevention, education, and control programs; 6) training; and 7) construction. Table 34 summarizes NHLBI's 1980 projections for 1982, using these categories of extramural research. (The reader should compare the categories in table 34 with those in tables 32 and 33. Also note that the actual appropriations for 1982 were $559.6 million, in contrast to projected needs of $732.4 million or a lowerbound esti-

**Table 32.- NHLBI Appropriations, Fiscal Year 1980 (dollars in thousands)**

| | | Grants and contracts | | | | | |
|---|---|---|---|---|---|---|---|
| | | R&D grants | | | R&D | Research training | |
| | Total | Projects | Centers | Others | contracts | Individuals | Institutions |
| Extramural research: | | | | | | | |
| Heart and vascular diseases | $309,913 | 176,545 | 33,568 | 11,479 | 67,942 | 3,107 | 17,272 |
| Lung diseases | 75,199 | 44,866 | 14,022 | 4,377 | 4,817 | 782 | 6,335 |
| Blood diseases and resources | 72,345 | 45,485 | 14,716 | 1,452 | 6,232 | 993 | 3,467 |
| Intramural research | 39,040 | – | — | — | — | — | — |
| Direct operations | 25,062 | – | — | — | — | — | — |
| Program management | 5,532 | – | — | — | — | — | — |
| Total | $527,091 | 266,896 | 62,306 | 17,308 | 78,991 | 4,882 | 27,074 |

SOURCE: National Institutes of Health.

**Table 33.—NHLBI Appropriations, Fiscal Year 1982 (dollars in thousands)**

| | |
|---|---|
| **Research grants** | |
| Research projects: | |
| Noncompeting projects | $211,293 |
| Administrative supplements | 1,455 |
| Competing projects: | |
| Competing renewals | 46,007 |
| New | 42,672 |
| Supplemental | 2,932 |
| Subtotal, competing projects | 91,611 |
| Subtotal, research projects | 304,359 |
| Research centers | 64,808 |
| Other research: | |
| Research career programs | 14,476 |
| Cooperative clinical research | 4,838 |
| Minority biomedical support | 2,112 |
| Other research related | 2,178 |
| Subtotal, other research | 23,604 |
| Total, research grants | 392,771 |
| **Training** | |
| Individual awards | **4,826** |
| Institutional awards | **22,948** |
| Total, training | **27,774** |
| **Research and development contracts** | **$56,050** |
| **Intramural research** | **48,442** |
| **Direct operations** | **28,100** |
| **Management fund** | **(26,293)** |
| **Program management** | **6,500** |
| Total | $559,637 |

SOURCE: National Institutes of Health.

**Table 34.—1980 NHLBI Projected Resource Allocation [a] for Fiscal Year 1982 (dollars in millions)**

| | Allocation | Lowerbound al location |
|---|---|---|
| Extramural research programs: | | |
| Heart and vascular diseases | $294.2 | $283.2 |
| Lung diseases | 79.2 | 75.8 |
| Blood diseases and resources | 85.5 | 79.6 |
| National research and demonstration centers | 50.5 | 14.6 |
| Prevention, education, and control | 60.0 | 49.1 |
| Training | 55.0 | 45.0 |
| Construction | 0.0 | 0.0 |
| Total extramural research programs | $624.4 | $643.4 |
| Intramural research | 56.5 | 50.0 |
| Direct operations and program management | 51.4 | 46.1 |
| Total | $732.4 | $643.4 |

**NOTE: The figures in this table were not the actual appropriations. The table is used to illustrate the various ways allocations can be made. See text for explanation.**

**[a] Tabulations give the primary thrust of activities, even though the activities generally involve more than one subprogram.**

**SOURCE: NHLBI 8th Annual Report, 1980,**

mate of $643.4 million. Projected needs have always been higher than actual appropriations. )

NHLBI is not the only Federal agency funding cardiovascular, lung, and blood research. This was recognized in the 1972 act through the requirement that an Interagency Technical Committee (IATC) be established to coordinate Federal health programs and activities in the cardiovascular, lung, and blood areas. The Director of NHLBI chairs the committee, which includes representatives from all Federal departments and agencies whose programs involve health functions or responsibilities. IATC'S first report was issued in 1977, and an update was provided in 1979,

In fiscal year 1979, NHLBI provided 63.8 percent of Federal funds, with other NIH institutes

providing 20.7 percent, and other Federal programs providing the remaining 15.5 percent. Figure 11 summarizes the distribution of funds according to disease categories, and figure 12 summarizes the distribution of funds according to the program elements of NHLBI's three divisions. These Federal funds were being used to support nearly 9,000 research projects in fiscal year 1979 (77).

In implementing its program strategy of initiating an ordered sequence of coordinated program activities, providing adequate program evaluation before application to health care, and evaluating the impact of implemented programs (i.e., NHLBI's program strategy response to the 1972 act), NHLBI conceptualizes the biomedical research spectrum as illustrated in figure 13. NHLBI considers the research spectrum from basic research to demonstration programs (fig. 13) as comprising the initial knowledge development phase of the technology transfer process (i.e., the scientific data base shown in fig. 14).

NIH's research institutes have the primary responsibility for knowledge development and the technical analysis phase of the judgment and decision steps in the technology transfer process (fig. 14), with the NIH Director's Office playing an increasing role as the technology moves toward specific nonscientific issues. NHLBI, because of its broad mandate, not only may take responsibility for technical analyses, but also may play a lead role in interface assessment and knowledge dissemination (76).

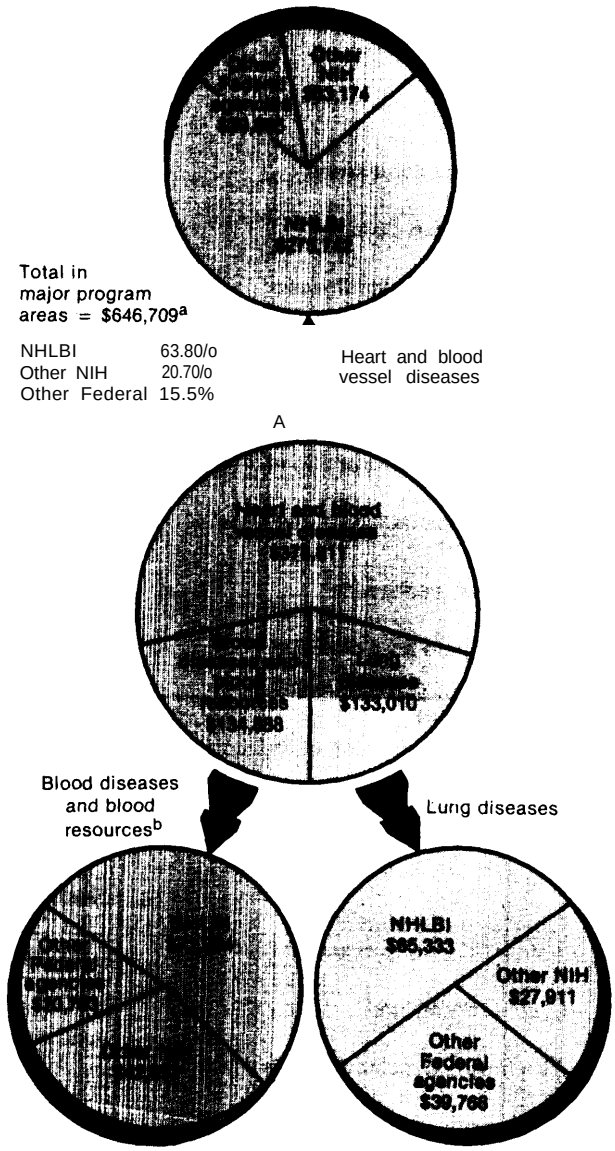
NHLBI created a Technical Consensus Development Committee in 1977, which adopted the following goal (76):

> To promote prompt adoption into practice of approaches that are technically valid, socially and ethically acceptable, and economically feasible, for prevention or control of heart, lung and blood diseases.

The Committee, which meets periodically, has the following agenda (76):

1. definition of process itself, and interaction with planning and evaluation systems already in place;
2. development of criteria for determining consensus candidates;

**Figure 11.— Distribution of Fiscal Year 1979 Funding Among Federal Agencies by Major Areas of the National Program (dollars in thousands)**

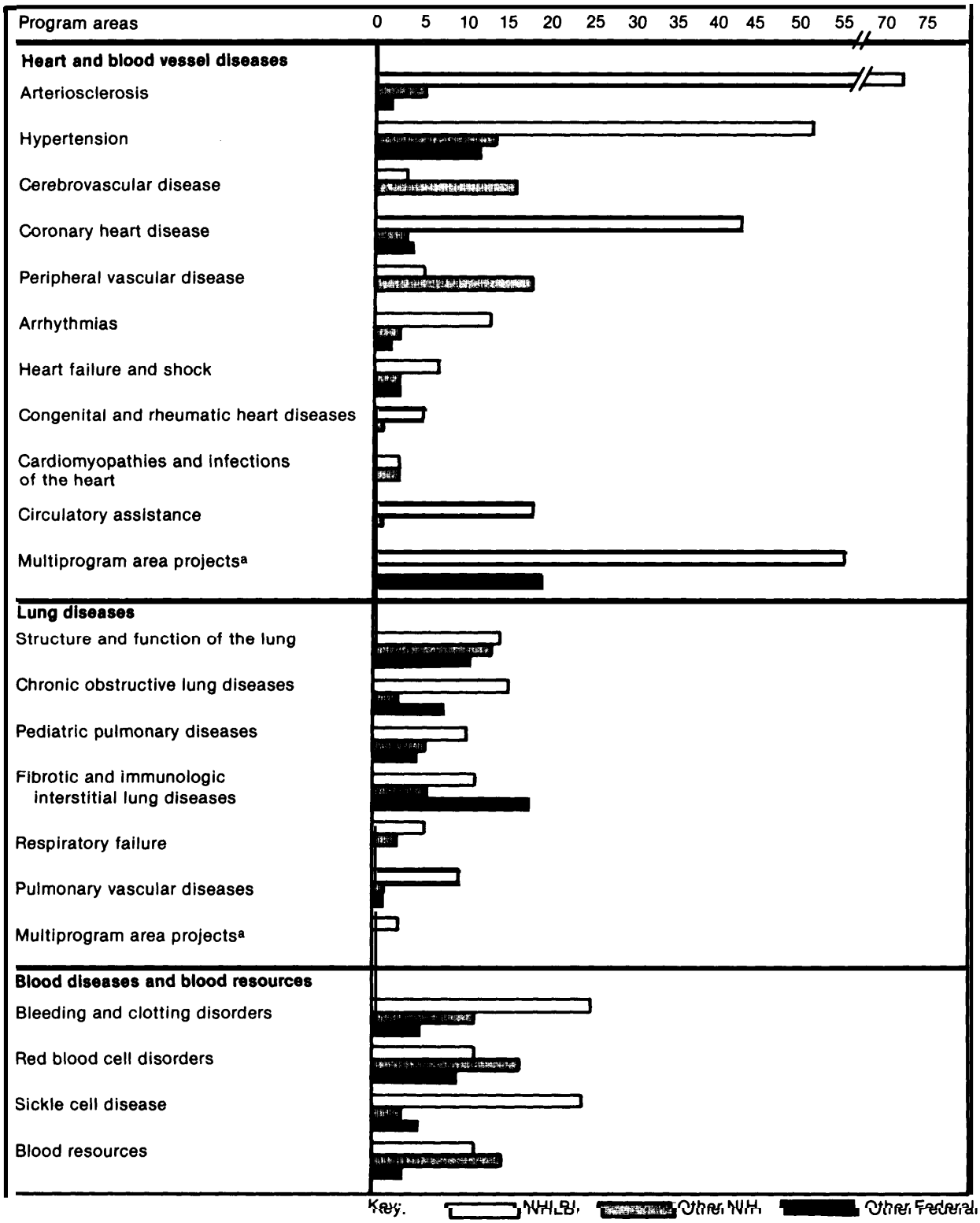



aTotal does not include unavailable funding data Indicated in tables.
bDoes not include any projects directly related to leukemias, blood cell formation, or the cellular immune system, but only those directly related to blood diseases and blood resources.

SOURCE: National Heart, Lung, and Blood Institute

3. development of criteria for determining relative priorities of consensus candidates;
4. formulation of a tracking system for technology consensus projects; and
5. designation of specific points at which to hold consensus exercises (e.g., completion of a clinical trial).

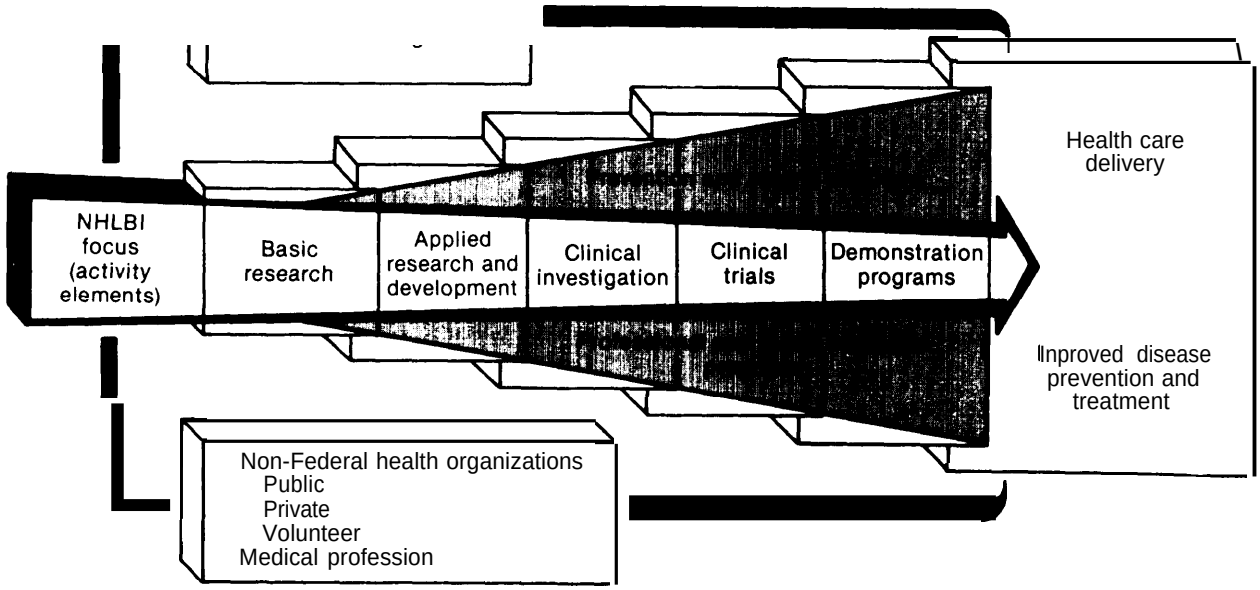
**Figure 12.—Fiscal Year 1979 Federal Funding Totals by National Program Area (dollars in millions)**




a projects which are directly related to more than one National program area.

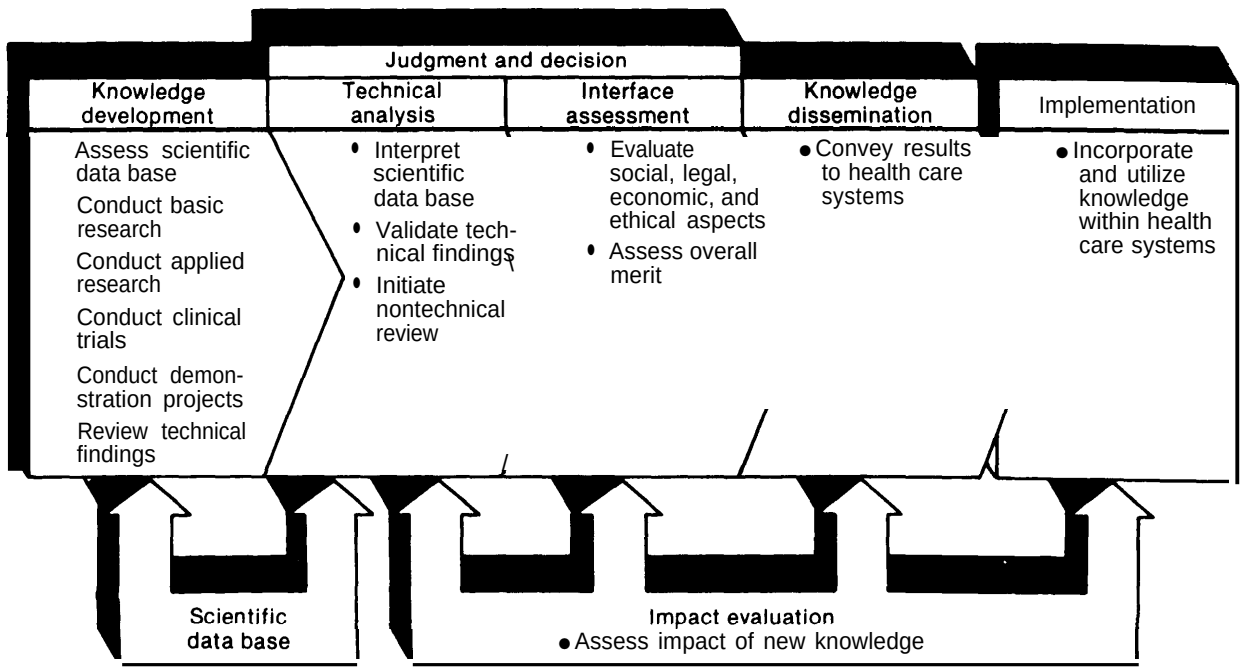
SOURCE: National Heart, Lung, and Blood Institute.

**Figure 13.—NHLBI's Conception of the Biomedical Research Spectrum**




SOURCE: National Heart, Lung, and Blood Institute.

**Figure 14.—NHLBI's Conception of the Technology Transfer Process**




SOURCE: National Heart, Lung, and Blood Institute

NHLBI technology transfer activities are followed by a coordinator in the Office of Program Planning and Evaluation. In 1978, concurrent with the establishment of the Office for Medical Applications of Research (OMAR) in the NIH Director's Office, NHLBI organized its own Medical Applications Program (MAP) in the Office of Program Planning and Evaluation. The MAP coordinator has the following resources available: 1) ad hoc MAP-Staff Working Groups selected from NHLBI's divisions and offices, 2) IATC, and 3) an NHLBI Advisory Council Working Group for Medical Applications.

MAP has two related but functionally separate sets of objectives. First are medical applications objectives incorporated within the program plans for each of the NHLBI operating units. Second are objectives at the level of the NHLBI Director's Office. The latter objectives are (75):

1. serve as a current source for an inventory and status information on all high priority "technologies in transition, " as identified and prioritized by NHLBI operating units.
2. insure coordination of technology development, assessment, and dissemination within NHLBI and between NHLBI and other portions of NIH or external agencies.
3. assist NHLBI operating units in providing visibility to their medical applications plans and accomplishment.
4. assist NHLBI operating units in maintaining awareness of advances in the state-of-the-science in technology assessment, technology validation, dissemination of technology developments to the clinical community, and diffusion of biomedical advances into standard clinical practice.
5. insure that a system for identifying and acting on priority technologies is incorporated into NHLBI's planning process.

These plans are still under formulation within NHLBI, with the assistance of a consultant from the Sloan School of Management at the Massachusetts Institute of Technology. However, the MAP objectives remain the same, with the overall program strategy still to be worked out.

The first objective is to serve as a source for an inventory and status information on high priority technologies—classified as emerging, new, or established technologies in transition—which NHLBI is actually developing or for which formal evaluations are planned or underway.

An emerging technologies list was generated by the divisions of NHLBI in 1979. This list (see table 35) was part of a list of several hundred technologies compiled by the Public Health Service Agencies for the (at that time) newly legislated National Center for Health Care Technology (NCHCT). However, the criteria for inclusion were considered too vague, and the pur-

**Table 35.—Emerging Technologies Identified by the NHLBI Divisions in 1979**

| |
|---|
| **Heart Division** |
| Clinical trials |
| Hypertension detection and followup program (HDFP) |
| Aspirin myocardial infarction study (AMIS) |
| Multicenter investigation of limitation of infarct size (MILIS) |
| Coronary artery surgery study (CASS) |
| Indomethacin v. surgery for patent ductus |
| Multiple risk factor intervention trial (MRFIT) |
| Cholestyramine to reduce lipids |
| Beta-blocker heart attack trial (BHAT) |
| Diagnostic/therapeutic technology |
| Methods for quantifying infarct size |
| Percutaneous transluminal coronary angioplasty (PTCA) |
| Circulatory assist devices |
| Long term |
| Noninvasive detection of atherosclerotic lesions |
| Totally implantable circulatory assist devices |
| ***Blood Division*** |
| Prenatal diagnosis of hemophilia |
| Prenatal diagnosis of thalassemia |
| Prenatal diagnosis of sickle cell syndrome |
| Antiplatelet agents for arterial thrombosis |
| Fibrinolytic agents |
| Prophylaxis for deep vein thrombosis (DVT) |
| Two new iron chelators tested in animals |
| Activated factor IX for hemophiliacs |
| Extracorporeal carbamylation of hemoglobin in sickle cell disease |
| Granulocyte transfusions |
| Plasmapheresis and cytapheresis |
| Fluorocarbons as blood substitutes |
| ***Lung*** **Division** |
| Noninvasive assessment of pulmonary hypertension |
| Noninvasive methods to monitor intracellular events |
| Noninvasive diagnosis of pulmonary embolism |

SOURCE: National Heart, Lung, and Blood Institute.

pose of compiling the list was not clear. Thus, in 1980, NHLBI defined an "emerging health care technology" as:

> . . . any technology under development that appears likely to be used in the practice of medicine within five years. This implies that the technology has passed a critical point in the development process such that validation of safety and efficacy in human subjects either has been initiated or is imminent.

NHLBI also set forth the following criteria for priority identification of emerging technologies: 1) potential benefit; 2) health risk; or 3) current or potential social, ethical, legal, or economic concerns. Finally, NHLBI identified the following uses for the emerging technology list (73):

1. monitoring of the diffusion / development process;
2. acceleration of development efforts;
3. conduct of additional validation studies;
4. analysis of the state of the science;
5. development of specific assessments from certain perspectives such as potential ethical, legal, or economic impact;
6. development of multifaceted assessments;
7. initiating consensus development;
8. development of a strategy for assessing third-party reimbursement recommendations;
9. dissemination of information for health planning;
10. general dissemination of information (pro or con); and / or
11. planning for impact evaluation.

The criteria mentioned above led to a much smaller list of emerging technologies in the 1980 NHLBI compilation. This list (see table 36) included eight emerging technologies, only four of which had been on the 1979 list.

In NHLBI's current compilation, in addition to emerging technologies, new technologies and established technologies in transition are also to be identified (75). Thus, some technologies on the 1979 list should appear under one of these two categories—e. g., coronary artery surgery (46) and beta-blockers for heart attacks (8).

New technologies are "those that may have passed the stage of clinical trials but are not yet widely disseminated, or those that are moving into wide scale usage without benefit of clinical trials. " Priority for identifying new technologies is given to "those which affect large population groups, represent major advances in terms of improved outcomes, have critical unanswered safety issues, and have significant economic implications."

Established technologies in transition are "those established technologies currently undergoing or likely to undergo major changes in their extent of usage or costs as a result of new research findings, or for which serious concerns have been raised concerning safety or effectiveness." Priority is to be given to "those that are the most widely used, have the greatest economic implications, or pose grave concerns for patient safety, and for which significant NHLBI resources are currently, or are planned, to be directed at developing or disseminating new knowledge, or in changing the degree to which the technology is applied. "

The year 1982 marked the 10th anniversary of the National Heart, Blood Vessel, Lung, and Blood Act of 1972, and NHLBI is currently compiling a list of the most important clinical advances of the past 10 years. Thus, three lists are being compiled: 1) emerging technologies; 2) more established technologies which warrant reexamination (new technologies and established technologies in transition); and 3) the most important clinical advances of the past 10 years.

**Table 36.–Emerging Technologies, NHLBI, 1980 Compilation**

| |
|---|
| **Therapeutic technologies** |
| Percutaneous transluminal coronary angioplasty[a] |
| Circulatory assist devices[a] |
| High frequency ventilation |
| Therapeutic plasmapheresis[a] |
| **Diagnostic technologies** |
| Ultrasound B-sound imaging |
| Subtraction radiography |
| Measurement of high density lipoprotein |
| Prenatal diagnosis of sickle cell disease[a] |

[a]Technologies which were On the 1979 list.

SOURCE: National Heart, Lung, and Blood Institute

## TECHNOLOGY TRANSFER ACTIVITIES

NHLBI has sponsored four consensus development meetings for OMAR in the NIH Director's Office: 1) transfusion therapy in pregnant sickle cell disease patients (April 1979); 2) improving clinical and consumer use of blood pressure measuring devices (April 1979); 3) thrombolytic therapy in thrombosis (April 1980); and 4) coronary bypass surgery (December 1980).

Since technology transfer involves the translation of basic research into effective and appropriate treatment, management, or prevention of diseases, much of what NHLBI supports is part of the technology transfer process. More specifically, the later stages of knowledge development—clinical trials and demonstration programs—are already far down the path toward a technology's incorporation into direct health care delivery and educational programs for the prevention of diseases. In fact, NHLBI has explicitly recognized the technology transfer functions of clinical trials and demonstration programs:

> The large-scale collaborative study or clinical trial has become an important, indeed, critical activity in the biomedical research spectrum. It is the clinical trial that determines most precisely the efficacy of treatment or preventive regimens. These large studies, which may cost tens of millions of dollars, impact both on research and medical practice. In testing hypotheses born from fundamental and clinical research they can point toward research areas where more work is required and where the results will have the most widespread benefit. They have the potential to improve the quality of health care and control costs through their careful comparison of alternative treatments **(42).**
>
> Demonstration programs test methods to introduce or facilitate delivering health care advances to the public. Demonstration activities, which are a recent addition to the Institute's programs, have been implemented to effectively translate research findings into health practices. Such programs will be of even greater importance as more clinically applicable information becomes available for dissemination from ongoing clinical trials **(79).**

Thus, NHLBI's technology transfer activities consist of clinical trials and demonstration programs which "deal with the application and dissemination of knowledge already developed and evaluated through research, but not yet effectively applied toward the prevention, control, and treatment of disease" (72). The technology transfer process previously described might be thought of as NHLBI's method of managing these activities as they apply to specific technologies.

A technology cannot be transferred unless it exists. When the 1972 act gave NHLBI responsibilities which, a few years later, would coalesce under the formal rubric of "technology transfer," the technologies that were ripe for transfer were technologies in cardiovascular diseases and to a much lesser extent in pulmonary and blood diseases. In the initial program plan following the 1972 act, the following five areas were to be given special emphasis (72):

- prevention of heart attacks—the greatest killer in our nation;
- high blood pressure education—millions of our citizens do not know that they have high blood pressure, that it may lead to serious complications such as stroke and death, and that treatment is available;
- expansion of the attack on lung diseases—a heretofore neglected area;
- development of a national blood policy—a critical national need;
- methods of controlling sickle cell disease.

Thus, the primary emphasis in the lung and blood areas had to be on knowledge development, while knowledge application was a more immediate reality for cardiovascular diseases. Furthermore, the two cardiovascular objectives were linked; hypertension is a major risk factor for heart failure and coronary disease, as well as for strokes.

NHLBI's support of clinical trials generally reflects the situation where knowledge application is a more immediate reality for cardiovascular diseases than for lung and blood diseases. Appendix C summarizes NHLBI's recently com-

pleted, current, and planned clinical trials. Three of these trials will be described shortly.

The demonstration activities in prevention, education, and control also have a heavy cardiovascular emphasis. These activities are initiated and/or implemented by the Office of Prevention, Education, and Control (OPEC) or by the operating divisions. OPEC's recent activities have included:

- the National High Blood Pressure Education Program, involving State and Federal agencies and over 150 private organizations;
- the Foods for Health project, a joint collaborative effort with Giant Foods, that is now serving as the basis for a number of nutrition education programs;
- the Blue Cross/Blue Shield demonstration effort to stimulate high blood pressure programs at the worksite (Blue Cross/Blue Shield has developed a nationwide marketing program in this area following the demonstration project);
- the High Blood Pressure TV Module, an alternative to the Public Service Announcement for conveying educational messages via TV;
- the Quit Smoking Community Intervention Program, which uses a series of TV smoking cessation segments coupled with local American Lung Association promotion and materials; and
- the Health Professionals Awareness of High Blood Pressure Media Messages, a survey of whether health messages in the lay media are absorbed by health professionals, to determine whether the lay media might be an alternative means (e. g., compared to professional journals) of reaching the medical profession,

Examples of demonstration activities under the operating divisions are the grant-supported community intervention programs and the contract-supported workplace intervention programs of the Division of Heart and Cardiovascular Diseases. The three community intervention programs—the Stanford, Minn., and Pawtucket, R.I. Heart Disease Prevention Programs—are attempting to demonstrate that a widespread community education and risk reduction effort will result in lowering cardiovascular risk factors that, in turn, will result in decreased cardiovascular mortality. The three workplace intervention programs—through the University of Maryland, Ford Motor Co., and Westinghouse Corp.—are evaluating the impact of high blood pressure control in the workplace.

As noted in the introduction to this chapter, age-adjusted cardiovascular disease death rates have fallen 25 percent in the decade between 1968 and 1978, compared to a 10-percent decline in age-adjusted death rates from noncardiovascular causes (see fig. 8). The rate of decrease also accelerated in 1973, **and now there is a 3-percent annual reduction** in deaths due to coronary heart disease and a 5-percent reduction in deaths due to strokes (105).

In 1972, NHLBI initiated two large programs. One was the National High Blood Pressure Education Program. The other was the Hypertension Detection and Followup Program.

The National High Blood Pressure Education Program, coordinated and staffed by NHLBI, involves State and Federal agencies and over 150 private organizations (36). Surveys on public knowledge about high-blood pressure conducted in 1973 and in 1979 showed the following changes. First, the belief that hypertension is a serious condition increased from 63 percent in the 1973 survey to 73 percent in 1979. Second, 83 percent of those surveyed in 1979 had had their blood pressure measured within the past year, compared to 73 percent in the 1973 survey. Third, about twice as many people knew in 1979 what a normal blood pressure was. Fourth, 40 percent more people understood that hypertension did not have reliable symptoms. And fifth, in the 1979 survey, more people knew that effective treatment was available, and more were also following their prescribed therapies (78).

The Hypertension Detection and Followup Program was a community-based randomized controlled trial involving 10,940 persons with high-blood pressure, comparing the effects on 5-year mortality of a systematic antihypertensive treatment program (stepped care, or SC)

and referral to community medical therapy (referred care, or RC). Stepped care patients were offered therapy in special centers, and therapy was increased stepwise to achieve and monitor reduction of blood pressure to or below set goals. Referred care patients were referred to their usual sources of care, with special referral efforts for those with more severe hypertension or organ system damage. Patients were apportioned among three diastolic blood pressure (DBP) strata (subclassified by age, sex, and race) on entry into the study: 90 to 104, 105 to 114, and 115 or greater mm Hg.

The study was designed to answer the questions which were unresolved by previous studies conducted within the Veterans' Administration's medical care system:

1. Is a systematic approach to antihypertensive therapy (stepped care) compared to community care effective in reducing risk of **5-year** mortality for all hypertensive adults in the community?
2. Can a substantial proportion of all hypertensive, detected in general populations, be brought under pharmacologic management aimed at reducing blood pressure to normotensive levels and kept under such management?
3. Do the benefits of therapy exceed severe toxicity in the stratum with mild hypertension, as well as in the more severe hypertensive strata?
4. Is antihypertensive therapy effective in young adults and in women and equally effective in blacks and whites?
5. Can morbidity and mortality from coronary artery disease be decreased by antihypertensive therapy?

The results of the clinical trial were as follows (34,35):

1. Over the 5 years, 50 to 65 percent of SC patients were at or below the goal DBP, compared to 30 to 44 percent in the RC group.
2. Five-year mortality from all causes was 17 percent lower for the SC group compared to the RC group, and 20 percent lower for the SC subgroup with the lowest entry DBP of 90 to 104 mm Hg. The latter finding is particularly significant, because about 70 percent of all hypertensives are in the lower DBP stratum, and approximately 60 percent of mortality attributable to high blood pressure occurs in people with this DBP range.
3. The 5-year stroke incidence was significantly less in the SC group (1.9 per 100 persons) than in the RC group (2.9 per 100 persons).
4. The death rate from strokes in the SC group (1.06 per 1,000 persons vs. 1.91 per 1,000 persons for the RC group) indicated that the stroke death rate decreased to near the level of stroke death rate in the general U.S. population (0.83 per 1,000 persons).
5. The SC group's reduction in mortality and morbidity from strokes occurred in all subsets: a) 45-percent reduction for those with entry DBP of 115 mm Hg or greater; b) 30-percent reduction in incidence among white women and decreased incidence in all subgroups; c) 27-percent reduction even in the youngest participants (ages 30 to 49 years at entry); and d) 45-percent reduction in incidence among the oldest participants (ages 60 to 69 years at entry).

Thus, this large clinical trial, with total costs approaching $70 million, showed more intensive care with available therapies could lead to a significant decrease in mortality and morbidity from hypertension and that these benefits were found in treating "mild" hypertensives as well.

The results of this study were first published in the *Journal of the American Medical Association* in December 1979 (34). In a sampling of physicians collected to see how timely dissemination of new medical information reached the practicing physician, 40 percent of family physicians were aware of the study within 2 months of publication, and 63 percent of internists learned of it within 6 months. Of the 40 percent of family physicians aware of the study, 98 percent were able to correctly answer questions about the reduction in mortality and the benefits of treating mild hypertension. Eighty percent of the family physicians and so percent of the internists learned of the study from medical journals, and 40 percent of the internists learned of it from

continuing medical education courses (the remaining percentages learned of the study from colleagues or the lay press) (110).

In sum, as a result of these activities, the public is much more aware of hypertension as a disease with serious but preventable consequences, new information on the effectiveness of treating even "mild" hypertension has been generated, and this information has disseminated rapidly to the medical community.

In 1975, the Aspirin Myocardial Infarction Study (AMIS) was initiated to test whether the regular administration of aspirin to men and women who had experienced at least one documented myocardial infarction (heart attack) would result in a significant decrease in mortality over a 3-year period. Secondary objectives were to evaluate the effects of aspirin on the incidence of coronary heart disease mortality, coronary incidence (defined as coronary heart disease mortality or definite, nonfatal myocardial infarction), and the incidence of fatal or nonfatal stroke.

Previous studies had suggested the possibility that aspirin use might lead to these effects, and together with the antiplatelet properties of aspirin, led to NHLBI's study.

The AMIS study included 4,524 persons between the ages of 30 and 69, randomized over a 13-month period to either 1 gram of aspirin (approximately three aspirin tablets) per day (2,267 persons) or to a placebo (2,257 persons) and followed for 3 years. After the random allocation, however, a difference ($p < 0.05$) was found between the two groups in the baseline distribution of seven characteristics such that the aspirin group had significantly higher percentages of patients with heart failure, angina pectoris, ECG-documented arrhythmias, and use of digitalis, nitroglycerin or long-acting nitrates, propranolol (or other beta-blockers), and "other drugs."

The results were as follows:

1. Total mortality during the entire followup period was 10.8 percent for the aspirin group and 9.7 percent for the placebo group. Adjusted for 15 baseline variables, including the seven for which the aspirin group had significantly higher percentages, total mortality was 10.5 percent and 10.0 percent, respectively.
2. Three-year mortality was 9.6 percent for the aspirin group and 8.8 percent for the placebo group.
3. Definite nonfatal myocardial infarction occurred in 6.3 percent of the aspirin group and 8.1 percent of the placebo group.
4. Coronary incidence (coronary heart disease mortality or definite nonfatal myocardial infarction) was 14.1 percent in the aspirin group and 14.8 percent in the placebo group.
5. Symptoms suggestive of peptic ulcer, gastritis, or erosion of the gastric mucosa occurred in 23.7 percent of the aspirin group and 14.9 percent of the placebo group.

The investigators reached the following conclusions (2):

> The studies that have been cited found trends in mortality favorable to aspirin. However, in none of these studies were the differences between aspirin and placebo unequivocally statistically significant when all enrolled patients were included in the analysis . . . The fact remains that in terms of the primary endpoint, AMIS found no benefit from aspirin. This trial is the largest completed and published investigation of aspirin in the post-MI population, and more weight must be given to its results. These results indicate that aspirin perhaps is helpful in reducing the frequency of non-fatal MI but leads to an increased incidence of side effects. They clearly indicate that the regular administration of aspirin in this dose does not reduce three-year mortality in patients with a history of MI. In summation, based on AMIS results, aspirin is not recommended for routine use in patients who have survived an MI.

Soon after publication of this clinical trial, it and five others (including two other newly published trials)--which had a total of over 10,000 myocardial infarction patients randomized between aspirin and double-blind placebo controls and in which over 1,000 patients died—were reviewed by the Society for Clinical Trials. The consensus that emerged was that aspirin did reduce the risk of death, but that the smallness of

the reduction **was** what had led to difficulties in interpretation even in the largest trials. It was estimated that, across all six trials, the overall reduction in the odds of reinfarction was 21 percent (standard error +/- 5 percent) and that some 70-odd deaths had been prevented (39).

Recently, NHLBI and NCI have initiated a clinical trial to test the preventive efforts of both aspirin (for cardiovascular mortality) and beta carotene or vitamin A (for cancer incidence). The study is a double-blind randomized placebo trial involving 21,500 healthy U.S. male physicians with initial ages of 50 to 75 years.

Policy analysts, preparing for the first renewal of the 1972 act, asked these questions in 1975 (109):

> Is there really anything new, in 1975, about coronary by-pass except the number of such operations performed? And has the coronary bypass procedure by now been shown to lengthen lives; or does it still mainly reduce pain symptoms of angina pectoris?

With an average cost of about $15,000 and up to 100,000 coronary bypass procedures performed annually in the United States (including celebrity patients such as Secretary of State Alexander Haig and, more recently, past Secretary of State Henry Kissinger), the questions being asked today are basically the same as those in 1975, with the exception of being more focused. For example, in what types of coronary artery disease can bypass surgery improve mortality? And is reducing symptoms a proper use of this technique? These and related questions are still being addressed in NHLBI's Coronary Artery Surgery Study, initiated in 1973 with a goal of 800 randomized patients to be followed for at least 4 years, and including a registry of 25,000 patients referred for coronary arteriography.

Related to this surgical therapy is the relatively new technique of percutaneous transluminal coronary angioplasty (PTCA), in which a special catheter with a tiny balloon at its tip is inserted in an arm or leg artery and passed up into the narrowed coronary artery, where the balloon is inflated to press the atherosclerotic plaque against the vessel wall to enlarge the narrowed area. The first angioplasty in a peripheral artery was performed by Dotter and Judkins in 1964, and the first coronary artery procedure was done in 1977 by Gruntzig.

NHLBI sponsored a workshop in June 1981 for investigators active in this field, and of the 205 procedures reported at the workshop, 116 were considered successful. The technique may be applicable to no more than 5 percent of patients undergoing coronary bypass surgery at the present time and is still considered experimental. NHLBI maintains a registry, and by early 1982, had over 80 centers in the United States, Canada, and Europe reporting a cumulative total of 3,066 patients (74).

These selected examples show both the extent and limitations of NHLBI's influence on the transfer of technologies under its purview. In the case of hypertension control, both established and new applications are converging to produce not only heightened awareness of the problem among the public and health professionals, but also significant effects on cardiovascular-related morbidity and mortality. In the case of aspirin use for preventing heart attacks, chance fluctuations in the risk factors of the aspirin v. control groups of the NHLBI-sponsored clinical trial led at least one group of reviewers to conclude that the trial mistakenly indicated no benefit. The momentum of coronary bypass surgery--reflected in the large numbers of procedures currently being performed—appears to have gone far beyond the bounds of accepted indications. Whether the NHLBI clinical trial can cause the medical community to temper its enthusiasm for this procedure remains to be seen. Finally, in the emergence of PTCA, NHLBI's establishment of a registry is an example of its monitoring of emerging technologies and its attempt to steer this new technology along a rational path of development and dissemination.

The implications of these clinical trials and demonstration programs and the technology transfer process adopted by NHLB1 are summarized in the following section.

## CONCLUSIONS

Under the National Heart, Blood Vessel, Lung, and Blood Act of 1972, NHLBI operates under an explicit mandate to help transfer the results of research in these areas to the public and health professionals. The 1972 act specified the kinds of technology transfer activities to be conducted and the minimal administrative approach which was to be adopted. Among the responsibilities specified in the 1972 act were "programs for field studies and large-scale testing, evaluation, and demonstration of approaches to these diseases" and "public and professional education in these diseases. " Health Information Programs were to provide the public and health professionals with information on these diseases, with special emphasis "to be placed upon disseminating information regarding diet, exercise, stress, hypertension, cigarette smoking, weight control, and other factors related to prevention." Prevention and control programs were to be established with other governmental and private health agencies, and national research and demonstration centers were to be established in these diseases.

In the intervening decade since the 1972 act, the context in which these transfer activities take place has expanded to include economic, legal, social, and ethical issues in addition to the traditional scientific issues of safety and effectiveness. These added emphases have led to organized efforts in the NIH Director's Office (i. e., OMAR activities), and within the Public Health Service (i.e., the now defunct NCHCT and its administrative successors). These broadened interests in technology transfer in turn have led to a parallel broadening of the objectives of NHLBI's monitoring of technology transfer activities.

The 1972 act provided direction to NHLBI in technology transfer through the specific mandates to perform large-scale clinical trials and to initiate demonstration programs in prevention, education, and control. When the NIH Director's Office established a formal technology transfer focal point in 1978 through OMAR, NHLBI organized its MAP under a coordinator in the insititute's Office of Program Planning and Evaluation in the same year. These internal MAP activities have consisted primarily of monitoring technology transfer activities as formulated by the component groups within NHLBI. MAP has been used for coordinating activities of groups within and outside of NHLBI and for summarizing the institute's activities, as reflected, for example, in the technology transfer format used in preparing the NHLBI Director's annual reports. And until the current, ongoing revision of MAP, NHLBI's "medical application accomplishments have not been synthesized into a single document, nor has there been a NHLBI focus to track and facilitate developing, assessing, validating, and transferring medical applications. The MAP plan provides a mechanism for routinely documenting activities and accomplishments and for the periodic evaluation of the NHLBI MAP" (75).

The current objectives of MAP are: 1) to serve as a source for an inventory and status information on all high-priority technologies in transition; 2) to coordinate activities within NHLBI and between NHLBI and other portions of NIH or external agencies; 3) to provide visibility to NHLBI's transfer activities and their accomplishments; 4) to maintain an awareness of the state-of-the-science of technology transfer methods; and 5) to ensure that MAP is incorporated into NHLBI's planning process (75). Past efforts have concentrated on objectives 2 through 4. The new emphases are on objective 1, the inclusion of new and established technologies in transition in addition to an emerging technologies list, as well as more precise criteria for identifyin$_g$ these technologies; and on objective 5, incorporating MAP into NHLBI's planning process. These objectives are to be linked by integrating the identification and tracking of technologies in transition into the NHLBI Implementation Plannin$_g$ Process.

This linkage raises the familiar issue of whether emphasizing targeted research and clinical application comes at the expense of basic research, especially at a time of restricted funds. At the time of the 1972 act, these concerns were barely raised (109), especially since the transfer

responsibilities were accompanied by increased funds. And, as already discussed, NHLBI implemented the legislated programs as additions to its basic research mission and passively monitored these activities. Currently, NHLBI emphasizes that technologies identified through any systematic process will originate with the divisions and branches and their advisory groups. The use of program advisory committees is seen as a method of identifying technologies that have reached an appropriate state of development and represent significant needs. Thus, targeted v. basic research is not a crucial issue,

On the other hand, downplaying a formal system of assessment at the Public Health Service level may filter down to the NHLBI effort, with the result that MAP's purpose remains to monitor and summarize technology transfer activities instead of being expanded to include it in the institute's program planning. This effect may be minimal as long as NHLBI concentrates on efficacy and safety criteria in its transfer functions, as this role would be consistent with its basic mission.

There are three other issues of importance for NHLBI's technology transfer activities, First, the formalization of NHLBI's MAP mirrors closely the development of technology transfer activities at the levels of the NIH Director's Office and of the Public Health Service. With the demise of NCHCT, a focal point for the extrascientific (i. e., economic, legal, social, and ethical) issues outside of NIH has been lost. But the impact of NHLBI's activities may be minimal, as there still exists OMAR in the NIH Director's Office to partially insulate NHLBI from being directly involved in these extrascientific issues.

Second, even if NHLBI continues to try to formalize MAP and integrate it into the institute's program plans, this activity may be relatively low on the institute's list of priorities. In a period of fiscal retrenchment, competition for funds within NHLBI will increase, and MAP may again revert to its monitoring and summarizing role.

Third, fiscal retrenchment would directly affect NHLBI's technology transfer activities. The medical community regards the large-scale clinical trial as a critical activity in the biomedical research spectrum and indispensable for determining the efficacy of treatment or preventive regimens (11,42). But the flow of technology does not simply proceed in one direction and along one path from basic research to clinical application. The Aspirin Myocardial Infarction Study and the Coronary Artery Surgery Study represent assessments of technologies already in use—the first to test a new indication for an old medicine, and the second to help clarify use of a surgical technique which is valid but costly. These evaluations of existing technologies, although a proper use of NHLBI's clinical trials program, compete with evaluations of emerging technologies for funding.

The research base in areas not yet ripe for transfer in the past decade—lung and blood diseases and selected areas of cardiovascular disease— is beginning to produce results. There will therefore be more emerging technologies to evaluate through clinical trials while the interest in reevaluating existing technologies is maintained. As long as NHLBI continues as the principal U.S. source of large-scale clinical trial support for these diseases, demands on this crucial link between research and clinical application, and the underlying competition between evaluations of emerging v. existing technologies, will increase.

A more immediate effect of fiscal restraints would be in NHLBI's demonstration programs. For example, the National High Blood Pressure Education Program was initiated in 1972. Ten years later, it is still funded through NHLBI. The only way in which new demonstration programs can occur is through additional funds or through termination or transfer of existing demonstration programs to other organizations. But demonstration programs often involve the "public goods" issue; i.e., the majority agree that these programs are needed, but no other organization wants to assume responsibility or has the funds to do so.

Thus, fiscal restraints may have the effect of retrenchment both in the management of technology transfer and in the specific activities which comprise the technology transfer process.