Review of the

National Institutes of Health Biomedical Research Training Programs

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TABLE OF CONTENTS

Foreword v

Task Force on Physician Scientist Training vii

Task Force on Training Opportunities in Clinical and Community-Based Study Designs and Methodology ix

Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists xi

Executive Summary xiii

I. Background 1

A. Overview 1

B. Task Force Procedures 1
1. Task Force on Physician Scientist Training 1
2. Task Force on Training Opportunities in Clinical and Community-Based Study Designs and Methodology 3
3. Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists 4

C. History of NIH Research Training Programs 4
1. Early Training Authorities and Activities 4
2. Changes in NIH Training Programs 5

II. Discussion and Recommendations 9

A. Early Recruitment of Talented Individuals into Biomedical Research Careers 9
1. Current NIH Programs 9
2. Early Recruitment Opportunity for Training Grants . . 10

B. Optimal Structure of Postdoctoral Research Training . . . 10
1. Length of Training 10
2. Training Structure 11
3. Application and Review Procedures 13
4. Other Aspects 14

C. Integration of Research Training with Clinical Certification Requirements and the Relationship of Research Training to Clinical Training 16

D. New Approaches and Opportunities for Research Training 17
1. Programs in Epidemiology, Biostatistics, or Related Topics 17
2. Predoctoral Individual Fellowships 18
3. Research Training in New Subject Areas 18

E. Trainee Stipends and Cost of Education 19
1. Trainee Stipends 19
2. Cost of Education 20

F. K-Series Awards 23

G. Data Collection, Monitoring, and Evaluation 24
1. Data Analysis 24
2. New Databases 25
3. Available Resources 25

Bibliography 27

FOREWORD

The Steering Committee is pleased to present this report on behalf of the three Task Forces established to review the biomedical research training programs of the National Institutes of Health (NIH).

Since their establishment in April 1989, the three Task Forces have been engaged, respectively, in review of traditional biomedical science-based training programs for physician scientists; development of an approach to train physicians and others in areas not being addressed adequately, e.g., epidemiology, biostatistics, and demography; and examination of the traditional predoctoral and postdoctoral training programs for nonphysician scientists. Members of the Task Forces want to express appreciation to those members of the scientific community and NIH staff who provided comments and resource information. Their efforts contributed substantially to this review. Appreciation is also expressed to Dr. Barbara Packard who served as rapporteur for this report.

The Steering Committee and members of the Task Forces are hopeful that this report will provide a framework for a productive research training effort and the preparation of biomedical scientists whose work will ensure the future success of the NIH mission.

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EXECUTIVE SUMMARY

In April 1989, Dr. James Wyngaarden, Director, National Institutes of Health (NIH), established three Task Forces to review NIH biomedical research training programs in terms of:

> Traditional biomedical science-based training programs to develop physician scientists.
>
> Areas of research training not currently addressed adequately or systematically, e.g., clinical trial design and methodology, biostatistics, epidemiology, and population demography.
>
> Traditional predoctoral and postdoctoral training programs for nonphysician scientists.

The Task Forces met separately to consider issues related to their individual charges and to develop recommendations. A Steering Committee, consisting of the chairs of each Task Force, was established to integrate the outcomes of the Task Forces. This report represents the deliberations, conclusions, and recommendations of the three Task Forces. A total of seven major issues were identified and addressed during the review of the NIH biomedical research training programs:

> Early recruitment of talented individuals into biomedical research careers.
>
> Optimal structure of postdoctoral research training for professional doctorates.
>
> Integration of research training with clinical certification requirements and the relationship of research training to clinical training.
>
> New approaches and opportunities for research training.
>
> Trainee stipends and cost of education.
>
> K-series awards.
>
> Data collection, monitoring, and evaluation.

Major conclusions and recommendations are summarized below.

Early Recruitment of Talented Individuals Into Biomedical Research Careers

Currently, inadequate numbers of individuals with professional doctorates are entering biomedical research careers. Studies of existing short-term training programs for health professional students suggest that such programs are effective in stimulating interest in research careers. Early recruitment efforts will be enhanced by providing opportunities for predoctoral research experiences as part of institutional training grant programs.

RECOMMENDATION

PROFESSIONAL PREDOCTORAL STUDENTS SHOULD BE ELIGIBLE FOR TRAINING ON INSTITUTIONAL TRAINING GRANTS DURING THE SUMMER OR ELECTIVE TIME FOR PERIODS OF BETWEEN THREE AND 12 MONTHS WITH A MAXIMUM OF 12 MONTHS. A MINIMUM OF SIX MONTHS SHOULD BE ENCOURAGED.

Optimal Structure for Postdoctoral Research Training

The objective of the National Research Service Award (NRSA) training programs is preparation of independent, productive researchers. A strong relationship exists between the duration of postdoctoral research training and subsequent success in receiving NIH independent research support. Research training for periods of 12 months or less is inadequate to prepare professional doctorates for successful research careers. It was concluded that, in most cases, postdoctoral research training for professional doctorate recipients should extend for a period of up to five years.

A limited commitment on the part of professional doctorate trainees and a lack of selectivity on the part of the training director may be two factors that result in ineffective institutional training grants. Revision of the payback requirement, coupled with a two-year minimum requirement for professional doctorate recipients appointed to training grants, should result in recruitment of trainees with increased commitment. Rigorous review of training program success in retaining individuals through completion of their initial training commitment will improve selectivity by training directors.

Applications for institutional NRSA grants need to include information in a standardized, tabular form in order to evaluate performance and possibly expedite review.

No apparent relationship exists between training grant size and trainee success, but review will ensure that the requested number of trainees is consistent with individual BID policies and the training institution's resources and ability to provide appropriate preceptors. Review also will consider the apparent advantage of grant applications that propose training both professional doctorates and academic doctorates in the same program. Special training experiences at institutions other than parent training institutions may be beneficial in certain cases, but provision for the training must be included in the grant application or subsequently approved by NIH staff.

RECOMMENDATION

A MINIMUM OF TWO YEARS OF TRAINING SHOULD BE REQUIRED FOR ALL PROFESSIONAL DOCTORATE APPOINTEES TO INSTITUTIONAL NRSA GRANTS. TRAINEES SHOULD BE ENCOURAGED TO APPLY FOR FURTHER RESEARCH TRAINING AND CAREER DEVELOPMENT THROUGH NATIONAL COMPETITION. TRAINING GRANT APPOINTMENTS MAY BE

EXTENDED BEYOND TWO YEARS UPON THE RECOMMENDATION OF THE TRAINING DIRECTOR AND WITH THE CONCURRENCE OF THE NIH.

THE NIH/DHHS SHOULD PLAN FOR MODIFICATION OF THE PAYBACK REQUIREMENT OF THE NRSA REAUTHORIZATION LEGISLATION.

REVIEW OF COMPETING RENEWALS FOR NRSA TRAINING GRANTS SHOULD FOCUS UPON PERFORMANCE, IN TERMS OF THE PREPARATION OF TRAINEES FOR PRODUCTIVE RESEARCH CAREERS.

NUMBERS OF TRAINEES IN TRAINING PROGRAMS SHOULD BE CONSISTENT WITH INDIVIDUAL BID POLICIES AND THE INSTITUTION'S RESOURCES.

THE PRESENCE OF BOTH M.D. AND PH.D. TRAINEES IN THE SAME PROGRAM SHOULD BE CONSIDERED FAVORABLY IN THE REVIEW OF NRSA TRAINING GRANT APPLICATIONS.

SPECIAL TRAINING EXPERIENCES AWAY FROM THE TRAINING INSTITUTION MAY BE PROPOSED AS PART OF THE TRAINING GRANT APPLICATION OR SUBSEQUENTLY TO NIH STAFF.

Integration of Research Training With Clinical Certification Requirements and the Relationship of Research Training to Clinical Training

The revised research training structure can be effectively integrated with the requirements for clinical training. The existing investigator track for board certification permits research training and satisfies the requirements for both board certification in internal medicine and subspecialty certification within the normal clinical training period. Differing approaches to integrating research training with clinical training are likely to exist, and they can be permitted as long as NRSA training grant appointments are not used to support clinical training.

RECOMMENDATION

MULTIPLE PATHWAYS SHOULD BE PERMITTED TO ACCOMMODATE THE NEEDS FOR CLINICAL CERTIFICATION WITHIN THE CONTEXT OF THE RESEARCH TRAINING EXPERIENCE OF TWO OR MORE YEARS.

New Approaches and Opportunities For Research Training

Expanded opportunities for research training and research career development are required to meet the demand for individuals capable of designing, implementing, and analyzing epidemiologic studies and clinical trials, as well as for individual experts in biostatistics.

Individual predoctoral fellowships are currently being used effectively within the Public Health Service. These fellowships may have potential

to complement NIH predoctoral training grants by increasing the number of institutions available for training. Such possibilities demonstrate the need for periodic reviews of the relevance of existing training programs to the current and future needs of the sponsoring BIDs. New programs should be initiated and old programs discontinued as appropriate.

RECOMMENDATION

ADVANCED PROGRAMS OF STUDY AND K-SERIES AWARDS SHOULD BE SUPPORTED IN EPIDEMIOLOGY, BIOSTATISTICS, OR RELATED TOPICS TO INCREASE PREDOCTORAL AND POSTDOCTORAL RESEARCH TRAINING OPPORTUNITIES. CURRENT NIH MECHANISMS ALSO SHOULD BE USED TO SUPPORT MASTER'S DEGREE-LEVEL PROGRAMS AND NONDEGREE CERTIFICATE PROGRAMS THAT FOCUS ON THESE TOPICS.

THE OPPORTUNITY FOR INDIVIDUAL PREDOCTORAL FELLOWSHIPS TO ADDRESS SPECIFIC NIH TRAINING NEEDS SHOULD BE REVIEWED.

NEEDS IN NEW RESEARCH AREAS AND APPROACHES FOR NIH RESEARCH TRAINING TO RESPOND TO THESE NEEDS SHOULD BE EVALUATED ON AN ONGOING BASIS.

Trainee Stipends and Cost of Education

Current NRSA stipend levels are below salaries paid to housestaff with comparable years of postgraduate experience. Consequently, individuals who elect to pursue research training are forced to accept a reduced salary. The NRSA stipend structure can be revised so that it provides an incentive for recipients of professional doctorates interested in research careers. Increased stipend levels also are needed for predoctoral and postdoctoral nonphysician scientist trainees.

Inclusion of some support for the cost of education is appropriate in institutional research training grants. However, with constantly rising tuition charges, declining NIH research training budgets in terms of constant dollars, and decreases in the number of predoctoral trainees, the NIH must seek approaches to stabilize the situation. A "two-tier cost of education (CoE) allowance" for predoctoral training, i.e., one level for private institutions and another for public institutions, would control the portion of the NIH training budget allocated to educational expenses. The annual decision regarding the CoE allowance can be made with the objective of maintaining at least a constant number of trainees. These two-tier CoE levels are also applicable to special NIH training programs.

The mechanism for research training support should be made more comparable across Federal agencies.

RECOMMENDATION

POSTDOCTORAL STIPENDS FOR PROFESSIONAL DOCTORATES SHOULD BE AT LEAST AS ATTRACTIVE AS CURRENT HOUSESTAFF SALARIES. STIPEND LEVELS ALSO SHOULD BE INCREASED FOR ACADEMIC TRAINEES. ANNUAL STIPEND INCREASES ARE NECESSARY TO COMPENSATE FOR INCREASED LIVING COSTS.

THE PROPOSED "TWO-TIER COST OF EDUCATION ALLOWANCE" AS A MECHANISM TO LIMIT TUITION PAYMENTS IS REAFFIRMED. THE SAME GENERAL PRINCIPLES SHOULD BE APPLIED TO SPECIAL NIH RESEARCH TRAINING PROGRAMS.

FEDERAL AGENCIES SUPPORTING BIOMEDICAL RESEARCH TRAINING SHOULD EXPLORE WAYS OF MAKING THEIR SUPPORT MECHANISMS MORE EQUIVALENT.

K-Series Awards

A full five years of career development support may be more than is needed for all individuals who have completed the two or more year appointment on a research training grant. A three-year career development award, when coupled with the two-year training experience, would provide professional doctorates with the total of five or more years of research experience deemed necessary to prepare them for a successful research career.

Salaries for K-series awards should be higher than corresponding stipends for training grant appointments. In this way, trainees will be offered a further incentive to seek independent support through national competition.

RECOMMENDATION

THREE-YEAR K-SERIES AWARDS SHOULD BE MADE AVAILABLE FOR PROFESSIONAL DOCTORATES. SALARIES SHOULD BE INCREASED TO $50,000 PER YEAR ON K-SERIES AWARDS.

Data Collection, Monitoring, and Evaluation

Regular reviews and analyses are necessary to determine the effectiveness of the NRSA training programs. A number of data sources are available to the NIH that offer opportunities for important insights into program performance. At present, they are not explored to the fullest extent possible. Collecting additional data will permit a more complete assessment of NIH training activities.

RECOMMENDATION

STANDARDIZED INFORMATION NECESSARY TO ASSESS PROGRAM PERFORMANCE SHOULD BE COLLECTED ON ALL INDIVIDUALS AND INSTITUTIONS RECEIVING NRSA RESEARCH TRAINING SUPPORT.

AVAILABLE NIH TRAINING DATA SHOULD BE ANALYZED FURTHER AND NEW DATABASES ESTABLISHED AS NEEDED.

I. BACKGROUND

A. Overview

The contribution of research training to the development of productive researchers and the advancement of biomedical science is widely recognized. Continued research progress can be ensured only if adequate numbers of appropriately trained individuals pursue careers in biomedical research.

On April 19, 1989, Dr. James B. Wyngaarden, Director, National Institutes of Health (NIH), reemphasized the importance of research training to the mission of the NIH by establishing three Task Forces to review the NIH biomedical research training programs, identify and assess issues, and make recommendations for improvements. He requested that the Task Forces complete their review so that implementation of recommendations could begin with the next major application cycle, i.e., January 1990. He asked them to focus upon:

> Traditional biomedical science-based training programs to develop physician scientists.
>
> Areas of research training not currently addressed adequately or systematically, e.g., clinical trial design and methodology, biostatistics, epidemiology, and demography.
>
> Traditional predoctoral and postdoctoral training programs for nonphysician scientists.

The NIH training program currently consists of a series of mechanisms of support, including the institutional training grant (T-series) and the individual fellowship award (F-series) supported through National Research Service Award (NRSA) funds, and the career development awards (K-series) supported through research project grants. While most trainees are supported initially on a training grant, individual fellowship grants are available at any stage of research training. Further development of research skills is supported through the career development awards. Individuals with advanced research experience may compete, at any time, for independent research support through either a First Independent Research Support and Transition (FIRST) award (R29) or a research project grant (R01) award.

This report is based on the deliberations of the three NIH Task Forces.

B. Task Force Procedures

1. Task Force on Physician Scientist Training

The Task Force was convened in May 1989, and charged with the responsibility to review the NIH training programs for physician

scientists and make recommendations for their improvement. A number of indicators suggest that improvements are, in fact, needed:

> The percentage of M.D. trainees who subsequently apply for and receive NIH research grants is unacceptably low.
>
> More than 60 percent of M.D.s are trained for 12 months or less. NIH data indicate that those who are trained for longer periods are more successful in competing for NIH support.
>
> Postdoctoral positions on training grants are sometimes used to support individuals other than those committed to a career in biomedical research.
>
> Some training grants have not been effective in producing physician scientists.

During its review of NIH training programs for physician scientists, the Task Force was asked to consider the following questions about the current training grant program:

> Is the training grant still the best way to introduce physicians to research?
>
> Should it be modified . . . or perhaps phased into a K-series . . . award to provide an adequate continuum of training?
>
> Are there ways to make the current NIH research training program more effective?
>
> Should the training grants be phased out for physician scientists or reduced in favor of the K-series approach?

The Task Force met eight times between May and August 1989. Dr. Wyngaarden met with members in May to deliver the formal charge and discuss several aspects of the topic with them. Over the course of their meetings, the members considered a number of issues, including:

> Early recruitment of talented individuals into biomedical research careers.
>
> Optimal structure of postdoctoral research training for professional doctorates.*
>
> Integration of research training with clinical certification requirements and the relationship of research training to clinical training.
>
> Trainee stipends.
>
> K-series awards for professional postdoctoral candidates.

* The Task Force designated the term "professional doctorates" to encompass other relevant professional degrees as well as M.D.s.

Background data were provided to the Task Force on these issues. In addition, discussion papers were prepared for review on (1) the structure and nature of an optimal research training program for professional doctorates, (2) a revised K-series award, (3) trainee stipends, and (4) the training grant application process and review criteria.

The Task Force shared its ideas with:

> The National Heart, Lung, and Blood Advisory Council (NHLBAC).
>
> The National Institute of Arthritis and Musculoskeletal and Skin Diseases Advisory Council (NIAMSAC).

In order to receive the broadest range of consultation, the Task Force members also invited the following individuals to meet with them:

> Dr. John A. Oates, Jr.
> Chairman, Department of Medicine
> Vanderbilt University
> Member, NHLBAC
>
> Dr. William Hazzard
> Chairman, Department of Medicine
> Bowman Gray School of Medicine
> Member, American Board of Internal Medicine (ABIM)
>
> Dr. Arthur Nienhuis
> Chief, Clinical Hematology Branch, NHLBI
> Member, ABIM

In addition, several letters were received from members of the scientific community, organizations, and NIH staff, who shared their views on the research training of professional doctorates with the Task Force.

2. Task Force on Training Opportunities in Clinical and Community-Based Study Designs and Methodology

The Task Force was convened on June 19, 1989, and Dr. Wyngaarden delivered the formal charge to develop an approach to train physicians and others in areas that are not being addressed adequately or systematically, e.g., clinical trial design and methodology, biostatistics, epidemiology, and demography. Members subsequently discussed features of advanced programs for research training and career development in epidemiology, biostatistics, or related topics as well as additional programs for health professionals. The Task Force also considered issues of eligibility and mechanisms of support. A draft Task Force report was reviewed at a second meeting on June 29, 1989. Thereafter, the Task Force used mail review to develop and complete an interim report for the Director, NIH, and for consideration at the July 27, 1989, meeting of BID Directors.

3. Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists

The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists met six times. At its first meeting on May 23, 1989, Dr. Wyngaarden charged members to examine traditional predoctoral and postdoctoral training programs for nonphysician scientists. He indicated that the outcomes for nonphysician scientists who previously had NIH research training support were good.

A number of important issues were identified for consideration, including:

- Data collection and evaluation studies.
- Problems regarding tuition and stipends.
- New approaches, opportunities, and needs for research training.

Working groups of the Task Force were established and each was assigned one of these topics. The full Task Force reviewed and modified draft reports from the working groups. A preliminary report, including a series of recommendations, was prepared and submitted for consideration by the Director, NIH, and the BID Directors.

C. History of NIH Research Training Programs

1. Early Training Authorities and Activities

The initial legislation that authorized the NIH to conduct and support training was provided in 1930 by the Ransdell Act (P.L. 71-251), the same legislation that formally established the then National Institute of Health. Thus, from its inception, the NIH has been directed to recognize training as one of its major responsibilities. Under the terms of the Ransdell Act, individual scientists could be designated ". . . to receive fellowships . . . for duty in the National Institute of Health . . ." or ". . . for the prosecution of investigations in other localities and institutions in this and other countries . . . ."

When Congress passed the National Cancer Act (P.L. 75-244) in 1937 and thereby established the first of the disease-specific institutes, it included in the legislation a provision for training in cancer. This provision led to the first major fellowship program supported by the U.S. Government. According to terms of the Act, research fellowships established under it were to provide ". . . such stipends or allowances . . . as the Surgeon General may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States or abroad . . . ." Because the National Cancer Act also authorized ". . . training and instruction in technical matters relating to the diagnosis and treatment of cancer . . .", the National Cancer Institute (NCI) focused its initial training efforts on postdoctoral research fellows and

clinical training for physicians to improve their capability in diagnosis and therapy. Awards for both kinds of training were made to individuals selected by NCI staff.

In 1946, the Public Health Service (PHS) Act provided explicit authority for grants for the support of training, and this authority was extended and expanded in the National Heart Act (P.L. 80-655) of 1948. The text of the National Heart Act specifically provided for the possibility of grants for training programs. It permitted the new National Heart Institute to:

> ". . . establish and maintain traineeships, in the Institute and elsewhere in matters relating to the diagnosis, prevention, and treatment of heart disease . . . the number of persons receiving such training and instruction, and the number of persons holding such traineeships, to be fixed by the Council, and in addition, provide for such training, instruction, and traineeships through grants . . . ."

Also, in 1948, the National Dental Research Act (P.L. 80-755) followed the pattern of authority for training set forth in the National Heart Act. The PHS Act amendments (P.L. 81-692) of 1950, which established the National Institute of Arthritis and Metabolic Diseases and the National Institute of Neurological Diseases and Blindness, provided very broad training authorities for the new Institutes and extended those authorities to all existing Institutes. Subsequent legislation establishing additional Institutes all contain comparably broad training authority.

The first departure from a system of awards to individuals occurred in 1948 with the initiation of undergraduate training grants. These training grants were made to professional schools to strengthen their undergraduate teaching capabilities in selected fields. The grants provided the same amount for each institution of a given type. They included no stipends for individuals but instead, provided funds for use at the recipient school's discretion to purchase equipment, acquire instructional material, and offer faculty salary support.

2. Changes in NIH Training Programs

Significant changes have occurred in NIH training programs since the 1930 passage of the Ransdell Act. The training grant mechanism was modified by the National Heart Institute in 1950 to provide support for graduate-level training and include funds for training stipends. In addition, the new graduate-level training grant differed from its undergraduate predecessor in that the award amounts varied from one institution to another. A further differentiation between the graduate and undergraduate training grant was subsequently introduced. Grantee institutions were permitted increased latitude in the management of the graduate grants; they were allowed to select trainees without prior central NIH review and to set the level of individual stipends. With these modifications, the basic pattern of the institutional training grant was developed.

An important change occurred in 1954, when part-time fellowships, usually for summer work, were initiated to stimulate the interest of medical and dental students in research and permit early identification of talent. Later in 1957, a program was established that permitted medical and dental students to spend a year in research between their preclinical and clinical years. It was also about this time that some training programs began to focus on the needs of faculty and research. Gradually, the use of clinical traineeships was phased out. The Division of Research Grants provided the initial NIH focus for support of research training in fundamental disciplines related to health, e.g., biophysics, epidemiology, and biostatistics. In 1958, these training grants and predoctoral training programs from the established Institutes were transferred to the Division of General Medical Sciences, now the National Institute of General Medical Sciences.

These developments, as well as a growing demand for scientists and teachers, an adequate pool of potential trainees, and expansion of the biomedical research effort, led to rapid expansion of NIH training programs in the late 1950s and early 1960s. The number of trainees supported by NIH under its original training authority reached over 16,000 in 1969. By 1971, NIH training grants and fellowships supported or assisted 37.5 percent of the nation's full-time graduate students in the medical sciences and 21 percent in the life sciences. However, in its presentation of the fiscal year (FY) 1974 budget, the Administration made an attempt to eliminate the award of all new training and fellowship grants.

Congress responded by providing new authority with the National Research Service Award Act of 1974 (Title I, P.L. 93-348). This Act abolished all previous training authorities under the PHS Act and consolidated them under the National Research Service Award (NRSA). It provided both predoctoral and postdoctoral support to individuals and additional support to institutions training such individuals. It also provided for a payback requirement* as a condition of receiving support. This provision was intended to discourage the use of this authority to support clinical training of physicians. In implementing the provisions of the NRSA, the NIH established individual postdoctoral fellowships (F32s) and institutional training grants for predoctoral and postdoctoral students (T32s).

During the 1970s, there was a decline in the number of trainees. For the first few years following passage of the NRSA legislation, NIH research trainees were supported by a combination of remaining commitments under the old training authority and the new NRSA authorizations.

* For each year of NRSA support, recipients were required either to serve for an equivalent period of time in research, teaching, or providing medical care to an underserved area or to reimburse the government for the cost of the training.

Since 1979, the number of full-time research training positions budgeted for the NIH under the NRSA has been relatively stable, fluctuating between a high of 11,197 in 1979 and a low of 10,382 in 1986. The number of positions was 11,181 in 1987.

The programmatic evolution of training grants was gradual across the NIH, and emphasis was individualized depending on the particular fields of science needed to carry out the mission of a Bureau, Institute, and/or Division (BID). The versatility and flexibility of the training grant made it an ideal vehicle for this effort.

The fundamental goal of the NIH research training programs is to prepare well-trained, highly qualified, and productive research investigators in fields relevant to the advance of biomedical science. The NRSA is the only current authority under which the NIH supports basic preparation of individuals for careers in biomedical research. Through a system of institutional training grants and individual fellowships, the trainee or fellow receives a stipend for full-time concentrated study and may elect, under supervision, an individual research focus. Funds are awarded for predoctoral and postdoctoral stipends, and for tuition where warranted, with a modest allocation to the institution to defray training-related expenses not covered by tuition.

II. DISCUSSION AND RECOMMENDATIONS

A. Early Recruitment of Talented Individuals Into Biomedical Research Careers

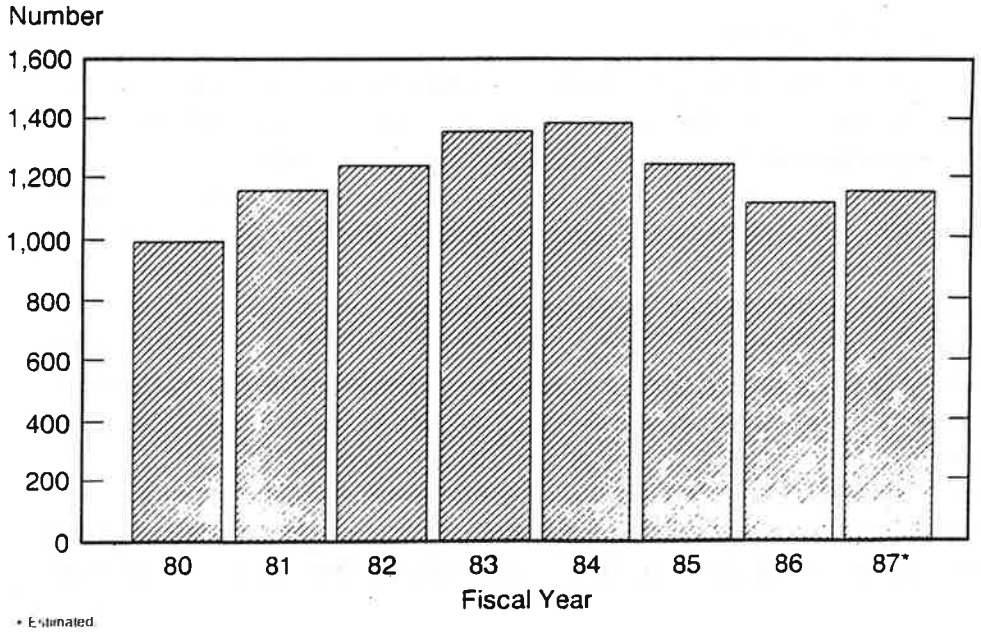
1. Current NIH Programs

The Task Force on Physician Scientist Training is concerned that inadequate numbers of individuals with M.D.s or other professional doctorates are entering into research careers. A study of the impact of the short-term training program for health professional students (T35) showed that program participants were twice as likely to express an interest in a research career at the time of graduation as were individuals who did not have the benefit of such an experience. Additionally, T35 trainees have research goals and demonstrate a relatively greater appreciation of the value of a basic science foundation preparatory to a research career. The NIH supported an estimated 1,156 appointments of individuals for short-term training in FY 1987 (Figure 1). Currently, the National Institute of Neurological Disorders and Stroke (NINDS) supports a limited number of short-term traineeships on its institutional NRSA training grants to provide professional predoctoral students with two or more "off-quarter" opportunities for involvement in research.

Such a program supported as part of the training grant may offer an effective mechanism for stimulating research interest among professional predoctoral students. It was agreed that both T35 and T32 training mechanisms are important training opportunities for professional predoctoral students and that both are needed.

Figure 1

Short-Term Research Training (T35s)
Number of Appointments



* Estimated

Source: NIH Data Book 1988

2. Early Recruitment Opportunity for Training Grants

The intent of the training program for professional predoctoral students is to provide opportunities for participation in biomedical research training over the course of, but prior to the completion of, professional doctorate training. The incorporation of training of professional predoctoral students into the institutional training grant offers several advantages. It introduces individuals, at an early stage of their professional training, to the concept of a continuum of research training and career development. The faculty of the training grant is available to the participating students, and the training director is expected to report on progress and success of the training. Students can become predoctoral trainees on training grants either at the institution from which the degree will be conferred or at another institution. Additionally, a participant in the predoctoral program can continue postdoctoral training on a training grant either at the institution from which the degree was conferred or at another one.

More opportunities, in addition to those currently available, are needed to stimulate interest in research careers among predoctoral students in health professional schools. Inclusion of professional predoctoral students on training grants will enhance efforts of early recruitment of talented individuals into biomedical research careers.

RECOMMENDATION

> Eligibility for training on an institutional training grant should be extended to include professional predoctoral students, whose training would be in summer or elective time for periods of between three and 12 months with a maximum of 12 months. A minimum of six months should be encouraged.

B. Optimal Structure of Postdoctoral Research Training

1. Length of Training

Early in its deliberations, the Task Force on Physician Scientist Training addressed the issue of the length of research training required to prepare professionally trained individuals for independent research careers. Data were reviewed that showed a strong relationship between the duration of postdoctoral research training and subsequent success in receiving NIH independent research support. The preparation of independent, productive researchers is the underlying objective of the NRSA Training Program. An important measure of the level of research development of trainees is their likelihood of submitting applications for and receiving NIH research grant support. While the current NRSA program permits support for postdoctoral appointments of up to 36 months, NIH data show that more than 60 percent of professional doctorate degree recipients are appointed to training grants for a total of 12 months or less (Figure 2). Other data indicate that the percentage of

M.D. trainees who became NIH grant applicants and awardees has been decreasing since FY 1976.

An analysis of professional postdoctoral trainees, FY 1976-1982, who subsequently became NIH grant applicants and awardees showed that the longer the period of training, the more likely an individual trainee is to apply for and receive NIH research grant support (Figure 3). The Task Force recognized that individuals may receive research training support from non-NIH sources. However, the fact remains that, overall, M.D.s have low NIH grant application and award rates.

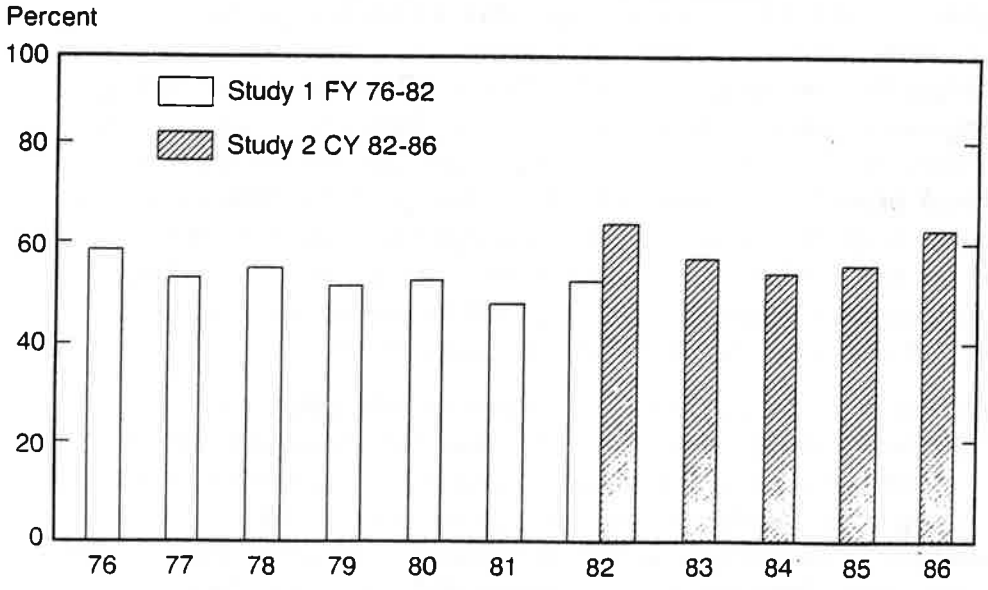
The Task Force and all of its consultants were unanimous in concluding that 12 months of postdoctoral research training is inadequate to prepare most individuals for independent research careers and that training should, in most cases, extend for a period of up to five years. Members expressed enthusiasm and confidence in the institutional training grant as a mechanism of support. They would like to see it more effectively utilized, particularly for professional postdoctoral training.

2. Training Structure

The apparent ineffectiveness of a number of training grants in producing physician scientists focused attention upon the role of institutional training grants in a redesigned research training structure. The lack of success of some training programs may be due to a limited commitment to research on the part of the trainees and to a lack of selectivity on the part of the training directors.

Figure 2

Postdoctoral MD Trainees Who Trained 12 Months or Less

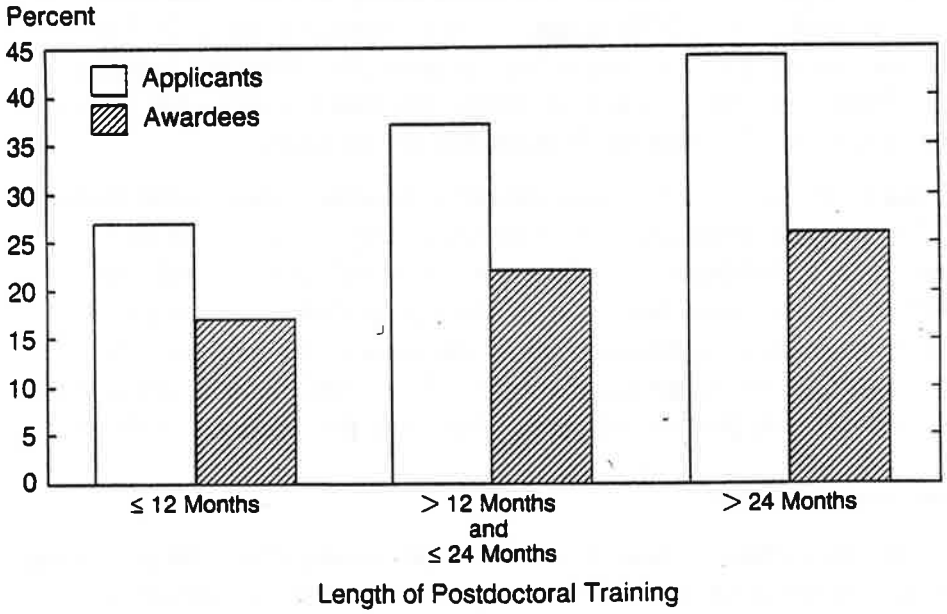


FY-Fiscal year
CY-Calendar year
Source: NIH, OD-OSPL

Figure 3

Postdoctoral MD Trainees Who Became NIH Grant Applicants and Awardees

FY 76 to 82



The requirement of a minimum of two years of research training and the modification of the NRSA payback requirement will serve to increase commitment on the part of trainees. With a minimum appointment period of two years instead of nine months, only individuals with a real interest in research careers will be likely to accept appointments. Incentive to complete the minimum appointment period would be provided by modifying the payback requirement so that it is incurred by the first year of training and satisfied by successful completion of the second year. It was recognized that the proposed modification to the payback requirement will need legislative action. The payback requirement also will need to be changed for the first year of an individual fellowship grant award (F32) to reflect the corresponding change for training grant awards. The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists believes that the payback provisions for such individuals also should be reconsidered. In view of the proposed modification of the payback requirements for trainees who are holders of professional doctorate degrees and the need for legislation to make such a change, NIH should develop an overall plan that addresses the entire payback requirement.

The need for research training opportunities extending beyond the first two years of training was considered. It was decided to allow optional appointments for a third or, in exceptional circumstances, fourth year on a training grant. While it was readily agreed that training directors should still be permitted to select individuals for research training, there was a concern about the appropriateness of delegating to them the decision to extend support to a trainee beyond the first two years.

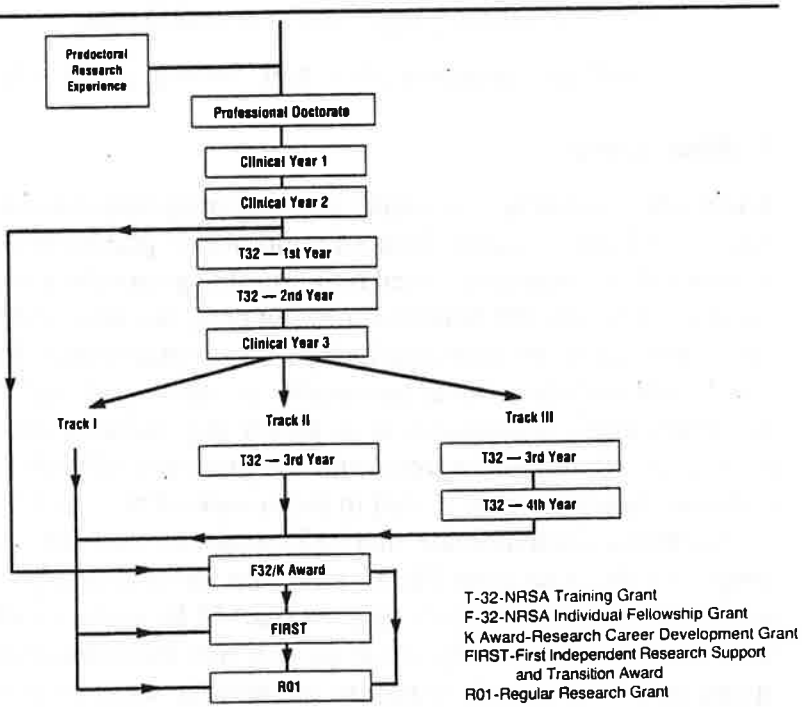
However, it was recognized that a rigorous review of the success of training programs in preparing individuals for independent research careers, when coupled with an NIH review of appointments for a third or, in exceptional cases, a fourth year of training, could be effective in ensuring that such appointments are appropriate. The proposal for a revised research training grant program for professional doctorates is illustrated in Figure 4. Multiple pathways are possible.

Improved selectivity by training directors can be ensured by rigorous review of training program success in retaining individuals through completion of the initial training commitment. Task Force members agreed that institutions should lose both training positions and funds for training positions filled by individuals who leave the program before completing their training experience. However, if a trainee receives an alternate award, such as an NIH individual fellowship or K-series award, or an equivalent award from non-NIH sources, a request for the balance of time and funds for the training position could be submitted to NIH staff for consideration.

3. Application and Review Procedures

Revised requirements for institutional NRSA training grant applications were developed by the Task Force. Applications will now be expected to convey aims that are consistent with the revised research training program and to describe how they will be addressed. In addition, certain information will be required in a standardized, tabular form to expedite review. The tables will include:

Figure 4
Research Training For Professional Doctorates



Current grant and contract research support and training support of the proposed training faculty.

Preceptor experience of present and proposed faculty supported by NRSA research training grants, NRSA fellowships, and by other means.

Research publications by trainees during the past five years.

Applications submitted and awards received by trainees for research support from NIH and other sources during the past five years, including those where they participated as a co-investigator.

Other support for training and current number of trainees of participating faculty.

In particular, trainee recruitment, selection, and activities will be described more fully and increased emphasis placed on the likelihood of the proposed program to achieve the stated aims on the basis of past record.

Revised review criteria include:

Past record of preceptors in research training.

Design and direction of the training program.

Caliber of preceptors.

Training environment, including attention to ethical standards of research.

Recruitment and selection plans for trainees, including underrepresented minorities and women.

Available training experiences and activities.

Career development plans and tracking process for trainees.

4. Other Aspects

Three other aspects of research training programs were addressed. It was agreed that arbitrary limits should not be placed by NIH upon the number of trainees permitted on a training grant since available data show no relationship between training program size and the subsequent development of trainees into independent researchers. Instead, the number of trainees should be consistent with individual BID policies and the institution's resources and its ability to provide appropriate preceptors. It also was agreed that the presence of both M.D. and Ph.D. trainees should be considered in the review of research training grant applications. Data indicate that M.D. trainees who are trained in programs that also train Ph.D.s are more likely to apply for and receive independent NIH research support than M.D. trainees who train only with other M.D.s. Finally, it was agreed that trainees could be allowed to spend up to one year in a training experience away from the parent

institution, with continued stipend support from the training grant. However, such a training experience could only be supported by a training grant if it was included either as part of the training grant application or subsequently approved by NIH staff.

RECOMMENDATION

The proposal for a revised training grant program includes a requirement for a minimum of two years of training for all appointees to institutional NRSA grants. After that time, trainees should be encouraged to apply for support for further research training (F32) and career development (K08, K11) through national competition. However, training grant appointments could be extended for an additional one or, in exceptional circumstances, two years upon the recommendation of the training director and with the concurrence of the NIH.

The NIH should develop a plan for appropriate modification of the payback requirement of the NRSA reauthorization legislation.

Review of competing renewals for NRSA training grants should focus upon performance. In particular, the review should consider the:

Past record of preceptors in research training.

Design and direction of the training program.

Caliber of preceptors.

Training environment, including attention to ethical standards of research.

Recruitment and selection plans, including minorities and women.

Available training experiences and activities.

Career development plans and tracking process for trainees.

The presence of both M.D. and Ph.D. trainees in the same program should be considered favorably in the review of research training grant applications.

The number of trainees permitted on a training program should be consistent with individual BID policies and the institution's resources, including its ability to provide appropriate preceptors.

Individual trainees should be allowed up to one year of special training experiences at institutions other than the parent institution with continued stipend support from the training grant, if proposed as part of the training grant application.

C. Integration of Research Training With Clinical Certification Requirements and the Relationship of Research Training to Clinical Training

In developing the proposal for a revised research training structure, the Task Force on Physician Scientist Training focused first upon the extent and nature of training required to prepare recipients of professional doctorates for independent research careers. It was realized, however, that any revision to the existing training structure would have to be compatible with the requirements for board certification. Therefore, views of representatives of the scientific community who were familiar with the clinical training requirements for board certification were sought.

Based upon the information received, it appears that the revised research training structure can be effectively integrated with the requirements for clinical training. An accepted investigator track for board certification already exists that permits qualified individuals to credit two years of intensive research experience toward the training time required for board certification in internal medicine. As a consequence, an individual following the investigator track can satisfy the requirements for internal medicine and a subspecialty in the same period of time required for individuals who pursue a clinical training program.

The integration of the proposed research training structure with existing investigator track for clinical training is illustrated in Figure 4. Given the numerous possibilities for integrating clinical training requirements into a research training program and the likelihood of wide variation in individual preferences, the Task Force elected not to endorse any particular approach. Instead, the Task Force endorsed the concept of permitting individual training grant programs flexibility in accommodating the needs for clinical training.

However, the use of the training grant mechanism to support clinical training is unacceptable. It is apparent that postdoctoral positions on training grants are sometimes used to support individuals other than those committed to careers in biomedical research. As Dr. Wyngaarden stated in a November 15, 1984, letter to NRSA training directors,

> "Since the goals of research training are clearly differentiated from the goals of clinical specialty training, the use of the training grant solely to meet specialty board requirements is a serious abuse of the mechanism. (Some specialty boards permit a year of research to count towards board eligibility. NRSA support for this period is warranted only if the trainee has shown clear interest in a research career.)"

The Task Force recognized that the NRSA training grant continues to be used inappropriately for clinical training by some training directors. As proposed earlier (Section B) in this report, improvements in

selection of trainees by training directors, loss of training positions and funds for positions filled by individuals who leave the program before completing their training, the revised review criteria, and modification of the payback provisions are expected to prevent this practice.

RECOMMENDATION

Multiple pathways should be permitted to accommodate the needs of individual trainees for specialty and subspecialty certification within the context of meeting the two-year required minimum research training experience.

D. New Approaches and Opportunities for Research Training

1. Programs in Epidemiology, Biostatistics, or Related Topics

The increased research focus on prevention of disease and on population-based studies requires expanded predoctoral and postdoctoral research training as well as research career development opportunities in the design, implementation, and analysis of various types of epidemiologic studies and clinical trials. (Clinical trials are defined as prospective evaluations of the diagnostic, preventive, or therapeutic effects of a drug, device, lifestyle, or procedure used or intended for use in the practice of medicine.)

The Task Force on Training Opportunities in Clinical and Community-Based Study Designs and Methodology developed a new approach for advanced programs in epidemiology, biostatistics, applied prevention research, or related topics. These programs, usually three to four years in duration, would include both didactic study and practical experience. Predoctoral training programs that lead to a Ph.D. or equivalent degree would be encouraged. Training will be based in institutions where the faculty is actively engaged in epidemiologic studies and clinical trials. Individuals who complete training would be capable of assuming leadership roles in the development and management of such studies.

Two additional types of programs for health professionals were identified by the Task Force to increase further the pool of research-oriented individuals available in these areas:

Master's degree-level programs of study in epidemiology, biostatistics, or related topics. Training would provide individuals opportunity to assume other important roles in epidemiologic studies and clinical trials. The didactic course work would be similar to that for advanced programs of study, but the practical experience provided would be less intensive.

Nondegree, certificate programs of approximately one-year duration (or equivalent) with an emphasis on epidemiology and biostatistics. At least 50 percent of an individual's effort would be in didactic course work. Rotation through epidemiologic

studies or clinical trials in different stages of development, observation in coordinating centers and other central study facilities, and extensive participation as an observer at clinical study meetings, such as Data and Safety Monitoring Committee meetings, would be included as practical training. Individuals completing such a program would be expected to participate more effectively in clinical studies.

Support for these programs would be provided through existing NRSA institutional and individual NRSA mechanisms as well as K-series awards developed for this purpose.

2. Predoctoral Individual Fellowships

The NIH abandoned the general programs of individual predoctoral fellowships when the NRSA was enacted because of the relatively large staff required for their review and administration and the difficulty of evaluating applicants so early in their careers. However, individual predoctoral fellowships currently are being used effectively by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), the National Center for Nursing Research, and the Minority Access to Research Careers (MARC) program.

The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists pointed out that awards under this mechanism can complement training grants. Such awards would allow access to predoctoral training support in institutions that are too small to justify a research training grant and in research areas that have not yet grown to a size that can support such training grants. Individual fellowships also allow students the greatest flexibility in choosing the training program best suited to them and in which they will feel most comfortable. The potential use of these fellowships to address specific NIH training needs should be reviewed.

3. Research Training in New Subject Areas

The establishment of new research training programs will vary according to the mission of each BID. The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists identified the need for NIH periodically to review training areas currently supported and to determine whether new areas need to be created or old areas eliminated. For example, there may be a need for more nonphysician researchers with training in human physiology and pathology. Therefore, a process should be put in place to evaluate the need for research training in underserved areas of biomedical and behavioral research as well as the need for new approaches in the use of existing mechanisms of support for training programs.

RECOMMENDATION

Advanced programs of study in epidemiology, biostatistics, or related topics should be supported to increase predoctoral and postdoctoral research training opportunities. K-series awards should be developed to expand research career development programs for these individuals.

Current NIH mechanisms also should be used to support master's degree- level programs of study in epidemiology, biostatistics, or related topics and nondegree certificate programs with an emphasis on epidemiology and biostatistics.

The opportunity for individual predoctoral fellowships to address specific NIH training needs should be reviewed.

An ongoing process should be instituted for evaluation of new research areas, approaches, and needs for NIH research training programs.

E. Trainee Stipends and Cost of Education

1. Trainee Stipends

Implementation of the new physician scientist research training concept will provide for training of individuals with a greater commitment to research. This is due to the minimum two-year requirement for research training, greater responsibilities on the part of the training directors and institutions, and more rigorous criteria for NIH review of new and competing renewals of training grant applications.

Fewer individuals may enter research training programs under the revised concept, but a greater percentage are expected to remain in research. The issue of whether stipend levels should be increased was discussed. An analysis of annual stipend levels for trainees was prepared and the current NRSA stipends and K-series award salaries as well as Association of American Medical Colleges (AAMC) data on housestaff salaries were examined. Stipend structures proposed by Task Force members and representatives of the scientific community were also considered. Concern was expressed that no increase in the stipend level is an important determinant in whether an individual remains on a training grant for a third year of training.

A proposed revision of trainee stipends was developed that would make trainee stipends comparable to current housestaff salary levels. It provides that individuals in the first postgraduate year (with zero years of experience) on a T award would receive a stipend of $25,000, which is essentially equal to the average salary for the first postgraduate (intern) year. Additionally, the structure assures that an individual is never required to accept a reduction in remuneration to pursue research training. The proposal, along with data on existing NRSA stipends and

K-series award salaries, is shown in Table 1 and Figure 5. Examples of how training stipends would be integrated with clinical salaries are presented in Figure 6.

The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists also recognized the need to increase both predoctoral and postdoctoral stipends. Its members emphasized that the agencies that support research training in the biomedical sciences, i.e., NIH, ADAMHA, and the National Science Foundation (NSF) should explore means of making the support mechanism more equivalent in terms of stipend levels, cost of education, and other trainee expenses.

2. Cost of Education

The general findings of relevant earlier reports of the NIH Committee on Payment of Tuition for Research Training Grants and the Subcommittee on Training Stipends of the Extramural Program Management Committee (EPMC) were reaffirmed by the Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists. The institutional research training grant programs continue to play a crucial role in graduate education and in the research training of biomedical scientists. It is appropriate that the budgets for these awards include some support for the cost of education. However, it should be noted that, as grants-in-aid, these NIH awards are not obliged to pay full costs. The past two decades have seen constantly rising tuition charges, a declining NIH research training budget in real dollars (except for occasional stipend increases), and, consequently, sharp reductions in the number of predoctoral trainees supported. Many of the NIH Institutes

Table 1
Trainee Annual Stipend Levels

Current NRSA Stipends & K-Award Salary Levels

T Award								
Predoctoral	6,500							
Postdoctoral								
Years of Experience*	0	1	2	3	4	5	6	7
	17,000	18,000	25,000	26,250	27,500	28,750	30,000	31,500
K Award	≤ 40,000							

Mean Housestaff Salaries: AAMC Data

Postgraduate Years**	PG 1	PG 2	PG 3	PG 4	PG 5	PG 6
1988 - 1989 Salaries	23,382	24,813	26,141	27,421	28,699	30,129
1989 - 1990 Salaries	24,288	25,792	27,189	28,537	29,861	31,128

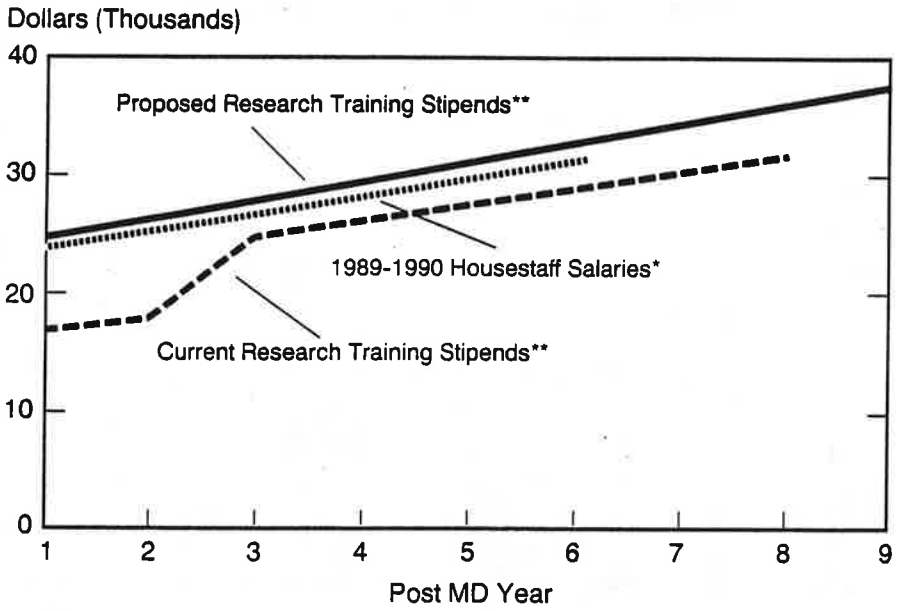
Proposed NRSA Stipends & K-Award Salary Levels

T Award									
Predoctoral	10,000								
Postdoctoral									
Years of Experience*	0	1	2	3	4	5	6	7	8
	25,000	26,500	28,000	29,500	31,000	32,500	34,000	35,500	37,000
K Award				≤ 50,000	≤ 50,000	≤ 50,000	≤ 50,000	≤ 50,000	≤ 50,000

* An individual with zero years of experience is in the first postgraduate year.
** An individual in the first postgraduate year has zero years of experience.

Figure 5

Housestaff Salaries and Research Training Stipends



* Determined solely by clinical years.
** Determined by all related experience.

Figure 6a

Clinical Salaries and Research Stipends Track I -- Two Year Option & Current ABIM Investigator Track Requirements

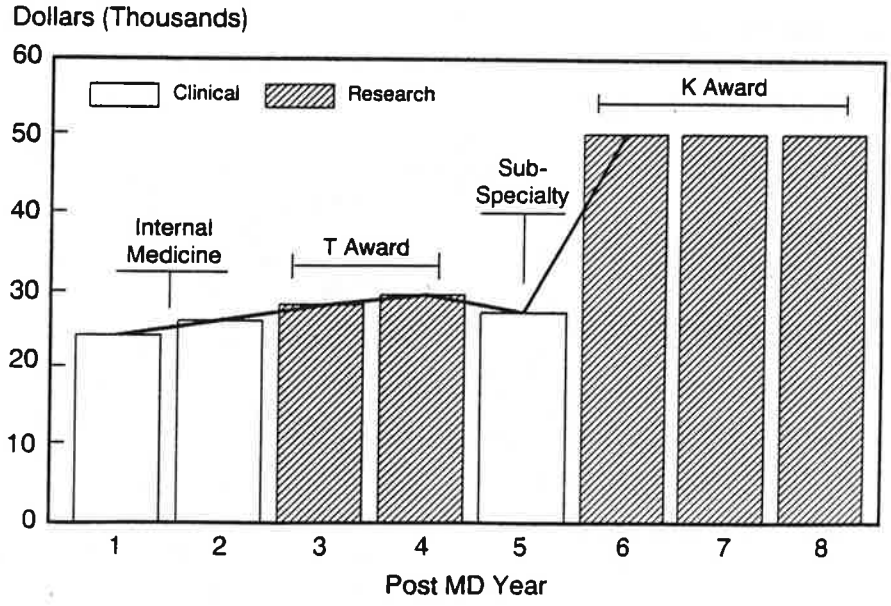


Figure 6b

Clinical Salaries and Research Stipends
Track II -- Three Year Option & Current
ABIM Investigator Track Requirements

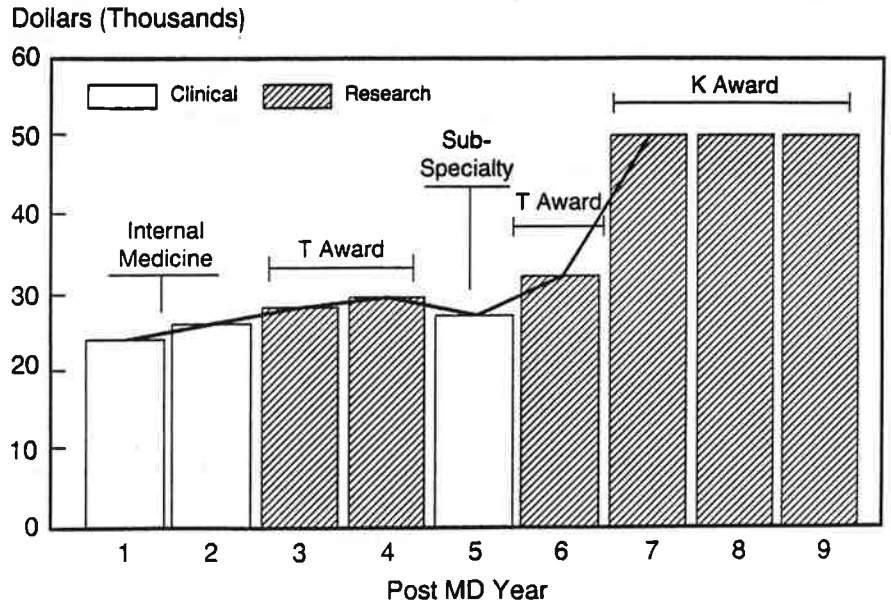
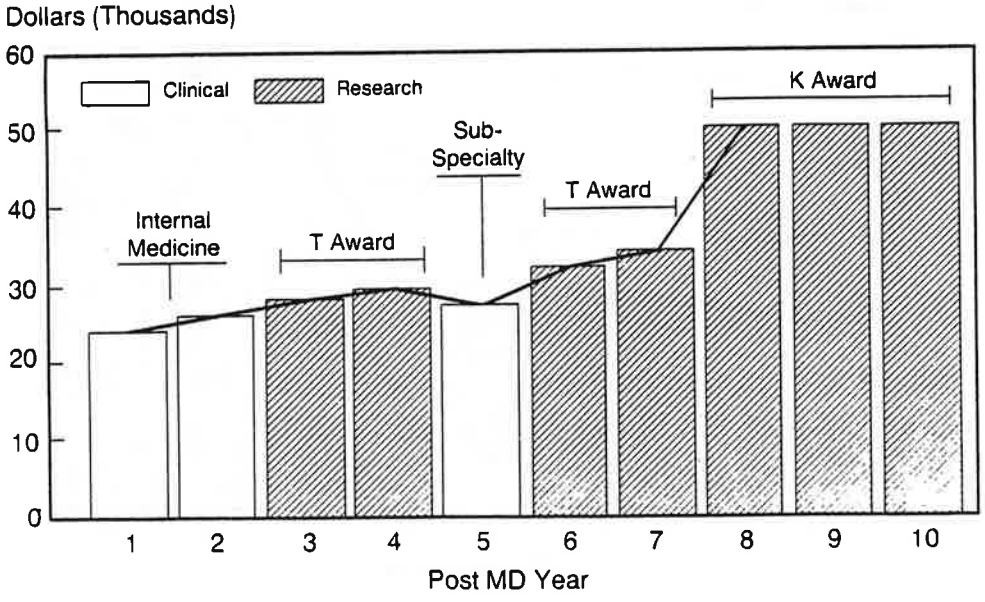


Figure 6c

Clinical Salaries and Research Stipends
Track III -- Four Year Option & Current
ABIM Investigator Track Requirements



periodically have frozen allowances for tuition to prevent an even greater decrease in the number of trainees.

The NIH Committee on Payment of Tuition for Research Training Grants proposed that NIH adopt a "two-tier cost of education (CoE) allowance" as a mechanism to control the fraction of the training budget designated for the CoE. It was reaffirmed that this mechanism seems to be the most practical and provides one CoE for predoctoral trainees at public institutions and another for those at private institutions.

Several other issues need to be taken into consideration in setting the yearly CoE allowance, the most important being the maintenance of *at least* a constant number of NIH-supported trainees. Annual increases in the research training budget would be requested in order to permit appropriate increases in the CoE allowance. Furthermore, although tuition is usually paid only for postdoctoral trainees who are enrolled in degree-granting programs, tuition payments for approved courses can be provided on a case-by-case basis. However, such payments should not exceed the predoctoral CoE allowance.

RECOMMENDATION

Levels of postdoctoral trainee stipends for professional doctorates should be increased to make them at least as attractive as current housestaff salaries. Levels of trainee stipends for predoctoral and postdoctoral nonphysician scientists should be increased each year, as needed, to compensate for the increase in the cost of living.

Those agencies of the Federal Government that support biomedical research training should explore ways of making the mechanism of support more equivalent in terms of stipend levels, cost of education, and other trainee expenses.

The proposal for NIH to adopt the "two-tier cost of education allowance" as a mechanism to limit tuition payments is reaffirmed. The CoE allowance for special NIH research training programs, such as the Medical Scientist Training Program (MSTP), should follow the same general principles.

F. K-Series Awards

Consistent with the overall five-year training concept, it was recognized that, after the minimum two-year research training experience on a training grant, a trainee would have the option to apply for an individual fellowship grant (F32), K-series award, FIRST award (R29), or a research project grant (R01) as illustrated in Figure 4.

The need was identified to modify the K-series awards to permit less than the current five-year duration. It was agreed that individuals may not need five more years for career development after completing the

minimum two years on a training grant. Therefore, a three-year award should be made available.

Summaries of several NIH K-series awards were reviewed. Presently, the NINDS offers the option of a three- or five-year K-series award, i.e., Clinical Investigator Development Award (K08).

The Task Force on Physician Scientist Training believes that three-year K-series awards are an important part of the revised training concept for physician scientists. It also believes that the salary support on an award received through a national competition (e.g., K-series award) after one or two years on a training grant should be higher, thus providing an incentive to compete for such an award. Salary levels for K-series awards were considered and members agreed that they should be integrated progressively with the stipend levels recommended for trainees on training grants (Table 1 and Figure 6).

RECOMMENDATION

Three-year K-series awards should be made available NIH-wide for professional doctorates. Salary levels for these awards should be increased to $50,000 annually.

G. Data Collection, Monitoring, and Evaluation

1. Data Analysis

The success of past and current training endeavors designed to provide scientists for biomedical research should be assessed. A large body of data exists that must be analyzed appropriately. Although the Committee on National Needs for Biomedical and Behavioral Research Personnel of the Institute of Medicine/National Academy of Sciences has collected and analyzed some of the data, particularly in regard to the overall opportunities for research training, more must be done. The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists emphasized the need for analysis of available data and for development of an ongoing process of data collection on all predoctoral and postdoctoral trainees and fellows, including the MSTP. This process is particularly important to the revised training program structure. Some of the items needed for evaluating programs are:

The numbers of Ph.D. and M.D. degree holders and predoctoral students supported each year. The numbers supported by institutional awards and individual awards should be recorded separately.

For each NRSA recipient, the length of NIH-supported research training, as well as additional training support mechanisms used by Federal agencies, the pharmaceutical industry, the Department of Veterans' Affairs, the Howard Hughes Medical Institute, and foundations.

The time lag between completion of research training and the subsequent submission of requests for research support.

The types of grant applications submitted.

The research grant application and award histories of former trainees and fellows in addition to information on their subsequent scholarly research pursuits.

2. New Databases

Because other data are necessary to evaluate research training activities in a meaningful way, each BID should work to develop and maintain its own database on training programs. Many items of importance appear in competing continuation applications. Of particular interest are the number of, and information regarding, underrepresented minorities and women:

Appointed to research training grants.

Supported by other research training and career development mechanisms and by the Minority Biomedical Research Support (MBRS) program.

3. Available Resources

The NIH has a number of resources available for analysis and assessment of the many aspects of research training. By using these resources more fully and continuously, collection of data can be greatly improved. Information is available in various files and documents including the payback file, the doctorate record file, the consolidated grant applicant file, and the trainee/fellow file.

It was recognized that a burden will be imposed on the NIH staff, collectively and at a programmatic level, by enhanced data monitoring and evaluation. In order to perform a careful analysis of the NIH research training programs, priorities will have to be set regarding the importance of each of these data files and how much information can and should be collected. It must be stated, however, that such data are essential if a thorough and critical analysis and evaluation of research training programs is to be performed. Evaluation funds should be considered for these studies.

RECOMMENDATION

A continuing process of data collection should be developed to capture information about all predoctoral and postdoctoral research trainees and fellows, including MSTP students, and their subsequent scholarly research accomplishments. A set of standards for data collection should be developed to ensure that information is uniformly recorded and can be compared across NIH. The need for new databases should be an important ongoing consideration in this process.

Available NIH training data should be analyzed further. The NIH should provide support, either directly or through contractual arrangements, to capture data from existing NIH files into a central file so that the information is readily available for evaluation studies. It is further recommended that consideration be given to using the one percent set-aside evaluation funds for these tasks.

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