

Review of NICHD Training and Career Development Programs



September 2015

Table of Contents

| Executive Summary | 1 |
|--|----|
| Introduction | 1 |
| Format and Scope of the Training Review | |
| Overarching Questions | |
| Task Force Recommendations (Overview) | |
| Individual NRSA Fellowships (F30, Diversity F31, Parent F31, F32) | |
| Institutional T32 Training Grants | 8 |
| Individual Career Awards | 9 |
| Institutional Career Development Awards | 9 |
| Educational Grants (T15 and R25) | 10 |
| Mentoring the Community | |
| Peer Review | |
| Review of NICHD Training and Career Development Programs | |
| Background | |
| Format and Scope of the Training Review | 12 |
| Members of Task Force | |
| Overview of NICHD's Training Programs | |
| Individual NRSA Fellowships | |
| Institutional NRSA Training Grants (T32 Programs) | 16 |
| Individual Career Development Award Programs | |
| Institutional Career Development Award Programs (K12) | |
| R25 Education Programs | |
| Analysis of the Data on NICHD Training and Career Development Programs | 21 |
| Data Collection and Analysis Methods | |
| Training and Career Development in the Context of the NICHD Budget | |
| Training and Career Development by Career Stage, Degree, and Grant Mechanism | |
| Training and Career Development by Career Stages | |
| Training and Career Development by Degree | |
| Training and Career Development by Grant Mechanism | |
| Training and Career Development by Research Field | |
| Success in Developing the Next Generation of Researchers | |
| Pre-doctoral Trainees | |
| Post-doctoral Trainees | |
| Individual K Awardees and K12 Scholars | |
| Fiscal Pressures on Training Programs | |
| Changes in the Mix of Individual Fellowships | |
| Increasing Numbers of K99-R00 Applications | |
| Rising Costs for K08 and K23 Career Awards | |
| Peer Review of Training Mechanisms | |
| Individual NRSA Fellowships | |
| Institutional Training Grants | |
| Individual Career Development Awards | |
| Institutional Career Development Awards | |
| Task Force Recommendations | |
| Individual NRSA Fellowships (F30, F31 Diversity, F31 Parent, F32) | 73 |

| Recommendations: | 73 |
|---|----|
| Institutional T32 Training Grants | 74 |
| Recommendations: | 74 |
| Individual Career Awards | 76 |
| Recommendations: | 76 |
| Institutional Career Development Awards | 77 |
| Recommendations: | 78 |
| R25 Grants for Short Courses | 79 |
| Recommendations: | 79 |
| Mentoring the Community | 79 |
| Recommendations: | 79 |
| Peer Review | |
| Recommendations: | 80 |
| | |

List of Exhibits

| Exhibit 1: Career Stage and Common Training and Career Development Mechanisms | . 23 |
|---|------|
| Exhibit 2: Training and Career Development Portfolio by Funding Mechanism | .24 |
| Exhibit 3: Training and Career Development Expenditures, 1983 – 2014 (adjusted and unadjusted for | |
| inflation) | . 25 |
| Exhibit 4: Training and Career Development as a Percent of Expenditures, 1983 – 2014 | . 26 |
| Exhibit 5: Training and Career Development as a Percent of Expenditures, 2014, by NIH IC | . 27 |
| Exhibit 6: Individuals Supported by Career Stage and Mechanism Group, 1990-2014 | . 28 |
| Exhibit 7: Proportion of Trainees at Each Career Stage Over Time, 1990-2014 | . 29 |
| Exhibit 8: Success Rate for Diversity F31 Applications, 2002-2014 | . 30 |
| Exhibit 9: Success Rate for Post-doctoral F32 applications, 2002-2014 | . 30 |
| Exhibit 10: Percent of 2014 Trainees by Degree Category, by Key Mechanisms | .31 |
| Exhibit 11: Training and Career Development Funding, Institutional v. Individual, 2014, by IC | |
| Exhibit 12: Training and Career Development Funding, Percent Institutional, 1983-2014 | . 33 |
| Exhibit 13: K12 Programs Supported by the NICHD | . 33 |
| Exhibit 14: F31 and F32 Fellowship and T32 Training Positions, FY 2014, by Mechanism | . 34 |
| Exhibit 15: Training and Career Development by Mechanism, 1986-2014 (unadjusted) | . 35 |
| Exhibit 16: Training and Career Development Cohort Size, FY 2014 | . 37 |
| Exhibit 17: Number of T32 and K12 awards by length of grant | . 37 |
| Exhibit 18: NICHD Funding Rates, 2010-2014, by Mechanism and Type | . 38 |
| Exhibit 19: Career Stage of Individuals Mentored by K24 awardees | |
| Exhibit 20: Doctoral Degree Date of Individuals Mentored by K24 awardees | . 40 |
| Exhibit 21: Subsequent Collaboration Between Mentors and Mentees | |
| Exhibit 22: Use of R25 Mechanism at NICHD, FY 2014 | .43 |
| Exhibit 23: T32 Programs by NICHD Branch | . 45 |
| Exhibit 24: Training and Career Development FY 2014 by Subject Area | .46 |
| Exhibit 25: Training and Career Development Funding, FY 2014, by Category and Mechanism Group | .47 |
| Exhibit 26: K01 Support by Research Area, 2007-2014 | . 48 |
| Exhibit 27: Former NICHD Research Trainees in Non-research Positions | . 50 |
| Exhibit 28: NICHD Former Trainees' Subsequent NIH Application Rates | .51 |
| Exhibit 29: Percent of Former NICHD Trainees Receiving Subsequent NIH Research Grants | . 52 |
| Exhibit 30: Current Positions of Former NICHD Pre-doctoral Trainees | . 53 |
| Exhibit 31: Current Positions Of Former NICHD Pre-doctoral Trainees (with Known Positions Only) | . 53 |
| Exhibit 32: Former Pre-doctoral NICHD Trainees in Faculty Positions, by Type of Position | . 54 |
| Exhibit 33: Career Trajectory of Former NICHD Pre-doctoral Trainees | . 55 |
| Exhibit 34: Current Positions of Former NICHD F32 Post-doctoral Trainees | |
| Exhibit 35: Former F32 NICHD Post-doctoral Trainees in Faculty Positions, by Type of Position | . 56 |
| Exhibit 36: Career Trajectories of NICHD F32 Post-doctoral Trainees | |
| Exhibit 37: Current Positions of Former NICHD T32 Post-doctoral Trainees | . 58 |
| Exhibit 38: Former T32 Post-doctoral NICHD Trainees in Faculty Positions, by Type of Position | . 58 |
| Exhibit 39: Career Trajectories of NICHD T32 MD only Post-doctoral Trainees | . 59 |
| Exhibit 40: Career Trajectories of NICHD T32 PhD or MD+PhD Post-doctoral Trainees | . 60 |
| Exhibit 41: Current Positions of Former NICHD Individual K Awardees | .61 |
| Exhibit 42: Former NICHD Individual K Awardees in Faculty Positions, by Type of Position | .61 |
| Exhibit 43: Trajectories of NICHD Individual K Awardees | |
| Exhibit 44: Current Positions of Former NICHD K12 Scholars | . 63 |
| Exhibit 45: Former NICHD Individual K12 Scholars in Faculty Positions, by Type of Position | . 63 |

| Exhibit 46: | Career Trajectories of NICHD K12 Scholars | 64 |
|-------------|--|----|
| Exhibit 47: | Individual Fellowship Awards by Mechanism and Level, in FY2013 and FY2014. | 66 |
| Exhibit 48: | New Fellowship Awards and Success Rates in FY 2015 (as of July 2015) | 66 |
| Exhibit 49: | Applications for Individual Fellowships, 2006-2015 | 67 |
| Exhibit 50: | Success Rates for Individual Fellowships, 2006-2015 | 67 |
| Exhibit 51: | K99 Applications, Awards and Success Rates, FY 2010-2015 | 68 |
| Exhibit 52: | T32 Scoring Patterns for FY 2010-2014 | 71 |

Executive Summary

Introduction

Scientific opportunities have never been as abundant and strong, with new technologies now emerging to understand health and disease from the molecular to the population level. At the same time, the biomedical research workforce is aging, and young, creative, and dedicated scientists are urgently needed. The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) supports training and career development programs to identify, develop, mentor, and support the next generation of researchers in areas essential to the Institute's mission. These key areas encompass disciplines as diverse as pediatrics, medical rehabilitation, reproductive health, population sciences, and basic sciences. With accelerated growth in scientific opportunities, it is crucial for the NICHD to optimize its investment in research training and career development programs.

Format and Scope of the Training Review

To inform the future directions of training and career development programs, NICHD leadership commissioned a comprehensive review of the various training mechanisms supported by the Institute, the funding resources committed to those programs, and the productivity and professional outcomes of former fellows, trainees, and scholars. The scope of the review covered individual fellowships, career development awards, institutional fellowships and career awards, and T15/R25 programs for supporting short courses. The review was carried out by a Task Force composed of NICHD staff and external members with knowledge of NIH training programs and biomedical research workforce issues. Members included representatives from NICHD's National Advisory Council; NICHD program directors who administer training programs; staff with expertise in review, policy, and program evaluation; and training experts from other NIH institutes and offices. The Task Force, organized and chaired by NICHD Training Officer, Dr. Dennis Twombly, held a series of meetings between May and September 2015. The Task Force studied extensive data analyses prepared by the NICHD Office of Science Policy, Analysis and Communication (OSPAC) to inform the deliberations and compilation of the final report.

Overarching Questions

The Task Force was charged with addressing a series of overarching questions as developed by NICHD leadership. These questions, along with the key conclusions of the Task Force are summarized below. Detailed data supporting these conclusions are contained in the body of the report (Analysis of the Data on NICHD Training and Career Development Programs).

1. Is the amount of funding NICHD commits to training awards the right amount? Are the allocations an appropriate percentage of the NICHD budget? How have these allocations evolved over time?

Like many research organizations, NICHD must balance funding for current research with investments in training and career development to build the capacity needed to sustain science in the future. In considering this delicate balance, the Task Force reviewed data on training efforts at other NIH Institutes and Centers (ICs), assessed the historical record, reflected on the current and future conditions in the biomedical research workforce, and took into account the breadth of the NICHD mission and the range of specialized skills needed to sustain the NICHD mission. In FY 2014, the NICHD spent slightly less than 6 percent of its overall funding on extramural training and career development, consistent with the historical levels of from 4.8 to 7.0 percent over the past 30 years. NICHD's budget share for training and career development is similar to levels in comparably-sized NIH ICs such as the National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the National Institute of Digestive Diseases and Kidney Disorders (NIDDK). Like all of NICHD's expenditures, funding for training and career development increased dramatically during the NIH "doubling period" from 1998 to 2003, but then decreased. Over the past 10 years, NICHD training and career development expenditures have decreased by about one-third in inflation-adjusted dollars, largely reducing (although not entirely eliminating) the increases of the doubling period. The Task Force recognized the importance of training and career development to the NICHD mission and the opportunities these programs offer to attract and retain excellent scientists. Maintaining the current level of training and career development support – or even providing for a modest increase when fiscally possible – will help ensure the future of the scientific enterprise.

2. Is NICHD supporting the correct ratio of awards at different career stages, i.e., predoctoral/ post-doctoral/ early faculty? Has this ratio changed over time?

NICHD supports programs targeted at different stages of training, ranging from pre-doctoral to early faculty levels. In FY 2014, NICHD supported between 313 and 542 individuals at each career stage – pre-doc, post-doc/fellow, and career (K) stages. Over the past 20 years, the numbers of awards at the career stage have more than doubled. Meanwhile, pre-doctoral and post-doctoral awards have decreased by 25-40 percent. The largest single factor behind the growth in career-level funding over this time frame is the relative increase in institutional career development (K12) programs. Contributing to a smaller degree were the addition of the K23 program in 2000 and the K99-R00 program in 2007.

NICHD's primary investments in research training for those with clinical degrees are in T32 training grants, institutional K12 awards, and certain individual career awards (K08 and K23). Those programs are targeted to individuals who have completed their clinical years of fellowship training and are gaining research experience for careers as physician-scientist or clinician-scientist investigators. Support is available through the assistant professor level. For individuals with non-clinical PhDs and other non-clinical degrees, NICHD provides support at pre-doctoral and early post-doctoral levels via individual fellowships and institutional training grants. The only mechanisms available to support late-stage post-doctoral fellows and junior faculty with PhD degrees are the K99-R00 and the K01 awards. These two programs receive comparatively less support as a proportion of the overall training budget or even the individual

K portfolio. Both programs also have significant eligibility restrictions. K99 eligibility is limited to fellows with no more than 4 years of post-doctoral experience. NICHD restricts eligibility for the K01 to just three subject areas. For these reasons, mechanisms of support are limited or altogether unavailable for advanced trainees with non-clinical PhD and other non-clinical degrees. The Task Force recommended allocating additional resources to fill this gap in the training pipeline. If the overall K budget cannot be increased, the committee recommended shifting funds from the K12 programs toward the individual career awards as a group.

3. Are there appropriate levels of commitment to the different training mechanisms? Are some mechanisms over- or underutilized?

Different NIH training and career development mechanisms represent distinct combinations of eligibility requirements, target populations, types of programs, allowable funding levels, and other program features. In considering funding by mechanism, the Task Force reviewed data on: (a) the shares of funding distributed through each grant mechanism; (b) the number of trainees supported; (c) the subsequent success of trainees supported by different mechanisms; and (d) the historical use of various mechanisms by NICHD and other NIH ICs. The Task Force members engaged in intensive discussions about the advantages and disadvantages of various types of programs and mechanisms. Although individual members had different preferences, ultimately the Task Force agreed that some changes in emphasis were needed. This rebalancing will help the NICHD maintain successful programs and mechanisms, encourage young investigators to engage with the NICHD, and maximize support for essential training and career development areas.

NICHD relies on institutional mechanisms (T32 and K12) to a far greater degree than most other NIH ICs. Over the past ten years, the proportion of institutional training has ranged from 75-80 percent of the overall training portfolio. The Task Force members recognized that institutional mechanisms offer a number of important advantages. Nonetheless, the Task Force agreed that these programs are over-utilized at NICHD and that a shift in emphasis is needed. The Task Force recommended that NICHD rebalance its training and career development programs to place more emphasis on individual as compared with institutional programs. There was general support for the approach of using institutional T32 programs more for training of predoctoral fellows, and using individual F32 awards for the training of post-doctoral fellows.

Among the individual K awards, the K23 mechanism receives by far the most support at NICHD, representing almost half of the individual K award portfolio. When combined with the clinical T32 and K12 awards, the investment in training of physician-investigators is relatively high. The Task Force recommended that funding for K99 awards should be increased to facilitate the transition of post-doctoral scholars to independent faculty status. This program is unique in being available to non-clinicians and clinicians, and to US Citizens as well as non-US Citizens. The NIH-wide Biomedical Workforce (BMW) and Physician-Scientist Workforce (PSW) reviews both strongly recommended increasing funding for the K99-R00 program. NICHD can more effectively balance the ratio of awards across mechanisms by establishing separate pay lines.

NICHD also sponsors the Midcareer Investigator Award in Patient-Oriented Research (Parent K24) program. The purpose of this program is to provide protected time for established investigators to devote to patient-oriented research and to act as research mentors primarily for clinical residents, clinical fellows and/or junior clinical faculty. Based on outcome data for K24 awardees and the individuals they mentor, the Task Force had concerns about the value and cost of this program. The committee suggested either reducing NICHD's investment in this program or establishing focus areas such as diversity mentoring.

4. Are the allocations to the fields supported by NICHD training appropriate for the NICHD mission, and are the types of training mechanisms appropriate for those fields? How are NICHD training and career development resources and numbers of trainees/awardees currently distributed across programs and areas of science? How does the current distribution compare with what NICHD has done in the past?

In general, the NICHD has chosen to limit thematic targeting for training and career development programs, with the majority of individual fellowships, individual career awards, and institutional T32 applications being received via non-specific "parent" funding opportunity announcements. Where NICHD has targeted programs by scientific area, the areas chosen have tended to be broad, such as pediatrics, reproductive health, and rehabilitation. T32 programs are supported in most disciplines within NICHD's mission and are fairly well distributed across the scientific branches. In contrast to the T32 grants, the K12 programs are more targeted, but to broad thematic areas. Applications are solicited via a Request for Applications (RFA) and awarded from specific funding allocations.

The training and career development grants supported by the NICHD cover a wide range of scientific disciplines and research topics. The different science areas are served by different training and career development mechanisms, and the distribution of career stages and degree category varies by science area. The general category with highest aggregate funding is pediatrics, followed by behavior, reproductive sciences, and rehabilitation medicine. The emphasis on pediatrics can be attributed to the heavy use of T32 training grants, institutional K12 programs, and individual K23 awards.

The Task Force concluded that NICHD's overall approach to balancing the portfolio across disciplines has been appropriate. The institute addresses a wide variety of training needs by targeting broadly or not at all, with a few exceptions. With this approach, however, applications submitted for parent announcements are selected for funding based almost entirely on priority score and pay line. Differences in application rates, quality of applications, or scoring standards across peer review groups can shift the distribution of awards across disciplines in unintended directions. Hence the institute needs to conduct periodic portfolio analyses to assess and re-balance the funding allocations. The committee recommended a more detailed examination of institutional K12 and T32 portfolios to determine if the commitments to certain disciplines align with the current training needs in those fields. Many of the institutional programs have been in existence for two or more grant cycles. Task Force members felt that too many T32 or K12 grants were simply providing an ongoing stream of

support for fellows in well-established departments or institutions without providing the "added value" expected of a thematically-focused institutional program. There was a sense that some scientific areas were over-represented or overlapping, and those programs should either be reduced in number or merged.

5. How do we define success of NICHD training programs? Are NICHD training programs successful?

The major goal for training and career development programs is to develop the next generation of the biomedical research workforce. Success for a training and career development program, then, can be defined primarily by the number of individuals who continued in a research career in the long run – whether that research career was in industry, government, or academia. As secondary measures, data on subsequent NIH applications, funded grants, and publications are important indicators of a successful research career. Task Force members concluded that any single metric of "success" was likely to underestimate which former trainees are actively engaged in research. The Task Force agreed that using multiple criteria would be a more sensitive and accurate way of gauging successful outcomes. Data on long-term career choices of former trainees showed that at least 76 percent of pre-doctoral trainees and 68-84 percent of post-doctoral trainees remained in research careers. About 83 percent of K awardees stayed in academic or research settings.

By these measures, the Task Force concluded that NICHD training and career development programs are largely successful. Because former trainees across all mechanisms tend to continue in research, the Task Force stressed the importance of striking the appropriate balance among grant mechanisms and career stages to ensure that all young investigators can take advantage of these opportunities. A few differences across programs were noted, however. As a general rule, those who receive individual post-doctoral fellowships (F32) have better outcomes than those who receive institutional T32 support only. For individuals with an MD degree only, those that received support from T32 programs tend to have less favorable outcomes when compared with individuals that were supported at the career level (either through individual K or K12 grants). Within the T32 and K12 programs, outcome measures for some institutions were lower than for others. NICHD should identify institutions that are having difficulty filling their slots or keeping their former trainees engaged in the research enterprise.

6. Are there training/workforce needs that have already been addressed or that still need to be addressed by our portfolio of training awards?

In an era of ever-tightening budgets and increasing numbers of applications, competition for training funds has become more intense, and success rates for a number of mechanisms have declined to critically low levels. In fiscal year 2015, for example, the success rates for Parent F31 and F32 fellowships were down to 10 percent. The success rate for K99-R00 applications was 15 percent. Graduate students, post-doctoral fellows, and even junior faculty consider such statistics when deciding whether a research career is a viable professional option. The

many years of required research training and substantial challenges of reaching independence can be discouraging to many talented individuals. To the extent possible, NICHD's commitments to training must be preserved and even increased. Limited funds for the various training mechanisms must be leveraged optimally and not committed to programs or disciplines that would otherwise thrive without the investment of scarce training resources.

NICHD's large investments in the institutional training portfolios, as well as the low success rates for new applications in peer review, may limit the institute's opportunities to promote exciting new areas of research. Although the committee appreciates the valuable features of institutional training programs, there were concerns about supporting too many programs in mainstream disciplines and supporting long-established programs at the expense of programs in emerging fields or areas of programmatic need. The Task Force suggested a number of steps to address the major imbalance in success rates for New (type 1) applications versus Renewal (type 2) applications for parent FOAs as well as for thematically-focused PARs. The institute should adopt strategies to enable more flexibility in selecting its training awards, as opposed to allowing pay lines to dictate programmatic balance. RFAs or PARs should be used to promote scientific areas where a current training need can be justified. In such cases, reviews should be structured to maximize competition and reserve funding for only the most outstanding programs.

NICHD has published a small number of T32 and K12 announcements to target narrower areas of research need, including pharmacology, intellectual and developmental disabilities, male reproductive health, systems developmental biology, and pediatric critical care. The attempts at building the pipeline of investigators in these narrower areas have resulted in relatively few grants, in part because of the poor success rates for new T32 applications. The only other targeted training program at NICHD is the K01, which is intended to attract and train investigators in three research focus areas: population sciences, rehabilitation medicine, and child abuse and neglect. The Task Force suggested expanding and/or rotating these K01 focus areas to provide programmatic flexibility at the individual career level.

One of the biggest obstacles for young scientists is making the transition from NIH-sponsored training mechanisms to independent support via research project grants. This is the point in the training pipeline when a substantial number of trainees decide to abandon research and pursue other career options. The NIH-wide New Investigator and Early Stage Investigator designations offer major advantages to individuals who are applying for their first R01 grant. Nevertheless, the high standards for research experience, publications, and preliminary data in R01 applications often cannot be met by new investigators. NICHD may wish to consider new approaches to increase the ability of New Investigators or individuals who received prior career development awards to secure initial stage research grants.

7. Are there fiscal pressures or other factors in the near future that have potential to impact NICHD's mix of training programs?

Pursuant to the recommendations of the NIH Biomedical Research Workforce task force, all NIH institutes were required to begin supporting the F30 and Parent F31 fellowship mechanisms starting in FY2014. The resulting avalanche of applications for these mechanisms has exacerbated a long-term trend of decreasing success rates for diversity F31 and post-doctoral F32 applications. In FY2015, the F30 and Parent F31 awards accounted for more than 50 percent of the new fellowship awards. The institute needs to settle on an approach that will preserve the most effective mix of fellowships. Given NICHD's historical commitment to diversity, and the exceptionally strong subsequent success of individuals who received F32 post-doctoral fellowships, the Task Force favored a greater emphasis on those two programs versus the F30 and Parent F31 mechanisms. Such an emphasis can be implemented by establishing differential pay lines within the groups of NRSA fellowships.

The recently released Physician-Scientist Workforce (PSW) recommendations called for increases in salary and research expense allowances for K08 and K23 mechanisms. No additional funds will be provided to satisfy these mandates. Without additional funds, implementation of the increases is projected to cut the success rates of these career awards from around 30 percent to less than 17 percent and reduce the number of scholar positions by 40 percent. The Task Force strongly recommended shifting some support from institutional K12 programs toward the individual K awards to maintain sufficiently attractive success rates and re-balance the overall career development portfolio. This strategy is also consistent with the PSW's more general recommendation to support more physicians-scientists through individual fellowships and career awards rather than institutional training and career development programs.

Finally, the numbers of K99-R00 applications have been steadily increasing over the past few years. Consequently, the success rates for those applications have dropped from above 35 percent to less than 15 percent. The Biomedical Workforce Report and PSW report both expressed strong support for the K99-R00 program. Because this program has proven so effective in facilitating transition of post-doctoral fellows to independent faculty positions, NIH has set a success rate target of 30 percent for K99 applications. As noted earlier, the K99 and K01 programs are the only mechanisms NICHD uses to support post-doctoral individuals with non-clinical PhDs and other degrees after the early post-doctoral stage. Physician-scientists are also eligible for K99-R00 awards, though relatively few apply. The PSW committee recommended modifying the language in the program announcement to encourage more clinically-trained applicants. The Task Force recommended committing more funds to this successful program to support more individuals and raise the application success rates. This can be accomplished by establishing different pay lines within the K-award mechanisms.

Task Force Recommendations (Overview)

The following is a high-level overview of Task Force recommendations based on the data analysis, discussions of those data, and identification of problem areas, imbalances, needs and opportunities. Detailed description of the rationale for the recommendations and suggested

implementation steps are included in the main body of the report (Task Force Recommendations). For simplicity of presentation, the recommendations are organized by funding mechanism and other topics considered by the committee.

Individual NRSA Fellowships (F30, Diversity F31, Parent F31, F32)

NICHD supports a relatively small number of individual fellowships compared to the number of slots on institutional training grants. Individual fellowships offer a number of distinct advantages, and outcomes of former awardees are better than students or post-doctoral trainees supported on institutional training grants. The overall sentiment of the Task Force was to increase the numbers of individual fellowship awards. In particular, there was agreement that fellowships were the best way of supporting post-doctoral scholars.

Recommendations:

- Increase support for individual NRSA fellowships by shifting funds from institutional T32 programs;
- Limit numbers of Parent F30 and F31 pre-doctoral awards to preserve Diversity F31 and F32 awards; and
- Establish differential pay lines for each of the fellowship mechanisms in order to address the impact of new mechanisms on numbers of applications, success rates, and award distribution.

Institutional T32 Training Grants

NICHD relies heavily on a spectrum of institutional training grants to support pre-doctoral and post-doctoral trainees. The T32 programs offer a variety of features and advantages, such as access to outstanding mentors, exposure to scientific courses and workshops, and training in research-related skills (e.g., lab management, ethics, teaching, grant writing, communication). The concept of a cohesive "program" within each institution was viewed by the Task Force as being essential to the success of these awards, particularly for pre-doctoral trainees. Although the committee appreciated the general value of the T32 programs, there were concerns about supporting too many programs in certain disciplines and supporting long-established programs at the expense of new programs in emerging fields or areas of programmatic need.

Recommendations:

- Reduce the overall commitments to Institutional T32 programs by moderately lowering the success rate from the recent average of around 30 percent. Savings from the T32 programs should be shifted to individual fellowship awards (Fs);
- Improve success rates for NEW applications or applications submitted in response to thematically-driven RFAs or PARs;
- Limit institutional T32 awards to a certain number per PI or institution;
- Establish expectations for turnover or phase-out of long-running programs; and

• Establish a minimum number of slots for T32 programs to assure a "critical mass", particularly for post-doc only programs; 3 fellows was considered a minimum.

Individual Career Awards

The Task Force was highly supportive of individual career development awards because they provide crucial funding for young scientists who are just starting their research careers and attempting to establish independence. Compared to other NIH institutes, NICHD's career award portfolio is heavily tilted towards institutional career awards rather than individual awards. The Task Force strongly recommended re-balancing the portfolio to increase the number of individual K awards. This is consistent with the recently published NIH Physician-Scientist Workforce (PSW) recommendations. In particular, there is a need to increase the commitment to K99-R00 awards. Adding one or more target areas to the K01 was suggested to provide a means of supporting awards in areas of programmatic need. The PSW recommendations also called for increased salary and research expense allowances for K08 and K23 awards. Those mandates will dramatically reduce the numbers of awards and the application success rates. Funds will be needed to preserve those programs as well as the other individual K awards.

Recommendations:

- Shift support from institutional K12 programs to individual K awards;
- Increase success rates for K99-R00 applications;
- Modify K08 and K23 salary and research expense allowances;
- Focus K08 and K23 awards on fellows/scholars at more junior levels; and
- Consider developing a process to modify the categories of research eligible for K01 funding.

Institutional Career Development Awards

NICHD supports a higher proportion of institutional career awards compared with other NIH institutes. Although the outcomes of scholars supported by K12 programs are generally very good, the Task Force had concerns about supporting long-established programs in an era of rapidly changing science and tight fiscal constraints. There were also concerns about duplication of support across institutions, multiple awards to single institutions or single PIs, and inadequate competition among applicants for thematically-focused RFAs. The primary conclusion reached by the Task Force was that NICHD should strategically and gradually moderate its commitment to institutional K12 programs.

Recommendations:

- Shift a portion of K funds from institutional K12 to individual K awards;
- Create multi-thematic institutional K12 programs;
- Consider consolidating reviews of K12 programs;
- Consider establishing expectations for the duration of K12 appointment; and

• Continue to monitor and analyze the impact of training programs, used alone or in combination, at various career stages.

Educational Grants (T15 and R25)

The T15 and R25 programs involve a wide variety of educational activities, including short courses and workshops in research approaches and methodologies, summer long intensive research experiences, and outreach/dissemination activities. The Task Force members felt that many of these programs were valuable to their respective fields. However, the Task Force also recognized the need to be sensitive to budgetary pressures posed by large programs or programs of especially long duration. There was general agreement that institutions sponsoring the programs or nominating participants should support a greater share of the costs.

Recommendations:

- Select programs/courses based on programmatic need rather than strictly by pay lines; and
- Consider moderately raising the maximum allowable direct costs, but set a high standard of justification for costs above the standard amount.

Mentoring the Community

The Task Force discussed the important need for mentoring of individuals at various stages of training. NIH has always encouraged mentoring by program staff and by senior investigators. The Task Force strongly urges the institute to invest in traditional and novel forms of mentoring to communicate funding opportunities and areas of research need. At the same time, the committee questioned the value of the K24 award for mentoring in patient-oriented research and recommended reducing the program or focusing on specific areas of mentoring need.

Recommendations:

- Commit more travel funds for program and review staff to mentor applicants/grantees at scientific meetings;
- Structure NICHD staff mentoring opportunities through webinars or other media;
- Host more meetings at NIH that target trainees, new investigators, and PIs seeking their first renewal;
- Create NICHD staff mentoring opportunities and more intensive follow-up for recipients of diversity awards (Diversity F31 fellows, recipients of diversity supplements); and
- Reduce and/or refocus K24 program.

Peer Review

Peer review is essential for ensuring high quality of fellowships, training grants, and career awards. Scoring patterns of review groups have the potential to unintentionally bias the

portfolios in certain directions. The Task Force members discussed a number of issues that often complicate the ability of reviewers to accurately and fairly assess scientific and technical merit of applications. The following recommendations were proposed to improve the peer review process.

Recommendations:

- Review the new SF424 and FOA instructions scheduled for release in FY 2016, and consider whether additional modifications to the instructions can improve consistency among applications;
- Review the new NIH training Data Tables and consider whether to recommend that K12 applications use a subset of the standard table set;
- Improve/Streamline Review Criteria for T32 and K12 applications; and
- Facilitate collaboration between SRO and PO in crafting review criteria.

Review of NICHD Training and Career Development Programs

Background

Created at the request of the President and with the support of the Congress in 1962, the NICHD was initially founded to realize a vision: to support the world's best minds in investigating human development throughout the entire life process, including a special focus on understanding developmental and intellectual disabilities and illuminating important events that occur during pregnancy. Since then, the NICHD has achieved an impressive array of scientific advances in its pursuit to enhance lives throughout all stages of human development, from preconception through adulthood, improving the health of children, adults, families, communities, and populations. The Institute's mission is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation. Because the NICHD's mission is broad, many scientific disciplines and research areas lie within the Institute's scope. The NICHD requires a wide-ranging portfolio of training and career development programs to promote scientific progress.

Format and Scope of the Training Review

To inform the future directions of training and career development programs, NICHD leadership commissioned a comprehensive review of the various training mechanisms supported by the institute, the funding resources committed to those programs, and the productivity and professional outcomes of former fellows, trainees, and scholars. The review was carried out by a Task Force composed of NICHD staff and external members with knowledge of NIH training programs and biomedical research workforce issues. Members included representatives from NICHD's National Advisory Council; experienced NICHD program directors; staff with expertise in review, policy, and program evaluation; and training experts from other NIH Institutes and Offices. The Task Force, organized and chaired by NICHD Training Officer, Dr. Dennis Twombly, held a series of meetings between May and September 2015. The Task Force studied extensive data prepared by the NICHD Office of Science Policy, Analysis and Communication (OSPAC) to inform the deliberations and compilation of a final report.

The scope of this review covers all of the individual fellowships and career development awards, institutional fellowships and career awards, and T15/R25 education programs, as follows:

- Individual National Research Service Awards (F30 Dual Degree Fellowships, Diversity F31 Pre-doctoral Fellowships, Parent F31 Pre-doctoral Fellowships, F32 Post-doctoral Fellowships)
- Institutional National Research Service Awards (T32 training programs)
- Individual Career Development Programs (K01, K08, K23, K24, K25, K99-R00)

- Institutional Career Development Programs (K12 programs)
- > R25 Education Programs (R25 & T15 Short Courses; R25 Summer Research Experiences)

It is important to note that not all training and career development takes place in programs specifically designated for this purpose. A great deal of training and career development work is conducted within research project grants, where pre- and post-doctoral researchers get valuable hands-on experience. In FY 2014, 610 pre-doctoral students and 349 post-doctoral researchers received part-time support on NICHD-funded R01 grants. Other vehicles for training include clinical research centers, laboratories, the NIH intramural programs, and university training efforts that are not supported by the NIH. These activities were deemed out of the scope of this review. However, the Task Force continually kept these experiences in mind and referred to these other mechanisms in their discussions. NICHD also sponsors the diversity and re-entry supplement programs and loan repayment program, all of which directly or indirectly support training. Those programs were not included within this review.

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Overview of NICHD's Training Programs

Research training and career development programs at NIH are designed to prepare individuals for careers in biomedical, behavioral, social, and clinical research. NICHD supports a variety of training mechanisms in research areas relevant to the institute's mission, including demography, social sciences, and population dynamics; male and female fertility and infertility; developing and evaluating contraceptive methods; improving the safety and efficacy of pharmaceuticals for use in pregnant women, infants, and children; HIV infection and transmission, AIDS, and associated infections; pediatric growth and endocrine research; child development and behavior; developmental biology and typical and atypical development; intellectual and developmental disabilities; gynecologic health conditions, including pelvic floor disorders; childhood injury and critical illness; and rehabilitation medicine.

Specific training mechanisms are targeted to aspiring research scientists with different academic backgrounds and at different career stages. Ruth L. Kirschstein National Research Service Awards (NRSA) support research training via individual pre- and post-doctoral fellowships and institutional research training grants. Individual career development awards (K-series) provide support for specific groups of scholars from senior post-doctoral to faculty levels. Mentored K awards provide protected time to obtain intensive research training under the guidance of an accomplished faculty investigator. Institutional career development programs support groups of scholars under the direction of an established Principal Investigator. These programs may recruit and train scholars on behalf of a single institution. Other programs are national in scope, providing mentored career development opportunities to individuals around the country.

Key features of NICHD's training and career development programs are outlined below.

Individual NRSA Fellowships

NICHD supports Individual Ruth L. Kirschstein National Research Service Awards for the research training of individuals at pre-doctoral and post-doctoral levels. Fellowships are available for pre-doctoral students through the Diversity F31 and Parent F31 programs. Students in formal dual-degree programs (MD/PhD, DVM/PhD, etc.) may be supported with F30 fellowships. F32 post-doctoral fellowships are used to provide advanced research training for individuals with doctoral degrees.

The provisions of individual NRSA fellowships were established by legislation adopted in 1974. Eligibility is limited to U.S. Citizens and Permanent Residents. Applications are prepared by the individual candidate in collaboration with a mentor and submitted by the sponsoring institution. Applications must describe a research project as well as a mentored training plan.

Applications are peer reviewed in the fellowship study sections at the Center for Scientific Review (<u>http://public.csr.nih.gov/StudySections/Fellowship/Pages/default.aspx</u>). Second-level

review of applications is carried out each Council round by NICHD's Training Policy Committee (TPC). The TPC reviews applications and forwards funding recommendations to the Director. In contrast to the Institutional Training Grants described below, NICHD selects which individual fellowships to award, how many, and in which fields.

Allowable costs for NRSA fellowships are established centrally by the NIH Office of Extramural Research (OER). Fellowship awards provide funds for stipends, tuition/fees, and an institutional allowance to help defray the cost of fellowship expenses such as health insurance, research supplies, equipment, books, and travel to scientific meetings. These levels are announced through periodic NIH Guide Notices, e.g., NOT-15-048.

NRSA fellowship programs sponsored by NICHD include:

- Parent F30: Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral MD/PhD or Other Dual-Doctoral Degree Fellowship – The purpose of this program is to enhance the integrated research and clinical training of promising predoctoral students who are matriculated in a combined MD/PhD or other dual-doctoral degree training program (e.g. DO/PhD, DDS/PhD, AuD/PhD, DVM/PhD) and who intend careers as physician-scientists or other clinician-scientists. Duration of support is limited to 6 years. NICHD first joined the F30 program in FY2014 and supported four 4 fellowships.
- Parent F31: Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship – The purpose of this program is to enable promising pre-doctoral students to obtain individualized, mentored research training from outstanding faculty sponsors while conducting dissertation research. The proposed mentored research training is expected to enhance the individual's potential to develop into a productive, independent research scientist. Duration of support is limited to 5 years. NICHD first joined the Parent F31 program in FY2014. In FY2014, NICHD supported 8 fellowships.
- Diversity F31: Ruth L. Kirschstein National Research Service Awards for Individual Predoctoral Fellowships to Promote Diversity in Health-Related Research – The purpose of this program is to stimulate the participation of pre-doctoral individuals from the following groups: A. Individuals from underrepresented racial and ethnic groups; B. individuals with disabilities; and C. individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in healthrelated research. Duration of support is limited to 5 years. NICHD has sponsored Diversity F31 fellowships for many years. In FY2014, NICHD supported 14 Diversity F31 fellowships.
- Parent F32: Ruth L. Kirschstein National Research Service Awards (NRSA) for Individual Post-doctoral Fellows – The purpose of this program is to enhance the research training of promising post-doctoral candidates who have the potential to become productive, independent investigators. Eligible individuals must have received a PhD, MD, DO, DC, DDS, DVM, OD, DPM, ScD, EngD, DrPH, DNSc, ND (Doctor of Naturopathy), PharmD, DSW, PsyD, or equivalent doctoral degree. Duration of total post-doctoral NRSA support is limited

to 3 years (F32 + T32 support). In FY2014, NICHD supported 62 fellowships under the Parent F32 FOA.

NICHD supported a total of 88 fellowship awards in FY 2014.

Institutional NRSA Training Grants (T32 Programs)

T32 awards are awarded to an institution to support groups of pre- and/or post-doctoral fellows. The number of positions or "slots" varies with each award. The number of slots for NICHD's T32 programs ranges from 2 to 13, with an average of about 5 slots per program. The PD/PI or "Training Director" for the T32s is typically a nationally and often internationally renowned scientist. The duration of support for pre- and post-doctoral fellows under any NRSA program is 5 years and 3 years, respectively. Eligibility for NRSA programs is limited to U.S. citizens, non-citizen U.S. nationals, or those lawfully admitted for permanent residence.

Institutional training grants provide a number of common elements. They provide intensive research experiences for trainees in a research specialty, under supervision of a established mentor. Trainees have a choice of mentors and are often able to rotate through several laboratories before settling on a final dissertation or post-doctoral sponsor. These research experiences are intended to expose trainees to the current concepts, methodologies and technological approaches in their chosen research fields.

These training grants also offer a variety of additional programmatic elements to enrich the overall training experience and provide skills that will be valuable to trainees as they pursue their professional careers. The most common include opportunities to travel to other labs or scientific meetings; courses and research seminars with institutional and national experts; and training in Responsible Conduct of Research (RCR), human & animal subjects protections, and communication skills (manuscripts, grant writing, oral presentations, public outreach). Consistent with recommendations of the NIH Biomedical Workforce committee, many programs now offer exposure to a variety of research-related careers outside of the conventional academic arena.

NICHD participates in the Parent T32 announcement, which attracts the overwhelming majority of applications. The institute has also published several other T32 announcements to promote training in specific areas of science relevant to the Institute's mission. The objectives of these programs are listed below:

 Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants (Parent T32) – The objective of this trans-NIH T32 program is to support pre-doctoral and post-doctoral research training programs in biomedical, behavioral, and clinical research (May 25 receipt date). Applications may be submitted in any research area relevant to NICHD's mission. (PA-14-015; 113 awards in 2014).

- **Post-doctoral Training Program in Obstetric and Pediatric Pharmacoepidemiology** (PAR-13-112; 2 awards 2014 & 2015).
- Pre-doctoral Training Program in Systems Biology of Developmental Biology & Birth Defects (PAR-13-019; 0 awards 2014, 2015).
- **Post-doctoral Research Training for Obstetricians and Gynecologists** (PAR-10-203, expired; 1 award in 2014).
- **Post-doctoral Research Training in Pediatric Clinical Pharmacology** (RFA-HD-16-015, new).
- Jointly Sponsored Ruth L. Kirschstein National Research Service Award Institutional Predoctoral Training Program in the Neurosciences – This trans-NIH T32 program supports broad, early-stage graduate research training in the neurosciences. Trainees are supported during years 1 and 2 of their graduate research training when they are typically not committed to a dissertation laboratory. Note: NICHD is phasing out its participation in this program (PAR-12-084).

NICHD supported a total of 116 T32 grants, and 597 trainees, in 2014.

NICHD accepts T32 applications for the May 25 receipt date each year. Peer review is conducted in NICHD's Scientific Review Branch by a single multidisciplinary Special Emphasis Panel. Peer reviewers have experience with institutional training programs either as PI or as a mentor as well as subject matter expertise in the scientific areas represented by the applications.

Individual Career Development Award Programs

The purpose of the individual career development awards is to provide a 3-5 year mentored research experience in the biomedical, behavioral, or clinical sciences. With exception of the K99 program, the K awards are restricted to US Citizens or Permanent Residents. The objective is to develop new research skills and provide a minimum of 75 percent release time for research and training activities. Most of the mentored K awards are targeted to junior faculty who need the career development experience in order to establish their research independence. Awards vary in duration from 3-5 years. NICHD has established a limit of 6 years of combined support on individual and institutional K awards. NICHD provides a salary contribution of up to \$75,000 per year, plus fringe, and research support of up to \$25,000 per year.

Individual career development awards supported by NICHD include:

• K01: Mentored Research Scientist Development Award – The purpose of this program is to provide support and protected time for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading to research independence. NICHD supports K01 awards in 3 areas <u>only</u>: Medical rehabilitation medicine, child abuse & neglect, and population research. In FY2014, NICHD supported 31 K01 awards.

- K08: Mentored Clinical Scientist Development Award This program provides support and protected time to individuals with a clinical doctoral degree for an intensive, supervised research career development experience in the fields of basic biomedical and behavioral research, including translational research. Applicants must have a clinical degree, such as MD, MD/PhD, DDS, or other clinical doctoral degree (e.g., PhD in clinical psychology, physical therapy, or nursing). Individuals with PhD degrees are eligible only if they have a clinical license to work with patients (e.g., clinical psychologists, physical therapists). In FY2014, NICHD supported 31 K08 awards.
- K23: Mentored Patient-oriented Research Career Development Award The purpose
 of this program is to support the career development of individuals with a clinical
 doctoral degree who plan to focus their research endeavors on patient-oriented
 research. Provisions of the program are similar to the K08 award. In FY2014, NICHD
 supported 98 K23 awards.
- **K25:** Mentored Quantitative Research Career Development Award The purpose of this award is to support productive professionals with quantitative (e.g., mathematics, statistics, economics, computer science, imaging science, informatics, physics, chemistry) and engineering backgrounds to integrate their expertise with NIH-relevant research. In FY2014, NICHD supported 2 K25 awards.
- K99-R00: Pathway to Independence Award This program is designed to facilitate transition of outstanding post-doctoral researchers or clinician-scientists from mentored research positions to independent, tenure-track or equivalent faculty positions, and to provide independent NIH research support during the transition that will help these individuals launch competitive, independent research careers. This is the only training or career development program available to non-citizens as well as US Citizens. Applicants must have no more than 4 years post-doctoral research experience at the time of application. Exceptions to the 4-year policy may be granted for family/medical leave, periods of unemployment, or employment in non-research positions. The K99 phase provides NICHD contributions for salary, fringe benefits, and research expenses. When the PI accepts an offer of a tenure track or equivalent faculty position, the NICHD Transition Committee conducts an administrative review of the R00 transition application. If the PI has demonstrated sufficient progress on the K99 career development plan, and the new faculty position satisfies the programmatic requirements, the 3-year independent R00 phase is activated. The R00 award provides \$249,000 total costs per year (direct costs + full indirect costs). In FY2014, NICHD supported 25 K99 awards.
- Midcareer Investigator Award in Patient-Oriented Research (Parent K24) The purpose of this program is to provide protected time to devote to patient-oriented research and to act as research mentors primarily for clinical residents, clinical fellows and/or junior clinical faculty. Associate Professors and Full Professors with a health professional doctoral-level degree are eligible. K24 awards are limited to those who have an active NICHD grant at the time of the award. Between 25 and 50 percent effort is required on the K24 award (and supported at the full institutional salary rate). In FY2014, NICHD supported 20 K24 awards.

In FY 2014, the NICHD supported a total of 206 individual K awards (excluding the K25).

Institutional Career Development Award Programs (K12)

The NICHD uses the Mentored Clinical Scientist Award (K12) Program to provide support to domestic institutions of higher learning to mentor clinical fellows and scientists and help them become independent research investigators. NICHD sponsors 9 different K12 programs targeted to specific research areas, such as pediatrics, obstetrics, women's health, men's reproductive health, and rehabilitation medicine. Some K12 programs are national, funding one site that oversees scholars at multiple institutions; some program are local (similar to T32 grants), funding multiple sites to train scholars at local institutions that receive the grants. Applications are all submitted in response to RFAs. Peer review is carried out by Special Emphasis Panels recruited by NICHD's Scientific Review Branch.

K12 programs at NICHD include:

- **BIRCWH: Building Interdisciplinary Research Careers in Women's Health** The BIRCWH programs provide mentored research training to clinicians and non-clinicians who will be engaged in basic, translational, behavioral, clinical, and/or health services research relevant to women's health or sex/gender factors. The program, sponsored by the NIH Office of Research on Women's Health and 6 other NIH ICs, provides grants to 14 different sites. NICHD contributes funds for a small number of scholars (RFA-OD-15-001).
- CHRC: Child Health Research Career Development Award The CHRCDA program was initiated in 1990 in response to the need for greater numbers of physician-scientists in pediatric research. The program supports scholars at 18 sites in pediatric departments and children's hospitals across the country through multiple grants to local sites. Research experiences cover a broad range of basic and applied biomedical science related to pediatrics (RFA-HD-16-018).
- MRHR: Male Reproductive Health Research Career Development Program These programs support the research career development of urologists, reproductive endocrinologists and other clinicians who have recently completed sub-specialty training and who are commencing basic, translational and/or clinical research relevant to male reproductive health (RFA-HD-12-187). The NICHD is currently phasing out this program.
- PCCR: Pediatric Critical Care Scientist Development Award The purpose of this program is to expand the cadre of investigators in pediatric critical care and to stimulate research into the scientific basis of critical care practice and the consequences of critical illness and injury for families and children (RFA-HD-14-019). The program is administered through a grant to a single institution, but supports scholars across the country.
- **PSDP:** Pediatric Scientist Development Program The PSDP program identifies promising pediatricians who have completed their clinical training and matches them with established mentors to provide a research career development experience leading to independence. Training activities can be in basic biomedical or clinical sciences, in the population sciences, in health services research, or in any other discipline relevant to the NICHD mission (RFA-

HD-12-209). The program is administered through a grant to a single institution, but supports scholars across the country.

- RSCD: Rehabilitation Sciences Career Development Award This program supports a
 national network of mentors to provide career development of rehabilitation researchers in
 one of the following three domains: physical/occupational therapy and allied health
 professionals, clinicians involved in neurological rehabilitation, or bioengineers (RFA-HD-12208). The program is administered through a grant to a single institution, but supports
 scholars across the country.
- **RMED:** Rehabilitation Medicine Scientist Training Program This program supports a national network of researchers to mentor clinically trained individuals from the field of physical medicine and rehabilitation (RFA-HD-11-081). The program is administered through a grant to a single institution, but supports scholars across the country.
- **RSDP Reproductive Scientist Career Development Program** This national K12 program, launched in 1988, provides mentored research training to physician-scientists in reproductive health, including obstetrics and gynecology (RFA-HD-13-015). The program is administered through a grant to a single institution, but supports scholars across the country.
- WRHR: Women's Reproductive Health Research Program The WRHR Program supports the career development of junior faculty in obstetrics and gynecology, and who are committed to an independent research career in women's reproductive health (RFA-HD-15-011). The program supports scholars at departments of obstetrics and gynecology across the country through multiple grants to 15 local sites.

In FY 2014, NICHD supported 64 K12 awards and 338 scholars.

R25 Education Programs

The R25 programs across NIH involve a wide variety of educational activities, including conceptual or methodological short courses, summer long intensive research experiences, and outreach/dissemination activities. Participants typically include graduate students, post-doctoral fellows, and faculty who seek new knowledge in their own disciplines or in new areas. Some R25 programs are designed to share research resources or knowledge with the lay public. NICHD currently supports the following R25 programs:

- Educational Programs for Demography and Population Science, Family Planning and Contraception, and Reproductive Research (R25) – This FOA supports educational activities and courses related to demography and population science, family planning and contraception, and reproductive research (PAR-11-292; 16 applications; 9 awards; Direct Cost cap \$175,000).
- NICHD Research Short Courses (R25) The purpose of this program is to develop and conduct short-term continuing education programs to improve the knowledge and skills of biomedical and behavioral researchers conducting research on reproductive,

developmental, behavioral, social, and rehabilitative processes. Short courses may range from a few days to up to 12 weeks in duration. Programs include both didactic and hands-on experiences, and may disseminate materials to the scientific community (PA-12-207; 20 applications; 3 awards; Direct cost cap = \$125,000; evolved from T15 FOA PAR-11-233.)

• Summer Research Education Experience Programs (R25) -- This program provides a venue for high school, undergraduate and science teachers to receive hands-on research experiences during the summer academic break. The goal is to foster a better understanding of biomedical, behavioral and clinical research and its implications (PAR-15-184; 8 applications; 2 awards; Direct Cost cap = \$100,000).

In FY 2014, the NICHD supported 22 R25 awards.

Analysis of the Data on NICHD Training and Career Development Programs

Data Collection and Analysis Methods

The NICHD's Science Policy, Planning, and Evaluation Branch led a team to collect and analyze data related to NICHD training and career development programs. To assess training and career development programs in the context of the NICHD budget, the team downloaded financial reporting data for NICHD and other NIH institutes from the NIH's historical budget files. The Biomedical Research and Development Price Index (BRDPI), calculated for NIH by the Department of Commerce's Bureau of Economic Analysis annually, was used to adjust for price inflation. Data on NICHD's training and career development expenditures, funding rates, and funding mechanisms was calculated from information downloaded from NIH's IMPAC II Central data system. Information on specific programs and individual trainees supported was derived from IMPAC II and other internal NIH data systems, as well as from progress reports of institutional training grants. Individual and institutional training grants were described and categorized according to scientific area through the NICHD's Child Health Information Retrieval Program (CHIRP), developed and maintained by the NICHD's Referral and Program Analysis Branch.

The data team also identified the subsequent positions held by former NICHD trainees. This analysis included:

- all pre-doctoral trainees, regardless of training program or mechanism, that received training support at any time from 1989 to 1991;
- all post-doctoral trainees, regardless of training program or mechanism, that received training support at any time from 1994 to 1996;
- all individuals supported under K 12 institutional career development awards at any time from 1999 to 2001;
- all individuals that received individual career development awards (K awards) at any time from 1999 to 2001.

These time frames were chosen to ensure that trainees would be well beyond the training phase of their careers and established in career positions.

Subsequent positions were identified by matching name, university or other affiliation, years of training, area of research, sex, degree, and other characteristics. Data sources included the faculty directory of the American Association of Medical Colleges (AAMC); university directories and other databases; LinkedIn and other social media sites; publication databases including Scopus, PubMed, and Web of Science; ORCID profiles; NIH IMPAC II data; and information retrieved from Internet searches. Separate searches were conducted for each individual by two different team members, and then the information was verified by a third team member. The analysis included 1,571 former trainees and career award recipients.

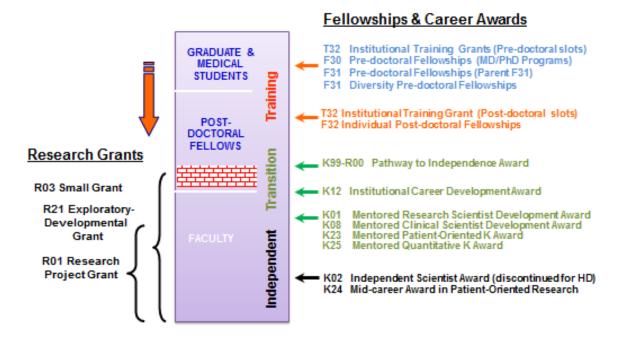
Subsequent NIH grants and grant applications were identified through IMPAC II, through the NIH person profile ID number. Each individual was searched in IMPAC II to account for cases of multiple identification numbers.

Training and Career Development in the Context of the NICHD Budget

This section addresses Overarching Question #1 - Is the amount of funding NICHD commits to training awards the right amount? Are the allocations an appropriate percentage of the NICHD budget? How have these allocations evolved over time?

The NICHD supports research training and career development programs from very early to later career stages, as illustrated in Exhibit 1. Early career programs are important to getting young people interested in science-related careers at a young age. Post-doctoral and early career awards can ensure that less experienced scientists receive the support, protected time, and mentoring needed to advance their careers and eventually become independent research scientists who can compete successfully for research project grants.





The various support mechanisms NICHD uses are designed to target specific career stages and also target researchers with different fundamental training and background. Each mechanism represents a unique combination of eligibility requirements and program features. For example, only clinicians are eligible for the K08 and K23 mechanisms, while the K01 mechanism is largely directed towards PhD researchers.

It is important to note that NICHD must comply with NIH policies on how various mechanisms can be used, and what eligibility restrictions govern each. For some mechanisms, individual NIH institutes can choose whether to participate and how to target eligibility; for other mechanisms, those decisions are made at the NIH level.

Exhibit 2 summarizes the funding levels of the mechanisms considered in depth by the Task Force.

| Activity Code | Type of Grant | Trainee Level | NICHD 2014 Grants | NICHD 2014 Funding |
|--------------------|------------------|---------------|----------------------|-----------------------|
| F30 | Individual | Pre-doctoral | 2 | \$68,762 |
| F31 | Individual | Pre-doctoral | 24 | \$852,444 |
| F32 | Individual | Post-doctoral | 62 | \$3,144,558 |
| Total F | | | 88 | \$4,065,764 |
| K01 | Individual | Career | 31 | \$3,836,307 |
| К08 | Individual | Career | 31 | \$3,750,437 |
| K23 | Individual | Career | 98 | \$11,628,420 |
| К24 | Individual | Mid-career | 20 | \$3,315,260 |
| К99 | Individual | Career | 25 | \$2,715,667 |
| Total individual K | | | 206 | \$25,246,091 |
| Т32 | Institutional | Pre- and | 116 | \$28,483,875 |
| | | post-doctoral | | |
| K12 | Institutional | Career | 64 | \$17,188,750 |
| R25 | Institutional | All | 22 | \$2,556,472 |
| T15 | Institutional | All | 6 | \$825,188 |
| Activity Code | Type of | Trainee Level | NICHD 2014 | |
| | Grant | | Trainees | |
| Total T32 trainees | | Pre- and | 597 | |
| | | post-doctoral | | |
| Total K12 trainees | | Career | 338 | |

Exhibit 2: Training and Career Development Portfolio by Funding Mechanism

Notes: Funding figures include NICHD's financial contribution to the BIRCWH program, but the number of grants does not reflect BIRCWH grants, because NICHD makes nominal contributions to a number of BIRCWH grants in order to facilitate the administration of the program. Similarly, T32 and R25 grant counts do not include grants where NICHD makes only a nominal contribution to the grant for administrative purposes.

As with other expenditures, training and career development expenditures are considered in the context of the overall NICHD budget. This is especially important given the changes in the overall NICHD budget over the past 30 years. As shown in Exhibit 3, like all NICHD and NIH expenditures, NICHD expenditures for training and career development programs increased between 1983 and 2014, although the increase is considerably more modest once inflation is taken into account. The rate of increase accelerated most rapidly during the period of time between 1997 and 2003, when the overall NIH budget received the largest increases. In absolute dollars, the NICHD training and career development expenditures have decreased. Over the past 10 years, NICHD training career development expenditures decreased by over one third (33.9 percent) in inflation-adjusted dollars. This rate of decrease has exceeded the decline in the NICHD budget. Therefore, over the past 10 years, NICHD training career development expenditures for decrease has exceeded the decline in the NICHD budget. Therefore, over the past 10 years, NICHD training career development expenditures have for the decline in the NICHD budget. Therefore, over the past 10 years, NICHD training career development expenditures has exceeded the decline in the NICHD budget. Therefore, over the past 10 years, NICHD training career development expenditures decrease has exceeded the decline in the NICHD budget. Therefore, over the past 10 years, NICHD training career development expenditures decrease has exceeded the decline in the NICHD budget. Therefore, over the past 10 years, NICHD training career development expenditures decrease has exceeded the decline in the NICHD budget. Therefore, over the past 10 years, NICHD training career development expenditures decreased as a share of the NICHD budget from 6.7 to 5.8 percent, as shown in Exhibit 4.

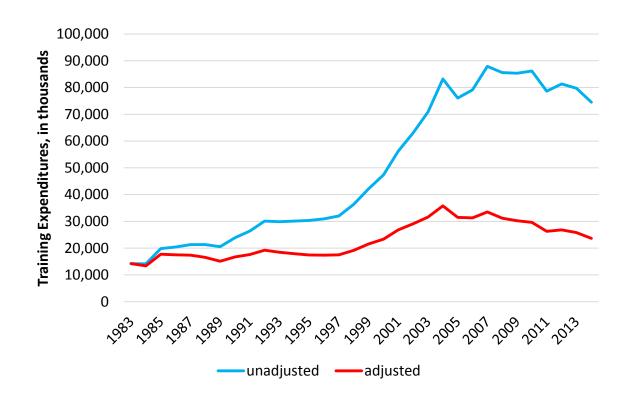


Exhibit 3: Training and Career Development Expenditures, 1983 – 2014 (adjusted and unadjusted for inflation)

Over the past 30 years, NICHD training and career development expenditures have taken up from 4.8 to 7.0 percent of the NICHD budget. In 2014, NICHD training career development expenditures were 5.8 percent of total of spending. This proportion is very similar to the figure from 1983, at 5.6 percent.

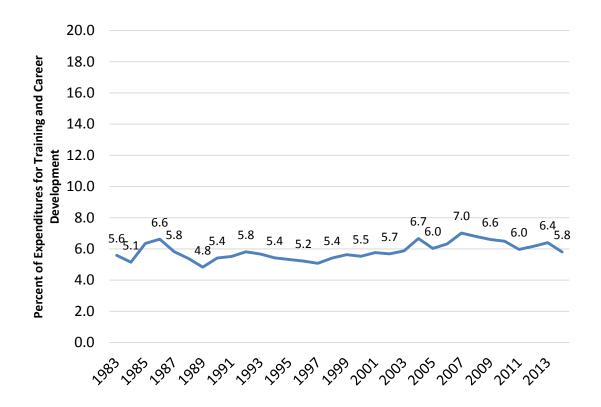


Exhibit 4: Training and Career Development as a Percent of Expenditures, 1983 – 2014

Across the NIH, training and career development expenditures vary as a percentage of total expenditures by NIH Institutes and Centers (ICs). Large ICs, like the National Cancer Institute (NCI), tend to have a smaller proportion of their larger budgets dedicated to training and career development. As shown in Exhibit 5, data from institutes similar in size to NICHD show a range from 4 percent at the National Institute of Neurological Diseases and Stroke (NINDS) to over 9 percent at the National Institute of General Medical Sciences (NIGMS). At 5.8 percent, NICHD's proportion of training and career development expenditures is higher than that of NINDS, roughly equal to the National Institute on Drug Abuse (NIDA), and slightly below the National Institute of Mental Health (NIMH) and the National Institute of Digestive Diseases and Kidney Disorders (NIDDK). The Task Force agreed that NICHD's training and career development expenditures were an appropriate proportion of the Institute's total budget.

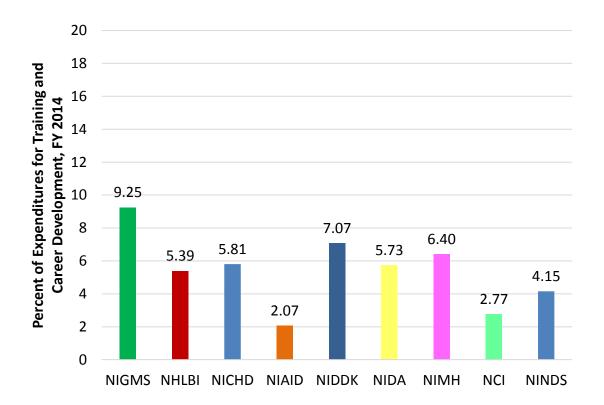


Exhibit 5: Training and Career Development as a Percent of Expenditures, 2014, by NIH IC

Training and Career Development by Career Stage, Degree, and Grant Mechanism

This section addresses Overarching Question #2 – Is the NICHD supporting the correct ratio of awards at different career stages, i.e. predoc/postdoc/early faculty? Has this ratio changed over time? – and Question #3 – Are there appropriate levels of commitment to the different training mechanisms? Are some mechanisms over- or under-utilized?

Training and Career Development by Career Stages

NICHD supports training and career development at career stages from pre-doctoral to midcareer awards. At the pre-doctoral level, trainees may be supported by institutional T32 grants, F30 pre-doctoral fellowships, F31 pre-doctoral fellowships, or F31 pre-doctoral diversity fellowships. Institutional T32 grants are awarded to senior investigators with strong records of mentorship and training. These senior investigators select pre-doctoral candidates to be supported by the T32 program. F30 pre-doctoral fellowships are reserved for individuals planning to complete combined MD and PhD programs. F30 and F31 pre-doctoral fellowships are individual grants. The pre-doctoral candidate, under supervision of their mentor, prepares and submits an application directly to the NIH for fellowship support. These applications are reviewed and the NIH selects individuals who will receive support. Additional F31 pre-doctoral fellowships are available to candidates with specific qualifications to increase the diversity of

the biomedical research workforce. At the post-doctoral level, individuals may be supported under a T32 institutional training grant, F32 individual post-doctoral fellowship, or K99 Pathway to Independence award. Individuals supported under T32 grants are selected by those institutions, while individual candidates submit F32 fellowship or K99 applications directly to the NIH.

Currently, NICHD supports between 313 and 542 individuals at each career stage – predoctoral, post-doctoral, career, and early stage investigator. Exhibit 6 shows the number of individuals supported by NICHD training and career development programs, by career stage and mechanism group, over time. The total number of individuals supported grew over time through 2010, but declined by 12.8 percent between 2010 and 2014 (from 1,413 to 1,232).

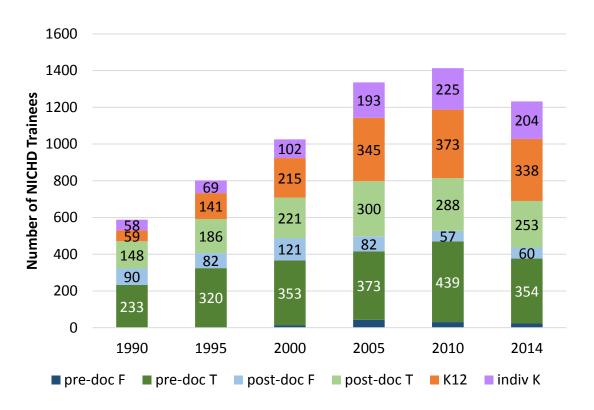


Exhibit 6: Individuals Supported by Career Stage and Mechanism Group, 1990-2014

The Task Force noted that the mixture of trainees by career stage also changed over time, as shown in Exhibit 7. In 1990, 39.6 percent of the total trainees supported were at the predoctoral level, but by 2014 this had declined to 30.7 percent. In contrast, the percent of trainees supported at the career stage (K awards) more than doubled, from 19.9 percent in 1990 to 44.0 percent in 2014. This document is provided for reference purposes only.

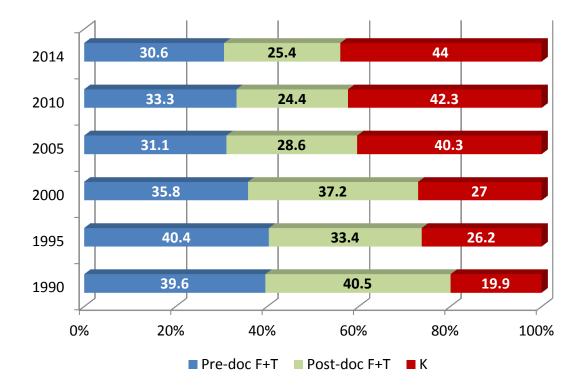
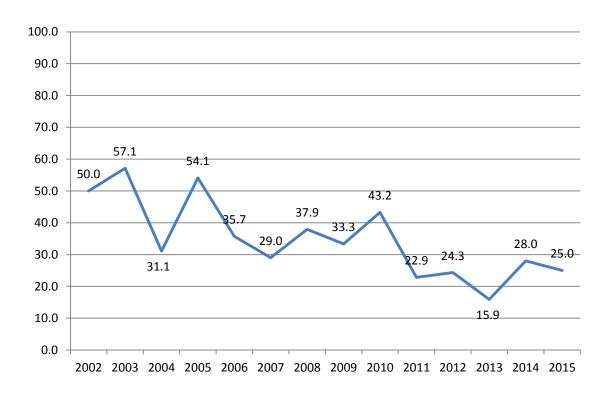


Exhibit 7: Proportion of Trainees at Each Career Stage Over Time, 1990-2014

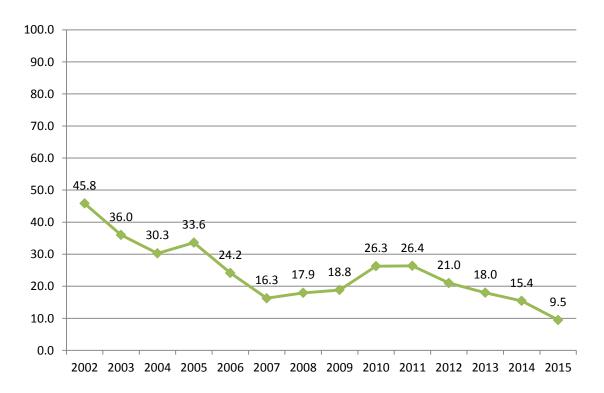
The Task Force agreed that it is important to maintain a balance in supporting trainees at different career stages. However, this balance can prove difficult to achieve within funding constraints. For example, a recent policy change at the NIH level required all NIH ICs to participate in the parent F31 mechanism, which provides pre-doctoral fellowships. Prior to 2014, NICHD did not accept applications under the parent F31. With decreasing funding levels available for fellowships, the inclusion of the parent F31 exacerbated a long-term trend of decreasing success rates for diversity F31 and post-doctoral F32 applications, as shown in Exhibits 8 and 9. The Task Force expressed concern about these trends, especially given the subsequent success of the individuals who received F32 post-doctoral fellowships. The Task Force supported establishing differential pay lines within individual fellowships. For this and for other reasons, shifting some funds from institutional to individual fellowships was also recommended, and this may help raise success rates and encourage applications.

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Training and Career Development by Degree

As described previously, several training and career development mechanisms are specifically targeted at clinician-scientists. Eligibility for the K08 and K23 mechanisms is limited to those with a clinical degree. For K08 and K23 mechanisms, a few clinical PhDs are included, but the overwhelming majority of individuals supported are MDs. As Exhibit 10 shows, the F32, K01 and K99 mechanisms are utilized almost exclusively by PhDs, although MDs are eligible to apply. PhDs without MDs make up only 11 percent of individuals supported under K12 grants. Finally, it is important to note that the rate of dual-degree MD+PhD holders – a group traditionally thought to be well-positioned for success – is highest for the K08 and K12 career scholars. The Task Force carefully considered the degree composition by mechanism when interpreting the data on success of training programs and in identifying program gaps.

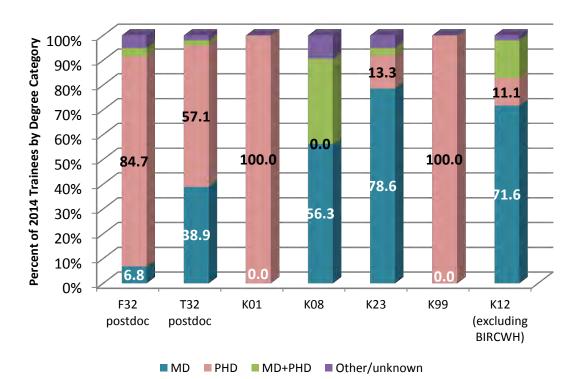


Exhibit 10: Percent of 2014 Trainees by Degree Category, by Key Mechanisms

Note: BIRCWH scholars were excluded from these calculations because NICHD supports only a small number of the total scholars in the BIRCWH program.

Training and Career Development by Grant Mechanism

Individual and Institutional Training and Career Development Awards

Many NICHD-supported trainees receive funding through institutional training and career development programs—T32 and K12 grants. As shown in Exhibit 11, NICHD relies more heavily on institutional mechanisms in comparison with other NIH ICs, with the notable exception of NIGMS.

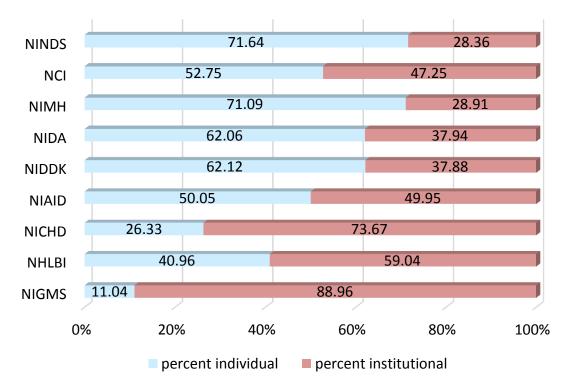


Exhibit 11: Training and Career Development Funding, Institutional v. Individual, 2014, by IC

As shown in Exhibit 12, NICHD's use of institutional mechanisms has ranged from 55 to 85 percent since 1983, peaking at the end of the doubling period. Over the past ten years, the proportion of institutional training mechanisms has ranged from 75-80 percent of the overall training portfolio.



Exhibit 12: Training and Career Development Funding, Percent Institutional, 1983-2014

The NICHD has used the K12 institutional career award mechanism to a much greater extent than other NIH ICs. In 2014 the K12 accounted for 38 percent of NICHD's expenditures on institutional training and career development programs (that is, T32 and K12 combined). The K12 programs supported by the NICHD are detailed in Exhibit 13.

| K12 Program | Туре | Topic Area | Median Funding, 2010-2014 | | 2014 Funding | |
|-------------|----------|-------------------------|------------------------------|-----------|--------------|-----------|
| BIRCWH | local | Women's health | \$ | 600,000 | \$ | 396,663 |
| WRHR | local | Reproduction | \$ | 5,437,000 | \$ | 1,796,706 |
| CHRC | local | Pediatrics | \$ | 6,546,721 | \$ | 7,842,840 |
| PCCR | national | Pediatric critical care | \$ | 864,000 | \$ | 778,000 |
| RMED | national | Rehabilitation | \$ | 1,019,094 | \$ | 1,019,094 |
| RSCD | national | Rehabilitation | \$ | 2,100,000 | \$ | 2,600,587 |
| PSDP | national | Pediatrics | \$ | 1,506,613 | \$ | 1,504,635 |
| RSDP | national | Reproduction | \$ | 1,519,064 | \$ | 1,250,225 |

| Exhibit 13. | K12 Programs | Supported by | the NICHD |
|-------------|--------------|--------------|-----------|
| LAHIDIC 13. | K12 HOgranis | Jupporteu b | |

Moreover, NICHD supports over 80 percent of its training positions (F and T mechanisms) through the T32, as shown in Exhibit 14.

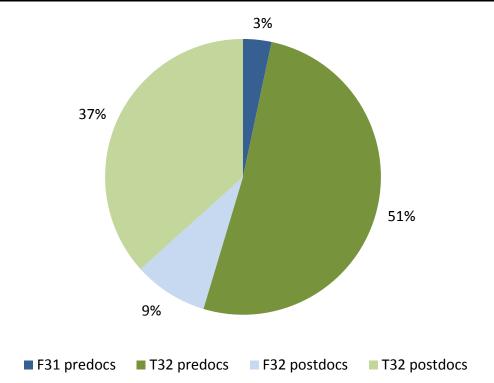
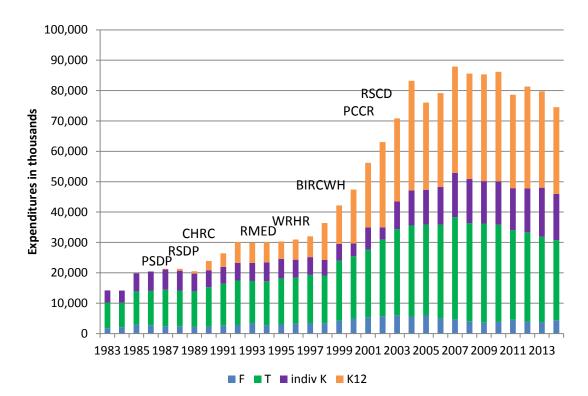
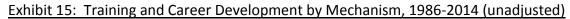


Exhibit 14: F31 and F32 Fellowship and T32 Training Positions, FY 2014, by Mechanism

As shown in Exhibit 15, the growth in funding for institutional mechanisms parallels the growth in K12 programs at the NICHD over the past 25 years. Three of NICHD's largest K12 programs – the Reproductive Scientist Development Program (RSDP), the Pediatric Scientist Development Program (PSDP), and the Child Health Research Careers (CHRC) program, were all established in the late 1980s. In the late 1990s, new K12 programs were added – the WRHR, Rehabilitation Medicine, and BIRCWH (primarily funded by ORWH). Smaller programs were added later.





The Task Force discussed the advantages and disadvantages of a variety of mechanisms for training and career development programs. The T32 programs, for example, can offer a comprehensive training program in an institutional context, where trainees at various levels have the opportunity to participate in organized activities with a cohort of individuals at the same institution. This also provides an efficient and effective mechanism for providing training on research support topics such as the responsible conduct of research, human and animal subjects protection, career options, and science communication. Because T32 programs are an asset to a top-tier department, high-level candidates can be recruited and selected by senior faculty members in the program who are close to the trainees and are well-positioned to attract and select top candidates. The T32 can lend prestige to clusters of investigators. T32 programs may foster multidisciplinary training by offering trainees different lab rotations and a selection of distinguished mentors; the activities of the program may also foster communication and support networking across labs. Finally, T32 programs can provide departments with flexibility to support young investigators who are especially promising but have limited track record to compete for funding on their own, who are researching new or underdeveloped areas of science, or who are working with mentors who have funding gaps and may be unable to support them through research grants or other means.

K12 programs share many of the advantages of T32 grants – the ability to provide a comprehensive program, to provide flexible funding support, and to work with a cohort of young investigators, for example. The NICHD has used K12s primarily to support MDs while they gain research training and experience not provided in medical school. Task Force

members were persuaded that such programs were important to keeping physician-scientists in the biomedical research workforce. Without the additional research experience and training that the K12 programs provide, these MDs may not yet be well-positioned to compete for an individual K award or research grant. This is especially true for certain demanding clinical subspecialties. After a few years on the K12, however, trainees/scholars are better positioned, and (as described later) do well in obtaining subsequent grants. (Indeed, MDs supported on K12 career programs are considerably more likely to apply for and receive subsequent NIH grants compared with MDs supported under a T32 post-doctoral program—probably reflecting a cohort of greater maturity.) NICHD has traditionally targeted K12 programs to areas that are specific to NICHD's mission but are broad in scope – pediatrics, rehabilitation, and reproductive health.

Individual grants and fellowships also have advantages for promoting training and career development. In an individual grant or fellowship, the individual student or post-doctoral fellow must conceive of a research project, learn grant writing skills, and navigate the NIH application process. The candidate will gain experience with review, summary statements, and possibly resubmission, and may develop relationships with NIH program staff. Successful applicants have a major accomplishment for their CV, making them more attractive candidates for future positions. The peer review process can bring a greater rigor to the selection of applicants. With individual grants, NIH has the opportunity to select which grants to award, how many, and in what specific fields. Successful awardees have more freedom from their mentor's research and fiscal pressures because they have their own independent funding. Finally, as described below, individual F and K awardees tend to be somewhat more successful in obtaining later NIH support, compared with those whose only support comes from institutional T32 grants.

The Task Force discussed two key issues specific to institutional training programs – ensuring an optimal cohort size and balancing the need for new and long-standing institutional programs.

Task Force members agreed that one of the key advantages of institutional training and career development programs is the opportunity to participate in organized activities as part of a cohort. Several members with experience in managing these programs stated that the cohort effect is particularly important for T32 programs. Exhibit 16 shows the cohort size for NICHD T32 programs in FY 2014. It was recognized that at any one time some T32 grants would be in the process of "ramping up" or "ramping down" their trainee pool, and it is important to give program directors every incentive to fill slots appropriately. Nonetheless, Task Force members believed that greater efforts to maintain a cohort size of at least 3-4 trainees, especially in T32 programs that include post-doctoral fellows, could be helpful in increasing the quality of the training experience.

| | T32 programs with only predoc trainees | T32 programs with only postdoc trainees | T32 programs with both predoc and postdoc trainees | All T32 programs combined |
|--------------------|--|---|--|---------------------------------|
| Average number of | 5.9 | 3.7 | 7.7 | 5.2 |
| trainees | | | | |
| Percent with fewer | 8.8 | 48.2 | 0.0 | 25.9 |
| than 3 trainees in | | | | |
| total | | | | |
| Percent with 4-6 | 64.7 | 46.4 | 34.6 | 49.1 |
| trainees in total | | | | |
| Percent with 7 or | 26.5 | 5.4 | 65.4 | 25.0 |
| more trainees in | | | | |
| total | | | | |
| Number of T32 | 34 | 56 | 26 | 116 |
| grants | | | | |

Exhibit 16: Training and Career Development Cohort Size, FY 2014

Note: these are numbers of actual trainees, not numbers of slots.

The Task Force also discussed the need to balance support for long-standing, highly successful institutions with the need to give new (and perhaps more innovative) institutions a fair chance at obtaining a T32 or K12 grant. As indicated in Exhibit 17, 33 percent of NICHD's T32 and 11 percent of NICHD's K12 grants have been funded for more than 15 years. Moreover, as shown in Exhibit 18, over the past 5 years the success rate for re-competing institutional training and career development grants at NICHD far exceeds the rate for new applicants. This trend is apparent at both the NIH and NICHD levels.

Exhibit 17: Number of T32 and K12 awards by length of grant

| | years 1-5 | years 6-10 | years 11-15 | more than 15 years |
|-----|-----------|------------|-------------|--------------------|
| K12 | 15 | 21 | 21 | 7 |
| T32 | 37 | 27 | 19 | 40 |

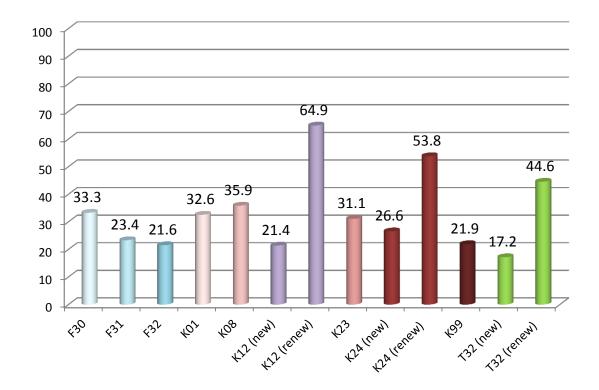


Exhibit 18: NICHD Funding Rates, 2010-2014, by Mechanism and Type

The Task Force recognized that some differential was to be expected, but the current gap was thought to be somewhat too high to encourage innovation in institutional programs. Several Task Force members felt that reviewers were inclined to over-emphasize an incumbent's track record at the expense of being forward-looking about what types of training are needed for the next generation of researchers. This tendency may arise from reviewers' need for metrics to distinguish among a large number of meritorious applications. Task Force members noted that in recent years, it has become more difficult to distinguish "new" applications from existing programs, especially after recent changes to NIH's resubmission policies.

Within individual career development awards, the Task Force also noted the differences in success rates across mechanisms, with the K99 having the lowest success rate. Although some differences are to be expected, the Task Force agreed that having very low success rates for some mechanisms can be very discouraging to young investigators. Because these discrepancies have been growing in 2013-2014, the Task Force suggested shifting funds within the individual K pool to balance success rates. (See recommendations section.)

Ultimately, the Task Force members agreed that both individual and institutional training mechanisms have their place. However, consistent with the recommendations of the NIH Biomedical Research Workforce Task Force, the NICHD Task Force recommended that NICHD rebalance its training and career development programs to place more emphasis on individual as compared with institutional programs. The Task Force noted that NICHD relied more

heavily on institutional mechanisms compared with other NIH ICs. Although institutional programs have important advantages and should be continued, the advantages of individual grants were equally compelling. Moreover, the need to increase funding rates for successful individual mechanisms, such as the F32, would require a shift in emphasis. (These recommendations are discussed in more detail in the "Recommendations" section below.)

K24 Mid-Career Awards

The K24 mechanism supports mentoring and protected research time for mid-career investigators, in an effort to encourage mentoring. The Task Force reviewed the K24 mid-career award in more detail because there were some concerns from the experts about the value and cost of this particular mechanism. Task Force members raised specific questions about the individuals who were being mentored by the K24 awardees and how they benefit from the support provided to their mentors. Data from NICHD K24 awards from 2007-2010 were reviewed. This time period was chosen to allow time for publications and grant applications to result from the K24. Data were analyzed to describe the characteristics of the mentors and mentees and whether they had worked together subsequently on publications or grant applications.

As shown in Exhibits 19 and 20, the "typical" person mentored by a K24 awardee is a junior faculty member who received their first doctoral-level degree 7-10 years previously. However, some more senior individuals are mentored as well.

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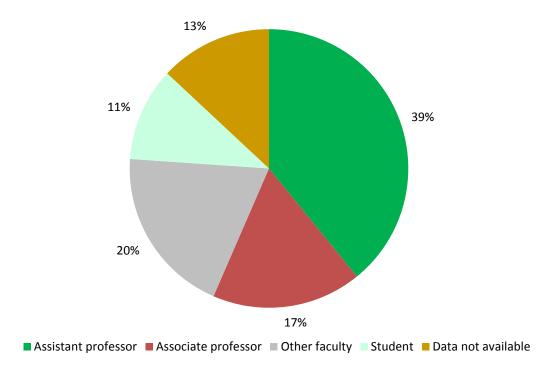
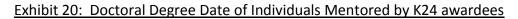
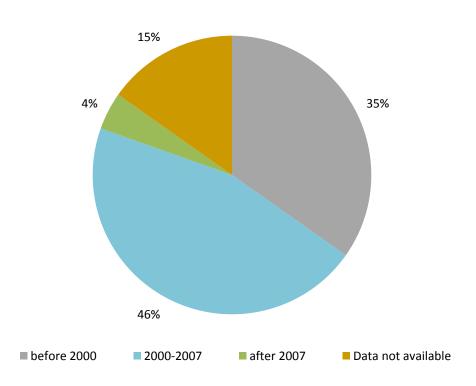


Exhibit 19: Career Stage of Individuals Mentored by K24 awardees





The data showed that subsequent collaboration between mentees and K24 awardees was not necessarily the norm. Specifically:

- Nearly 90 percent of publications credited to the K24 grants do not include mentees as authors.
- In the majority of cases, individuals mentored under K24 grants do not work with their mentors on subsequent grants or publications.

As shown in Exhibit 21, most mentees of individuals supported by a K24 did not work with their K24 mentor on a subsequent grant or publication within 5 years of the K24 award.

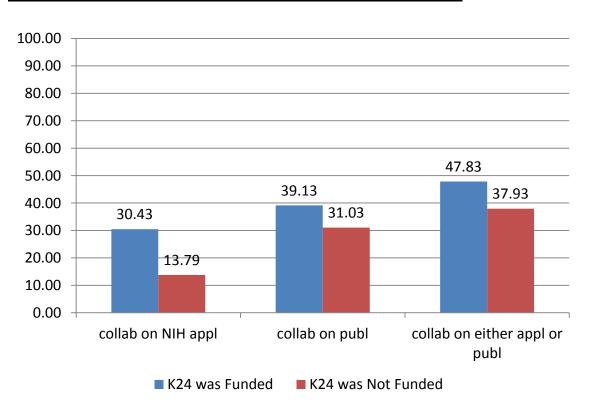


Exhibit 21: Subsequent Collaboration Between Mentors and Mentees

Applicants who received K24 funding were more likely to work with their mentees on subsequent grants and publications compared with individuals whose K24 applications were not successful (including only mentees on the initial application), as shown in Exhibit 21 above. Mentees of successful K24 applicants were also more likely to apply for and receive NIH grants compared with mentees of unsuccessful K24 applicants, although this finding did not reach statistical significance. There was one diversity-focused funded K24. Mentees on that grant were as likely or more likely to publish, subsequently work with their mentors on publications and grants, and to submit NIH grant applications and receive funding.

It is probable that some of the mentoring that takes place on the K24 grant could be characterized as "career mentoring" – advice on career choices, for example – and not scientific

mentoring. In those cases, subsequent collaboration may not be expected. Given the career stage of most K24 mentees, however, Task Force members did not see career mentoring as requiring the level of support of a K24 grant. The Task Force expressed concern that the K24 mechanism was not as useful as it could be; moreover, because it is supporting mid-career investigators' salary, the K24 is relatively high in cost. The Task Force suggested reducing the number of K24 awards, limiting the effort supported to 25 percent, limiting eligibility to PIs with only one R01-level grant, and establishing focus areas – particularly mentoring of diverse individuals – for the K24 program.

R25 Education Grants for Short-term Courses

As detailed in Exhibit 22, a variety of branches within NICHD use the R25 mechanism to support short courses. The courses supported under the R25 mechanism provide short-term skill training to investigators in specific areas. Although they are not traditional training and career development programs, R25 grants can fill important needs and provide state-of-the-art training in emerging research tools and techniques.

The cost of R25 grants varies widely and the use of R25s varies across NICHD branches. Although there was some discussion of the cost of R25s and support for institutional commitment, the Task Force hesitated to adopt cost limits. Instead, Task Force members suggested that NICHD could allow for costs above a standard amount, but set a high standard for justifying such costs. This document is provided for reference purposes only.

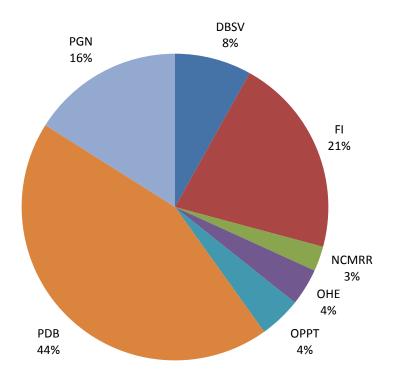


Exhibit 22: Use of R25 Mechanism at NICHD, FY 2014

| Branch | Total R25 Funding, FY 2014 | Total R25 grants, FY 2014 | |
|---------------------|----------------------------|---------------------------|--|
| DBSV | 190,224 | 2 | |
| FI | 495,191 | 3 | |
| NCMRR | 61,683 | 2 | |
| OHE | 91,775 | 1 | |
| ОРРТ | 103,644 | 1 | |
| PDB | 1,030,095 | 9 | |
| PGN | 376,616 | 4 | |
| Average (mean) cost | 106,783 | | |
| Median cost | 100,461 | | |

Training and Career Development by Research Field

This section addresses Overarching Question # 4 – Are the allocations to the fields supported by NICHD training and career development programs appropriate for the NICHD mission, and are the types of training mechanisms appropriate for those fields? How are NICHD training and career development resources and numbers of trainees/awardees currently distributed across programs and areas of science? How does the current distribution compare with what NICHD has done in the past?

The training and career development grants supported by the NICHD cover a wide range of scientific disciplines and research topics. The majority of applications for training and career development support come to the NICHD via "parent" funding opportunity announcements. In general, these FOAs accept all applications that fit within NICHD's broad overall mission, without restricting eligibility to specific research areas. A few FOAs issued by the NICHD are targeted to scientific areas within the NIHCD mission. Most of these targeted announcements encompass areas that are narrower than the NICHD mission, but are still broadly defined – including pediatrics, reproductive health, or rehabilitation. A few narrower areas have also been targeted, including pharmacology, pediatric critical care, and child maltreatment. However, these narrower areas have not resulted in large numbers of grants.

For T32 programs, the result has been a relatively even distribution across NICHD branches, as shown in Exhibit 23.

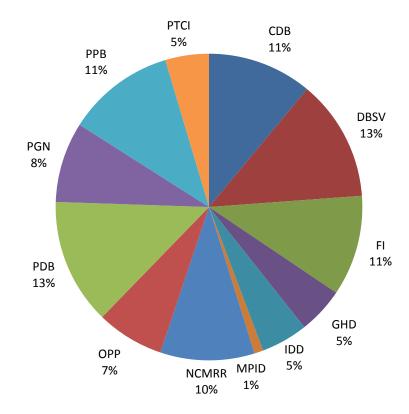


Exhibit 23: T32 Programs by NICHD Branch

| Branch | Number of T32 grants | Direct Costs | Pre-doc Slots | Post-doc Slots | Total Slots |
|--------|-------------------------|--------------|---------------|----------------|-------------|
| CDB | 11 | \$3,145,351 | 33 | 28 | 61 |
| DBSV | 16 | \$3,642,568 | 87 | 7 | 94 |
| FI | 14 | \$3,019,772 | 27 | 34 | 61 |
| GHD | 5 | \$1,392,386 | 7 | 17 | 24 |
| IDD | 5 | \$1,408,342 | 17 | 12 | 29 |
| MPID | 1 | \$268,258 | 0 | 4 | 4 |
| NCMRR | 11 | \$2,829,901 | 34 | 24 | 58 |
| OPP | 9 | \$2,028,216 | 23 | 17 | 40 |
| PDB | 13 | \$3,778,958 | 69 | 17 | 86 |
| PGN | 11 | \$2,415,778 | 0 | 40 | 40 |
| PPB | 14 | \$3,244,526 | 2 | 46 | 48 |
| PTCI | 6 | \$1,309,819 | 5 | 16 | 21 |
| Total | 116 | \$28,483,875 | 304 | 262 | 566 |

Whether funding through a targeted or a broad-based FOA, training and career development grants funded by the NICHD cut across a number of areas relevant to the Institute's mission. Exhibit 24 shows the FY 2014 overall training and career development (F, K, T32, K12)

expenditures classified by broad areas, including pediatrics, behavior, developmental biology, and rehabilitation.

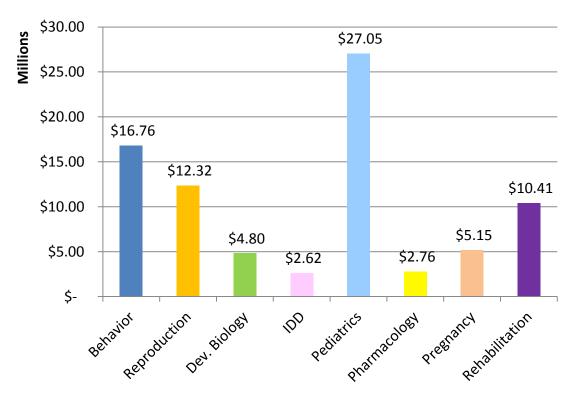


Exhibit 24: Training and Career Development FY 2014 by Subject Area

Over the past 5 years, NICHD's overall training and career development expenditures decreased, as shown earlier. Expenditures decreased in pediatrics, reproductive health, and developmental biology—both in absolute amount and relative to other research areas. Expenditures did increase in rehabilitation over this period.

The different science areas are served by different training and career development mechanisms, and the distribution of career stages and degree category also varies by science area. All fields use institutional T32 grants. Fields that support a larger proportion of pre-doctoral researchers, such as developmental biology, tended to rely more heavily on T32s.

The majority of K12 programs are targeted to MDs. NICHD uses the K12 program only in pediatrics, reproductive health, and rehabilitation. In each of these areas, the K12 program represents at least one-third of total funding for that category. (See Exhibit 25.)

Note: categories are overlapping and should not be added.

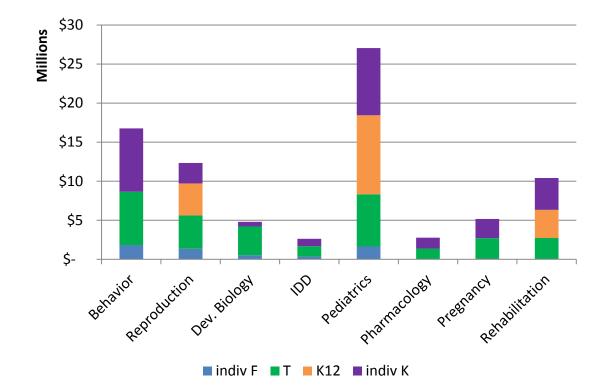


Exhibit 25: Training and Career Development Funding, FY 2014, by Category and Mechanism Group

Support for pre- and post-doctoral researchers varies by category. A full 84 percent of trainees in developmental biology are supported at the pre-doc level, while only 7 percent of trainees in rehabilitation research are supported at the pre-doc level. Similarly, support for MD and PhD researchers also varies by field. In behavioral research, 72 percent of trainees were PhDs, while 70 percent of rehabilitation trainees were MDs.

NICHD accepts K01 applications in three areas only – child maltreatment, population dynamics, and rehabilitation. Exhibit 26 shows NICHD K01 expenditures by subject area. Population dynamics receives 56 percent of the funding, rehabilitation research 37 percent, and child maltreatment 7 percent.

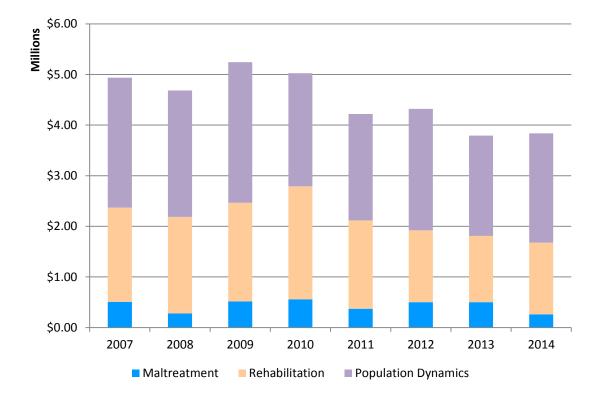


Exhibit 26: K01 Support by Research Area, 2007-2014

The K01 and the K99 are the two primary mechanisms of career development support for PhD scientists at the NICHD. However, not all PhD researchers at the appropriate career stage will be eligible for career development support from NICHD. Investigators are eligible for K99 support only if they are within 4 years of their PhD, and researchers outside of the three designed areas are not eligible for the K01. The Task Force agreed that this was an important gap in NICHD's training and career development programs (see Recommendations section).

The Task Force reviewed detailed data on training programs by PI and institution to assess the potential for unnecessary duplication or overlap within research fields. The Task Force did not find evidence of widespread duplication or overlap. Most of the institutions that had multiple institutional training grants had grants in clearly distinct fields, such as pediatrics and reproductive health. However, there were 10 institutions that held more than one T32 program in the same broad area, and there were 9 PIs that held more than one T32 or K12 individually. The Task Force recommended that additional scrutiny be applied to applications from institutions or PIs that currently hold a T32 or K12 in a similar area (see recommendations section).

The Task Force also reviewed data on the degree of concentration by institution in NICHD's training and career development programs. The data showed that the 20 percent of institutions with the most total trainees supported 60 percent of all trainees. The concentration was similar for individual and institutional grants, and when funding or the

number of trainees were considered. The Task Force did not view this level of concentration as inappropriate.

Success in Developing the Next Generation of Researchers

This section addresses Overarching Question #5 – How do we define success of NICHD training programs? Are NICHD training programs successful?

The Task Force discussed the objectives of NICHD's training and career development programs, and agreed that the most important goal of these programs is to develop the next generation of the biomedical research workforce. Success for a training and career development program, then, was defined primarily by the number of individuals who continued in a research career in the long run – whether that research career was in industry, government, or academia. As a secondary measure, the Task Force also reviewed data on subsequent NIH applications and funded grants. Finally, the career trajectories of applicants and non-applicants were also analyzed. This analysis included:

- all pre-doctoral trainees, regardless of training program or mechanism, that received training support at any time from 1989 to 1991;
- all post-doctoral trainees, regardless of training program or mechanism, that received training support at any time from 1994 to 1996;
- all individuals supported under K 12 institutional career development awards at any time from 1999 to 2001;
- all individuals that received individual career development awards (K awards) at any time from 1999 to 2001.

These time frames were chosen to ensure that trainees would be well beyond the training phase of their careers and established in career positions.

Data on subsequent positions were found for two-thirds of pre-doctoral trainees, 90 percent of post-doctoral trainees, and over 95 percent of career awardees. To develop an *upper bound* estimate of the number of trainees in non-research positions, individuals who were not traced were counted as working outside of a research career.

Exhibit 27 shows the percent of former trainees, by career stage, in non-research positions (both clinical and non-clinical). Between 75 and 80 percent of career awardees and post-doctoral F32 awardees continued in long-term research careers, as did two-thirds of T32 post-doctoral trainees and nearly half of pre-doctoral trainees.

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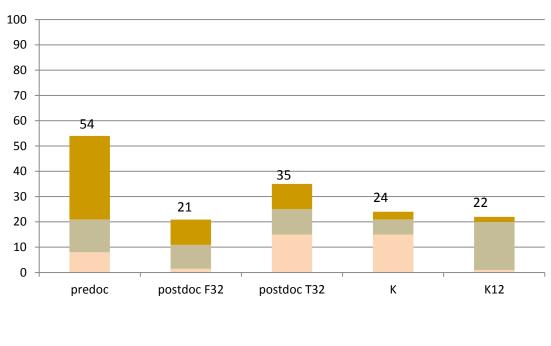


Exhibit 27: Former NICHD Research Trainees in Non-research Positions

Clinical Care Not clinical care Unknown

Exhibit 28 shows a summary of the subsequent NIH application rates of NICHD trainees, by career stage and grant type. As expected, the later the career stage, the more likely the trainees were to apply for an NIH grant.

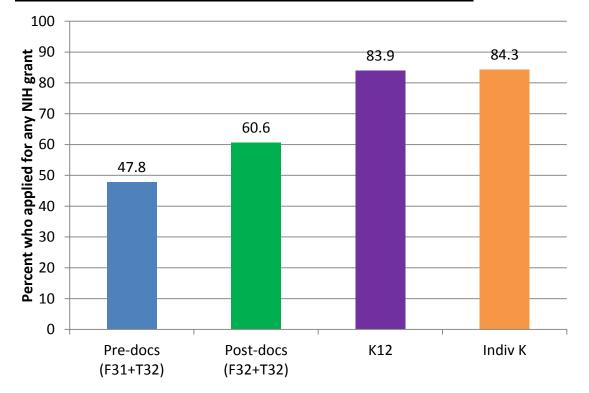


Exhibit 28: NICHD Former Trainees' Subsequent NIH Application Rates

A similar pattern is apparent when examining how former trainees received NIH grants. Exhibit 29 shows that the majority of former NICHD trainees at the career stage received at least one subsequent NIH research grant, as did a significant number of former trainees from earlier career stages.

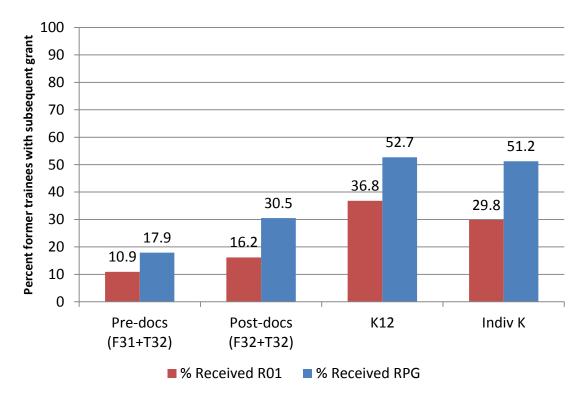


Exhibit 29: Percent of Former NICHD Trainees Receiving Subsequent NIH Research Grants

Note: RPG= Research Project Grant.

More detailed for each of these groups is provided below. Within groups, some variations in outcomes were apparent by degree and others by mechanism. For example, within the post-doctoral category, outcomes differed by mechanism (F32 compared with T32) and also varied among individuals with an MD degree only as compared with individuals who had a PhD or an MD and a PhD. The differences are described in detail below.

Pre-doctoral Trainees

The distribution of pre-doctoral trainees' subsequent positions is shown in Exhibit 30. About one-third of pre-doctoral trainees went into academic positions and for about one-third, their position could not be traced, leaving the remaining one-third in industry, clinical, government, and other positions.

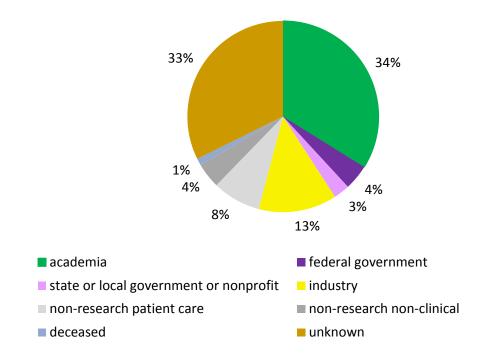
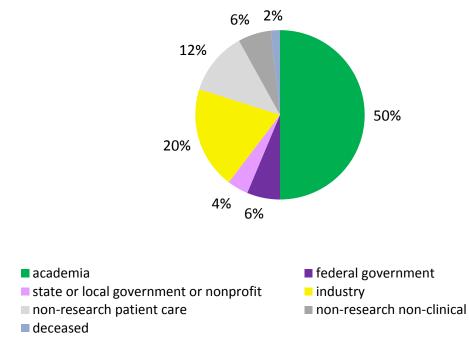
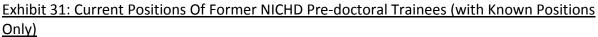


Exhibit 30: Current Positions of Former NICHD Pre-doctoral Trainees

When only the individuals with known positions are included, half (50 percent) of the former pre-doctoral trainees had current positions in academia and 20 percent were in industry (see Exhibit 31).





As noted above, half of former pre-doctoral trainees with known positions were faculty. Of these, nearly 80 percent were in academic or research faculty positions, and only 20 percent were in teaching or clinical faculty positions (see Exhibit 32).

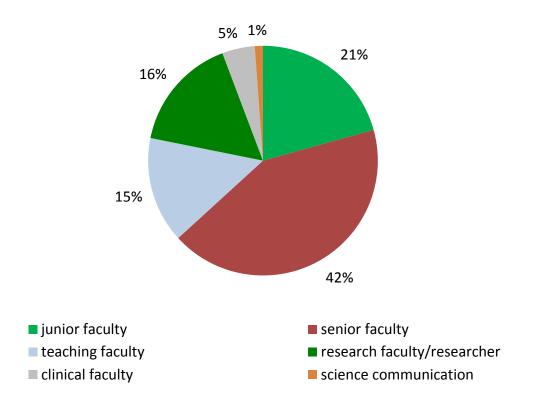


Exhibit 32: Former Pre-doctoral NICHD Trainees in Faculty Positions, by Type of Position

About one half of pre-doctoral trainees applied for at least one NIH grant after their training, and the majority of those that applied received at least one grant. Exhibit 33 shows the grant and career trajectories of pre-doctoral trainees. To summarize:

- A total of 441 pre-doctoral trainees received support from NICHD.
- Of those 441 trainees, slightly fewer than half (48 percent) subsequently applied for at least 1 NIH grant.
- Non-applicants were generally similar to applicants in their subsequent positions, except that non-applicants were more likely to have "unknown" positions.
- Of the 211 applicants, about 2/3 (63 percent) received at least 1 NIH grant.
- Of the individuals who received a grant, the majority (60 percent) received some type of research project grant (RPG). Slightly fewer than half (46 percent) of the individuals who received an RPG received a K or F grant prior to the RPG.

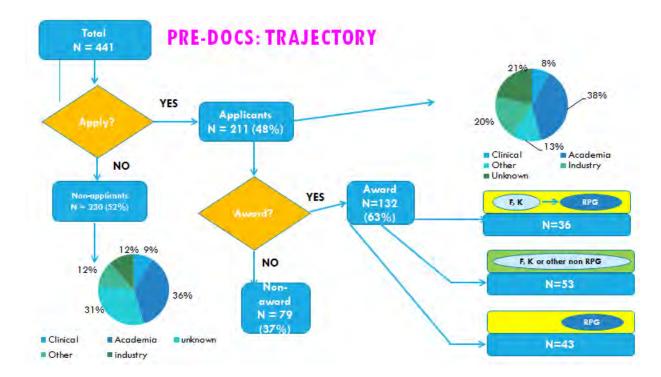


Exhibit 33: Career Trajectory of Former NICHD Pre-doctoral Trainees

Post-doctoral Trainees

For post-doctoral trainees, three groups were considered separately – F32 post-doctoral trainees (who were mostly PhDs), T32 post-doctoral trainees with MD degrees only, and T32 post-doctoral trainees with PhDs or MD+PhDs.

F32 Post-doctoral Trainees

The distribution of current positions for F32 post-doctoral trainees is shown in Exhibits 34 and 35. About two-thirds of F32 post-doctoral trainees went into academic positions. An additional 16 percent went into industry. For about 10 percent, their position could not be traced, leaving the remaining in clinical, government, and other positions. Of the two-thirds in academic positions, over three-quarters of former F32 post-doctoral trainees had achieved senior faculty positions.

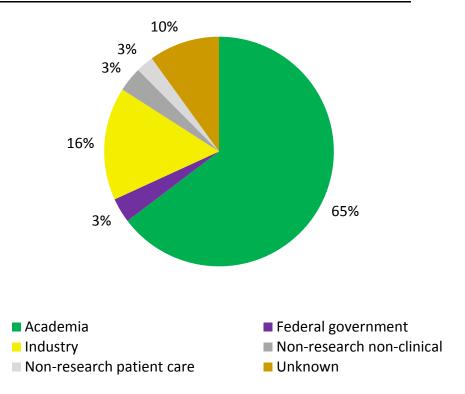
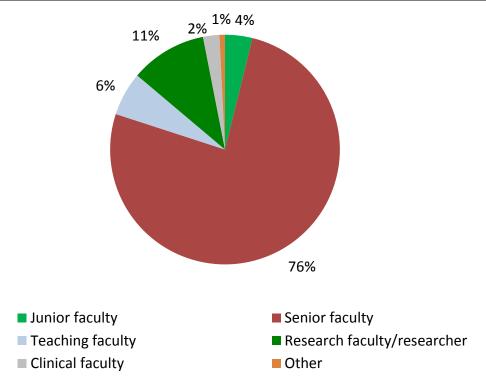


Exhibit 34: Current Positions of Former NICHD F32 Post-doctoral Trainees





About two thirds of F32 post-doctoral trainees applied for at least one NIH grant after their training, and two thirds of those that applied received at least one grant. Exhibit 36 shows the grant and career trajectories of F32 post-doctoral trainees. To summarize:

- A total of 201 F32 post-doctoral trainees received support from NICHD.
- Of those 201 trainees, 65 percent subsequently applied for at least 1 NIH grant.
- Non-applicants were more likely to have "unknown" positions and less likely to have academic positions compared with applicants, although this finding did not reach statistical significance.
- Of the 130 applicants, about 2/3 (65 percent) received at least 1 NIH grant.
- Of the individuals who received a grant, nearly all (98 percent) received some type of research project grant. 92 percent of individuals received an RPG without first receiving a K award.

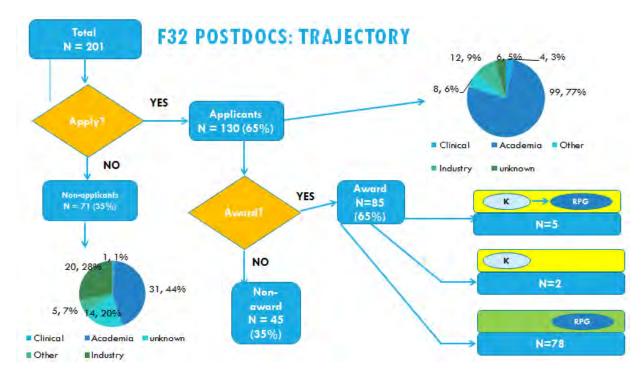


Exhibit 36: Career Trajectories of NICHD F32 Post-doctoral Trainees

T32 Post-doctoral Trainees

The distribution of current positions for T32 post-doctoral trainees is shown in Exhibits 37 and 38. Half of T32 post-doctoral trainees went into academic positions. An additional 10 percent went into industry, and 15 percent into clinical positions. For about 10 percent, their position could not be traced, leaving the remaining in industry, government, and other positions. Of the former T32 post-doctoral trainees in academic positions, about two thirds had achieved senior faculty positions.

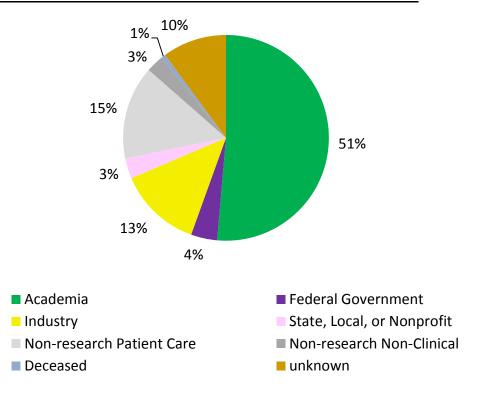
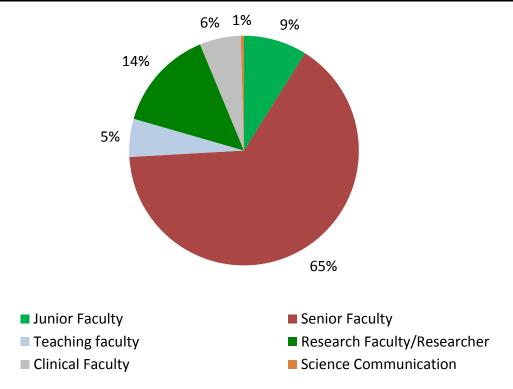


Exhibit 37: Current Positions of Former NICHD T32 Post-doctoral Trainees

Exhibit 38: Former T32 Post-doctoral NICHD Trainees in Faculty Positions, by Type of Position



The subsequent grant trajectories of T32 post-doctoral trainees varied sharply between MDs and PhD or MD+PhDs. The MDs were significantly less likely to apply for and receive NIH grants. Exhibit 39 shows the grant and career trajectories of T32 post-doctoral trainees with MD only degrees. To summarize:

- A total of 98 post-doctoral trainees with an MD only received T 32 support from NICHD.
- Of those 98 trainees, 35 percent subsequently applied for at least 1 NIH grant.
- Non-applicants were more likely to have clinical or "unknown" positions and less likely to have academic positions compared with applicants.
- Of the 34 applicants, 71 percent received at least 1 NIH grant. This figure was comparable to the success rate for PhDs it was simply that MDs were far less likely to apply.
- Of the individuals who received a grant, the majority received at least one RPG. However, most of these individuals received an F or K grant prior to the RPG.

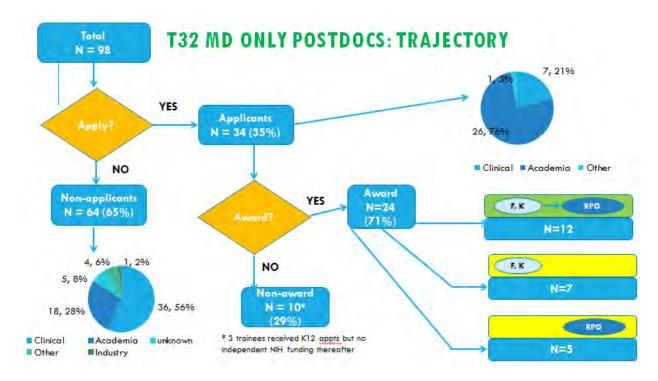


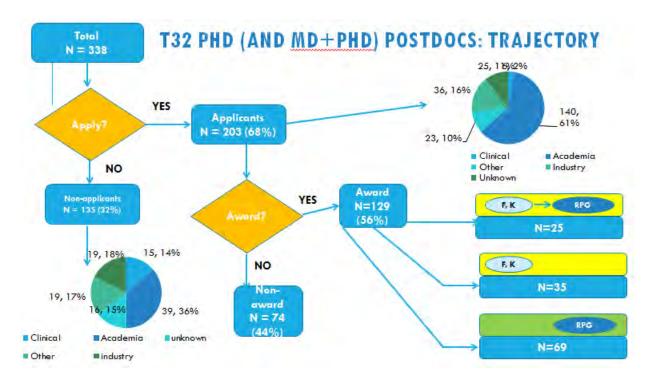
Exhibit 39: Career Trajectories of NICHD T32 MD only Post-doctoral Trainees

The trajectories were very different for T32 post-doctoral trainees with a PhD or MD+PhD degree. In terms of subsequent success, PhD or MD+PhD post-doctoral trainees resembled the F32 cohort far more than the MD T32 cohort. Exhibit 40 shows the grant and career trajectories of T32 post-doctoral trainees with PhD or MD+PhD degrees. To summarize:

- A total of 338 post-doctoral trainees with PhD or MD+PhD received T32 support from NICHD.
- Of those 338 trainees, 68 percent subsequently applied for at least 1 NIH grant.

- Non-applicants were more likely to have industry positions and less likely to have academic positions compared with applicants, although this finding did not reach statistical significance.
- Of the 203 applicants, 56 percent received at least 1 NIH grant. This was lower than the figure for MDs, but far more PhDs applied.
- Of the individuals who received a grant, the majority received at least one RPG, and most individuals received an RPG without a previous F or K grant.

Exhibit 40: Career Trajectories of NICHD T32 PhD or MD+PhD Post-doctoral Trainees



Individual K Awardees and K12 Scholars

The distribution of current positions for individual K awardees is shown in Exhibits 41 and 42. Over three quarters of individual K awardees went into academic positions. An additional 15 percent went into clinical work. The remaining were found in industry, government, and other positions. Of the former K awardees in academic positions, 83 percent had achieved senior faculty positions.

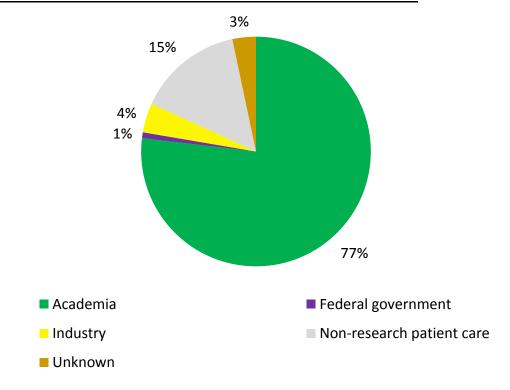


Exhibit 41: Current Positions of Former NICHD Individual K Awardees

Exhibit 42: Former NICHD Individual K Awardees in Faculty Positions, by Type of Position

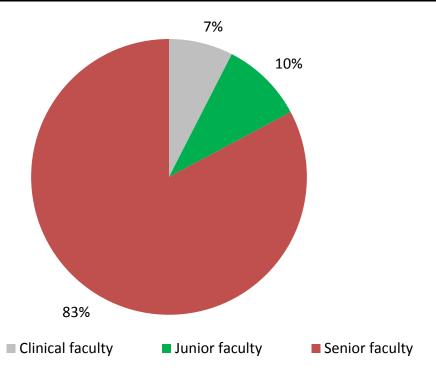


Exhibit 43 shows the grant and career trajectories of K awardees. To summarize:

- A total of 121 individuals received individual K support from NICHD.
- Of those 121 trainees, 84 percent subsequently applied for at least 1 NIH grant.
- Non-applicants were more likely to have clinical positions and less likely to have academic positions compared with applicants, although this finding did not reach statistical significance.
- Of the 102 applicants, 62 percent received at least 1 NIH grant.
- Of the individuals who received a grant, all received at least one RPG, and over half (58 percent) received an R01.

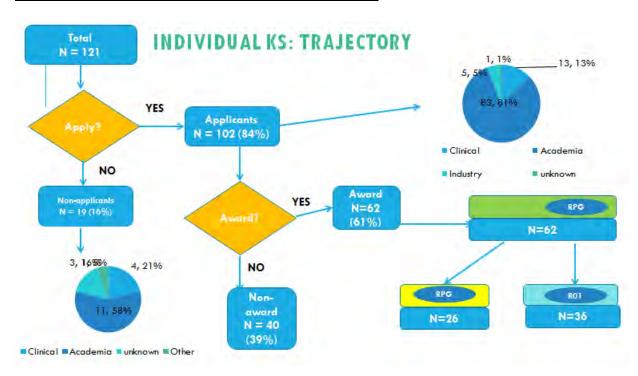


Exhibit 43: Trajectories of NICHD Individual K Awardees

The distribution of current positions for K12 scholars is shown in Exhibits 44 and 45. The distribution is very similar to that for individual K awardees, with over three quarters of K12 scholars going into academic positions. K12 scholars were slightly less likely than individual K awardees to go into clinical care; this was true within the group of K and K12 trainees with MDs only. Within academia, however, K12 scholars were more likely to have clinical appointments. The results ultimately indicated that similar percentages of K and K12 individuals were leaving the research track for clinical-type positions; however, for K12 scholars these were more likely to be clinical practice.

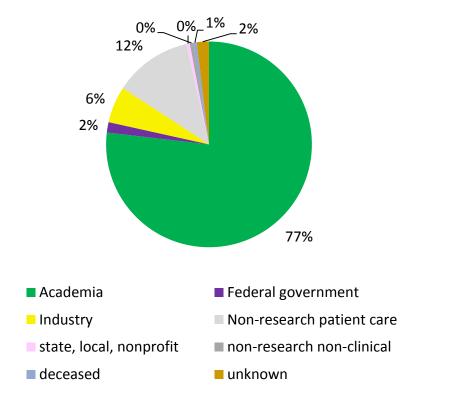


Exhibit 44: Current Positions of Former NICHD K12 Scholars

Exhibit 45: Former NICHD Individual K12 Scholars in Faculty Positions, by Type of Position

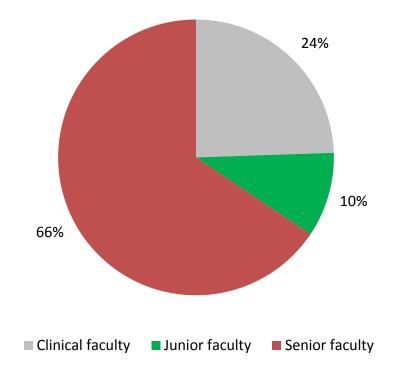


Exhibit 46 shows the grant and career trajectories of K12 scholars. To summarize:

- A total of 372 individuals received K12 support from NICHD.
- Of those 372 trainees, 84 percent subsequently applied for at least 1 NIH grant.
- Non-applicants were more likely to have clinical positions and less likely to have academic positions compared with applicants.
- Of the 312 applicants, 76 percent received at least 1 NIH grant (including individual Ks).
- Of the individuals who received a grant, 83 percent received at least one RPG, and 58 percent received an R01. However, 17 percent received an individual K award only.
- For this cohort of K12 scholars, those who did and who did not receive a subsequent K award were equally successful in obtaining subsequent research project grants.

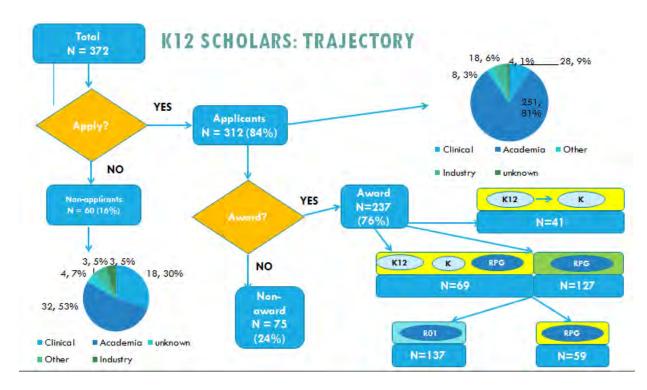


Exhibit 46: Career Trajectories of NICHD K12 Scholars

The long-term outcome data analysis indicates that participation in training and career development programs helps develop scholars into independent researchers. Overall, individuals who participate in NICHD training and career development programs tend to continue in research careers, including applying for and obtaining NIH funding. The long-term outcomes for the cohorts of trainees examined varied somewhat across training field, degree, and mechanism. For example, as a group, MDs who were supported under the T32 program had considerably fewer subsequent NIH applications compared with other trainees.

Key limitations in these types of long-term outcome analysis, however, pointed out the need for more real-time monitoring and assessment of intermediate outcomes. Specifically, in order to observe long-term research career outcomes, a cohort was chosen that is one or more decades away from their initial training experiences. The training programs that generated these outcomes have changed and evolved on their way to becoming the training programs of today. Moreover, many individuals participate in multiple training and career development programs at different career stages, making attribution of success by program or mechanism more difficult. Several Task Force members expressed support for NICHD stepping up its realtime monitoring and analysis of both the intermediate, as well as long-term outcomes, of training programs. In addition, these efforts could include more extensive analysis by institution, to better identify factors associated with individual success.

Fiscal Pressures on Training Programs

This section addresses Overarching Question # 7 – Are there fiscal pressures or other factors in the near future that have potential to impact our mix of training programs?

Changes in the Mix of Individual Fellowships

Pursuant to the Biomedical Workforce recommendations, all NIH institutes were required to begin supporting the F30 and Parent F31 fellowship mechanisms starting in fiscal year 2014. Until that year, NICHD participated only in the Diversity F31 and Parent F32 programs. The avalanche of new fellowship applications over the past two years has threatened NICHD's ability to continue supporting its ongoing programs. The institute needs to settle on an approach that will preserve the most effective mix of fellowships. Given NICHD's commitment to diversity, and the particularly impressive career outcomes of former F32 fellows, adjustments need to be made to preserve those programs. NICHD has already begun considering different pay lines for the four fellowship mechanisms. Even so, there has been a major shift in the types of individuals and career stages the Institute is supporting. In FY2015, the F30 and Parent F31 awards accounted for more than 50 percent of the new fellowship awards (Exhibit 47). At the same time, the success rates for all of the fellowships have dropped to alarming levels (Exhibits 48, 49, and 50). The success rates for Parent F31 and Parent F32 applications were 10 percent in FY2015. The Task Force felt strongly that this trend is sending a highly discouraging message to the extramural community. NICHD must take immediate steps to restore and even increase the numbers of individual fellowships. One suggestion was to target certain priority areas. The ICs are not allowed to limit applications to certain areas (eligibility), but they can publish a programmatic preference for priority areas or certain types of individuals. For example, the institute could communicate a strong interest in supporting individual F32 post-doctoral fellowships and establish pay lines accordingly.

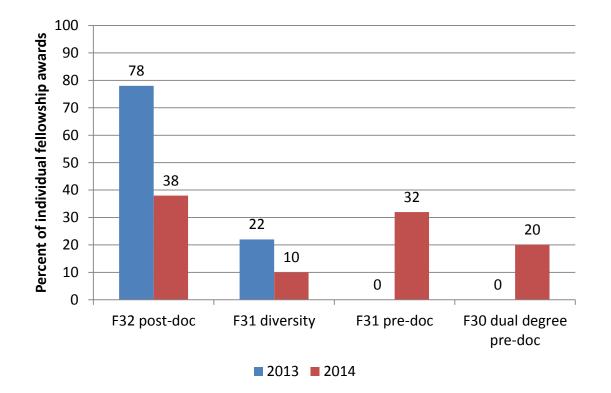
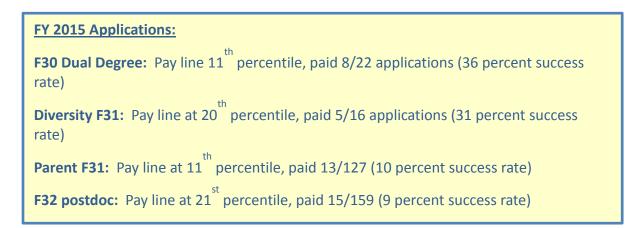


Exhibit 47: Individual Fellowship Awards by Mechanism and Level, in FY2013 and FY2014

Exhibit 48: New Fellowship Awards and Success Rates in FY 2015 (as of July 2015)



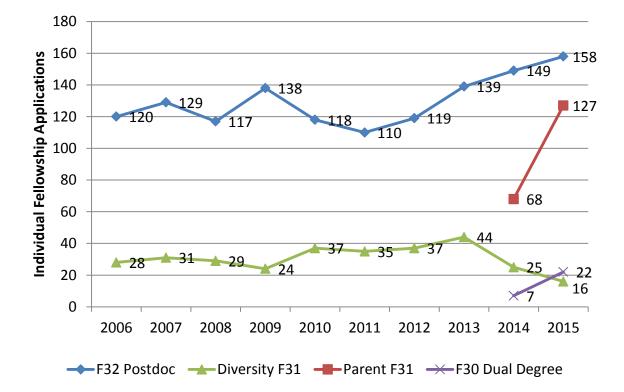
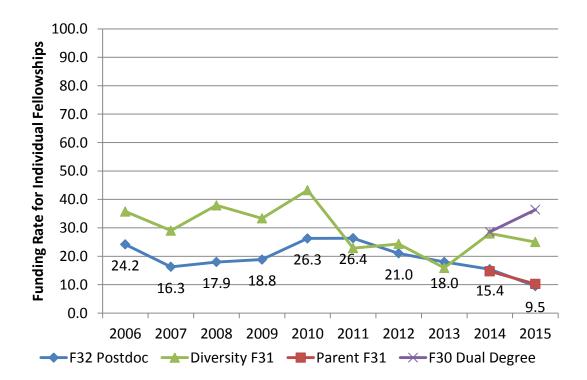


Exhibit 49: Applications for Individual Fellowships, 2006-2015





Increasing Numbers of K99-R00 Applications

The NIH Biomedical Research Workforce assessment stated that the K99-R00 program has worked well in accomplishing its primary objective, to accelerate the transition of the most promising post-doctoral fellows into independent faculty positions. One of the BMW recommendations was to reduce the maximum limit of post-doctoral experience from 5 years to 4 years. In addition, NIH established a success rate target of 30 percent. At the time, NICHD's success rate was close to that level. However, the number of K99-R00 applications has been steadily increasing over the past few years (Exhibit 51). The success rate for those applications has now dropped from above 35 percent to less than 15 percent. Since the K99 and K01 programs are the only career-level mechanisms available to young investigators with PhD degrees, NICHD would need to make adjustments in other commitments to raise the success rates to more encouraging levels.

| FY | Applications | Awards | Funding Rate |
|------|--------------|--------|--------------|
| 2010 | 45 | 17 | 38 percent |
| 2011 | 64 | 16 | 25 percent |
| 2012 | 64 | 15 | 23 percent |
| 2013 | 83 | 13 | 16 percent |
| 2014 | 108 | 12 | 11 percent |
| 2015 | 81 | 12 | 15 percent |

Exhibit 51: K99 Applications, Awards and Success Rates, FY 2010-2015

Rising Costs for K08 and K23 Career Awards

In 2012, NIH launched a comprehensive assessment of the Physician-Scientist Workforce (PSW) as a follow-up to the Biomedical Workforce review. The objective of the PSW assessment was to examine the pipeline of physician-scientists and make recommendations to strengthen the workforce. The issues and proposals were discussed by the Advisory Committee to the Director and approved by Dr. Collins. Implementation is being coordinated by the NIH Office of Extramural Research.

One recommendation highlighted in the report was to support more physicians through individual fellowships rather than institutional training grants. Other recommendations included modifying K08 and K23 policies to increase the attractiveness of those awards, and modifying the K99-R00 funding opportunity announcement to encourage more physician-scientist applicants. However, no additional funds will be provided to the institutes to support the cost of implementing these recommendations. The following PSW recommendations will have a major impact on NICHD career development programs:

- Raise the minimum NIH salary contribution to \$100,000. NICHD and several other ICs currently have a cap of \$75,000. Based on 129 K08/K23 scholars supported in FY2014, this change will cost NICHD approximately \$3.23M per year, resulting in a 20 percent reduction of K08/K23 awards and a decrease in application success rates from 30 percent to 23 percent.
- *Enforce protected time for K scholars.* Although all mentored K awards require a minimum of 75 percent effort, current and former scholars report that institutional demands are cutting into the intended protected time.
- Allow salary increases to occur during project period. The supporting NIH institutes will be required to make these adjustments and provide the funds. The percent increase has not yet been determined by OER.
- Increase the research expense cap to \$50,000. NICHD and several other ICs currently have a maximum allowance of \$25,000. This change will cost approximately \$3.23M per year, resulting in another 20 percent decrease in K08/K23 awards and a further change in success rate from 23 percent to 17 percent.
- Increase the number of K08/K23 awardees transitioning within 5 years to R01s above current levels.

NICHD must adapt to all of those changes with limited funding for the career development programs. Moreover, there will likely be pressure on NICHD to extend the K08/K23 salary and expense limits to scholars supported on K12 programs. Principal investigators of the K12 programs have long been requesting higher allowances. The inevitable consequences of the PSW recommendations will be a major reduction in the number of individual career awards and application funding rates falling into the mid- to low teens. Those consequences will send the opposite message from the stated objectives of the ACD and PSW committee.

Peer Review of Training Mechanisms

This review of NICHD's training programs did not focus on review issues because a separate review of the Scientific Review Branch (SRB) was conducted 2 years ago. However, a number of review issues and suggestions were raised in the course of the Task Force's deliberations. These are summarized in the sections below. More detailed background and analysis is included for the T32 review process to provide context for some of the Task Force Recommendations.

Individual NRSA Fellowships

Applications are peer reviewed in the fellowship study sections at the Center for Scientific Review (<u>http://public.csr.nih.gov/StudySections/Fellowship/Pages/default.aspx</u>). Second-level review of applications is carried out each Council round by NICHD's Training Policy Committee (TPC). The TPC reviews applications and forwards funding recommendations to the Director. In contrast to the Institutional Training Grants described below, NICHD selects which individual fellowships to award, how many, and in which fields.

Institutional Training Grants

Peer review of T32 applications is conducted in NICHD's Scientific Review Branch (SRB) by a single multidisciplinary Special Emphasis Panel. SRB selects reviewers who have experience with institutional training programs (as PI or mentor) as well as subject matter expertise in the scientific areas represented by the applications. NICHD accepts T32 applications only for the May 25 receipt date each year. The current format for reviewing T32 programs was implemented in 2012 following an assessment of T32 reviews up to that point.

Until 2012, NICHD reviewed the vast majority of T32 applications in the standing subcommittees of the Division of Scientific Review (currently named the Scientific Review Branch). In addition to these review assignments, some applications were reviewed in Special Emphasis Panels (SEPs). In 2011, for example, there were 17 SEPs that reviewed from one to three applications. NICHD conducted an analysis of review workload and scoring trends for all of these committees from 2007 onward. The number of applications differed substantially by committee, as did the scoring standards and ultimate success rate of the applications. For any given year, some disciplines and branches were far more successful than others. Although these discrepancies tended to balance out over time, it was clear that the review format itself had a major influence on the portfolio distribution.

Starting with the 2012 round of applications, NICHD began reviewing all T32 applications in a single dedicated review panel. The purpose was to better standardize scoring across disciplines and to provide greater confidence in the funding decisions for any given year. At the time, a number of other NIH institutes (NIDCR, NIDCD, NINDS, NEI, NIA, NCI) were also using single review committees to evaluate their T32 applications. This format offered a number of potential advantages:

- all T32 applications are reviewed together and are compared side-by-side;
- panels include experts on institutional training programs as well as experts in the subject areas covered by the applications;
- review and program staff can provide common instructions and standards for scoring;
- scoring standards of reviewers from different fields can be compared and harmonized;
- combined review improves consistency in how the administrative structure, programmatic elements, and mentoring plans are evaluated;
- reviewer expectations for trainee outcomes can be calibrated across disciplines; and
- all applications for a given fiscal year can be considered together for funding.

The Office of Extramural Policy (OEP) conducted an additional analysis of T32 scoring for fiscal years 2010-2014, a period following the change to the current 1-5 peer review rating scale in 2009. Two key factors affect the comparability of the data over this time period. First, the Institute transitioned to the single committee review format in 2012. Second, the NICHD extramural program prior to 2013 consisted of 4 major Centers and 12 branches within those 4 Centers. In 2013, three of the Centers were dissolved and replaced with 12 extramural

branches. The National Center for Medical Rehabilitation Research (NCMRR) continued under a separate Congressional mandate. Although many of the current branches are similar in mission to the previous branches, a direct comparison of data at the branch level is only possible for FY2013 and FY2014.

| | FY 2014 | FY 2013 | FY 2012 | FY 2011 | FY 2010 |
|---------------|-----------|-----------|-----------|-----------|-----------|
| Total | N=63 | N=62 | N=75 | N=87 | N=80 |
| Applications | | | | | |
| PAYLINE BAND | PS 10-25 | PS 10-19 | PS 10-22 | PS 10-18 | PS 10-20 |
| Funded | 18 (29 %) | 15 (24 %) | 27 (36 %) | 27 (31 %) | 25 (31 %) |
| Applications | | | | | |
| Type 1 | 1 (5 %) | 6 (40 %) | 5 (19 %) | 9 (33 %) | 11 (44 %) |
| New | 1 | 3 | 4 | 6 | 2 |
| Amended | 0 | 3 | 1 | 3 | 9 |
| Туре 2 | 17 (95 %) | 9 (60 %) | 22 (81 %) | 18 (67 %) | 14 (56 %) |
| New | 10 | 7 | 14 | 11 | 9 |
| Amended | 7 | 2 | 8 | 7 | 5 |
| Not Discussed | 33 (52 %) | 26 (42 %) | 15 (20 %) | 8 (9 %) | 9 (11 %) |

Exhibit 52: T32 Scoring Patterns for FY 2010-2014

Exhibit 52 shows the number of T32 applications falling within the pay line for fiscal years 2010-2014. The pay line over the 5-year period has remained fairly steady around a Priority Score of 20. The number of funded T32s, however, has dropped from the 25-27 range in 2010-2102 to the 15-18 range in 2013-2014. This parallels a drop in the number of T32 applications submitted to the NICHD from a high of 87 in 2011 to the low 60s in 2013-2014. One of the most important factors in determining priority score and funding success is whether an application is a new or renewal application. This strongly influences the year-to-year variability in funded applications across branches and disciplines. Over the past five years, the funding success rate for new T32 programs has generally been decreasing, while the funding success rate for renewal T32 programs has generally been increasing. In FY2014, for example, only one out of 18 funded applications was new, while 17 (95 percent) were renewals. The aggregate funding rate for new T32 applications over the 2010-2014 time frame was 17.2 percent (Exhibit 18). The aggregate funding rate for renewal applications was 45 percent. These data indicate that reviewers are more likely to give better scores to ongoing T32 programs that have a documented record of success, rather than take a chance on a new T32 program that may or may not succeed. Once a new program does get funded, however, the likelihood of being renewed in subsequent cycles is high.

The number of applications that were "Not Discussed (ND)" increased substantially following the change from multiple standing study sections to single SEP review. The ND rates are currently on par with the peer review standard of not discussing approximately half of

applications. The intent of this process is to allow more time for discussion of the best applications. When T32 applications were reviewed within standing study sections, the number of T32 applications was typically small and reviewers were reluctant to "Not Discuss" them. Some of this reluctance may have been associated with reviewers not wanting to disadvantage their respective fields of science by damaging the prospects of an uninterrupted pipeline of new trainees. The higher current ND rate may contribute to the inability of new (Type 1) applications to compete for funding since novel programs without an established track record are more likely to be in the lower half of the preliminary score distribution.

Individual Career Development Awards

Individual career development award applications are reviewed in the standing subcommittees of the Scientific Review Branch. The numbers of applications reviewed in any given cycle are generally small and include the different award mechanisms (K01, K08, K23, K24, K25, K99). Until 2015, a single pay line was used for all individual K mechanisms. Although this system for making funding decisions is straightforward, variations in quality or numbers of applications across study sections or different reviewer scoring standards can potentially influence the relative distribution of K mechanisms or the subject areas of the awards. In 2015, a higher pay line was set for K99 applications because the increasing numbers of applications had resulted in a success rate of just 13 percent. Success rates for K08 and K23 applications were near 30 percent.

Institutional Career Development Awards

Institutional K12 applications are all submitted in response to RFAs. Most funding opportunity announcements are re-issued at 3-5 year intervals. For some programs, competitions are held on successive or alternate years. Peer review is carried out by Special Emphasis Panels recruited by NICHD's Scientific Review Branch. The numbers of applications submitted in response to the K12 RFAs can vary considerably. Those selected for funding are chosen based on the program set-asides and the distribution of priority scores from the reviews. As with the T32 applications, the funding rate for renewal applications is far higher than for new applications. The aggregate funding rate for new (Type 1) K12 applications in fiscal years 2010-2014 was 21 percent. The funding rate for renewal (Type 2) applications was 65 percent. These data not only highlight an important discrepancy in scoring standards, but also a lower than ideal level of competition for these programs as a whole. Task Force members discussed possible alternative approaches for reviewing these programs, including consolidated review groups covering broader disciplinary areas or even a single "parent" FOA with single committee review.

Task Force Recommendations

The following Recommendations were developed by the Task Force based on the data analysis, discussions of those data, and identification of problem areas, imbalances, needs and

opportunities. A brief overview of these recommendations is included in the Executive Summary. For simplicity of presentation, the recommendations are organized by funding mechanism and other main topics considered by the committee.

Individual NRSA Fellowships (F30, F31 Diversity, F31 Parent, F32)

NICHD supports a relatively small number of individual fellowships compared to the number of slots on institutional training grants. In FY2014, for example, there were 607 pre- and postdoctoral slots on T32 programs versus 83 individual fellowship awards. Individual fellowships offer a number of distinct advantages, and outcomes of former awardees are better than students or post-doctoral trainees supported solely on institutional training grants. The recent addition of F30 and Parent F31 mechanisms has caused a dramatic reduction in the proportion of post-doctoral support within the NRSA fellowship group. Likewise, there has been an alarming drop in success rates for fellowships as a whole due to increased numbers of applications. The success rates for Parent F31 and F32 applications were just 10 percent in FY2015. This sends a discouraging message to the community, especially when the individual fellowships are highly successful training mechanisms. Institutions are encouraging their students to write applications, often as part of a grant-writing course. If applicants receive a reasonable score but still do not meet the criteria for funding, it can be devastating news right at the time we hope to attract talented individuals into scientific careers. The overall sentiment of the Task Force was to increase the numbers of individual fellowship awards. In particular, there was agreement that fellowships were the best way of supporting post-doctoral scholars.

- Increase support for individual NRSA fellowships Individual fellowship awards are extremely valuable for attracting students and post-doctoral fellows into research areas supported by NICHD, and for providing intensive mentored training opportunities. These programs are very successful. Collectively, former fellows have a strong track of staying in academia and other research-related careers, publishing papers, and applying for and obtaining subsequent research grants. Given NICHD's particularly high commitment to institutional awards, along with the plummeting success rates for individual fellowship applications, the Task Force recommended shifting a portion of funding from institutional to individual NRSA fellowships to raise success rates and encourage applications.
- Limit numbers of Parent F30 and F31 pre-doctoral awards to preserve Diversity F31 and F32 awards Addition of the F30 and Parent F31 mechanisms has threatened NICHD's historical commitment to pre-doctoral Diversity F31 fellowships and post-doctoral F32 fellowships. The Task Force was strongly in favor of individual fellowship awards, particularly for post-doctoral scholars. NICHD should take steps to continue support for diversity and post-doctoral fellows within the current funding climate. NICHD should also be especially scrupulous about not supporting applications that are outside the Institute's mission.

 Establish differential pay lines for each of the fellowship mechanisms in order to address the impact of new mechanisms on numbers of applications, success rates, and award distribution – Historically, NICHD has set a single pay line for all individual fellowships. Single pay lines allow the numbers of applications and scoring behavior of study sections to drive the institute's commitment to particular sets of individuals and career stages. Separate consideration of pay lines by the Training Policy Committee and NICHD leadership will allow more strategic balancing of these programs.

Institutional T32 Training Grants

NICHD relies heavily on a spectrum of institutional training grants to support pre-doctoral and post-doctoral trainees. The institute supports PhD students and post-doctoral trainees in basic science disciplines, but it also supports a large number of clinical fellows in basic research and patient-oriented research. NICHD provides substantial support for the fields of pediatrics, obstetrics/gynecology, reproductive sciences, population sciences, developmental biology, and rehabilitation medicine. The Institute has targeted some under-represented subject areas with thematically-focused RFAs or PARs. The T32 programs offer a variety of features and advantages, such as access to a collection of outstanding mentors, exposure to scientific courses and workshops, training in research-related skills (ethics, teaching, grantsmanship, communication), and a sense of participating in a thematic focus with like-minded colleagues and faculty. T32 programs can offer training opportunities that are not always available to individual fellows or students/post-doctoral trainees supported on research project grants. The concept of a cohesive "program" was considered by the Task Force as being essential to the success of these awards, particularly for pre-doctoral trainees.

- Improve success rates for NEW applications or applications submitted in response to thematically-driven RFAs or PARs The success rates for new T32 applications are far below the rates for renewal applications. The aggregate funding rate for new T32 applications over the 2010-2014 time frame was 17.2 percent (Exhibit 18). The aggregate funding rate for renewal applications was 45 percent. Peer reviewers place heavy emphasis on past performance and outcomes of former trainees. They tend to be skeptical about programs in new, innovative or unfamiliar areas. This discourages the development of new programs overall, as well as programs in cutting-edge or under-represented research areas. As a result, NICHD continues supporting established programs and misses out on new opportunities such as newly formed departments, departments with younger faculty, and emerging areas of research. NICHD should support high quality programs while allowing sufficient flexibility for change. Some of the steps suggested by the Task force included:
 - Cluster applications during review (new vs renewal)
 - When deciding which applications to discuss or not discuss, set different cutoff lines for new versus renewal applications.
 - Use separate pay lines for new vs renewal applications

- Establish a select pay band to enable selection of new programs based on programmatic need or new opportunities
- Convey NICHD's interest in supporting novel or higher-risk programs when developing review criteria for RFAs or PARs. Staff should tailor FOA scope and review criteria to target new priority areas based on documented need.
- Limit institutional T32 awards to a certain number per PI or institution Although T32 application success rates have been near 30 percent for at least the past 5 years, there is strong demand and competition for these programs. Some PIs and departments have developed parallel programs to enable support for more of their students or fellows. NICHD has traditionally taken steps to limit slot growth so limited funds can be distributed more broadly. NICHD should consider additional ways of limiting concentration of training programs at the top-ranked institutions, many of which would be successful in attracting and funding trainees with other resources. This will not only require examination of NICHD's portfolio, but also T32 awards in related subjects sponsored by other ICs.
- Establish expectations for turnover or phase-out of long-running programs Data
 presented to the Task Force showed that a significant proportion of T32 programs have
 been in existence for more than two funding cycles. Although T32 program mentors must
 stay abreast of their fields and maintain strong funding, the Task Force felt that some
 programs were using T32 funding to support students and post-doctoral trainees within
 their departments without adding value or evolving substantially over time. NICHD should
 consider protocols for turning over programs after a certain duration. This will also help to
 address the poor success rates for new applicants.
- Evaluate factors leading to "drop-out" from the research pipeline and the most effective use of combined support mechanisms The Task Force recommended a more detailed assessment of which T32 programs are achieving successful outcomes. Some programs are clearly doing well. However, outcomes for T32 trainees with MD degrees are notably worse than other cohorts. In the data presented to the Task Force, only 35 percent of MD-only trainees ever applied for another NIH award. Many of these individuals assume clinical or academic faculty positions where research participation either isn't expected or isn't encouraged. NICHD needs to optimize its investment in training of physician-investigators so these individuals remain engaged in research.
- Establish a minimum number of slots for T32 programs to assure a "critical mass", particularly for post-doc only programs; 3 fellows was considered a minimum The success of T32 programs requires a "program identity" and sufficient critical mass to provide strong interactions among faculty and trainees. Task Force members viewed fewer than 3 trainees as inadequate for an effective program. Some applicants propose supporting only one or two post-doctoral fellows along with a group of pre-doctoral trainees. If not well-integrated into the program, those post-doctoral fellows will not enjoy the benefits of what a T32 award should offer. In many cases, this problem is raised and noted during the review process. However, NICHD could communicate an expectation for a minimum number of trainees as part of the Table of IC-specific Information, Requirements, and Staff Contacts.
- Implement more stringent standards for institutional programs and mentors to fit NICHD mission guidelines Mentors and training opportunities may not reflect the mission or

current needs of NICHD. The Institute should be more selective in accepting application assignments or awarding grants that are not sufficiently within the overall mission.

Individual Career Awards

The Task Force was highly supportive of individual career development awards because they provide crucial funding for young scientists who are just starting their research careers and attempting to establish independence. In the data presented to the Task Force, the grant application rate for former K awardees was 84 percent, and 63 percent of all K awardees were successful in obtaining at least one research project grant. Compared to other NIH institutes, NICHD's career award portfolio is heavily tilted towards institutional career awards rather than individual awards. The Task Force strongly recommended re-balancing the portfolio to increase the number of individual K awards. This is consistent with the recently published NIH Physician-Scientist Workforce (PSW) recommendations. In particular, there is a need to increase the commitment to K99-R00 awards. Adding one or more target areas to the K01 was suggested to provide a means of supporting awards in areas of programmatic need. The PSW recommendations also called for increased salary and research expense allowances for K08 and K23 awards. Those mandates will dramatically reduce the numbers of awards and the application success rates. Funds will be needed to preserve those programs as well as the other individual K awards.

- Shift some support from institutional K12 programs to individual K awards Former recipients of individual K awards have strong track records of entering research-related positions and obtaining subsequent NIH research grants. Furthermore, a substantial number of former T32 trainees and K12 scholars used independent K awards to become competitive for research grants. The Task Force strongly recommended increasing support for individual K awards.
- Increase success rates for K99-R00 applications Due to steadily rising numbers of K99 applications, the NICHD success rate is now down to 15 percent. NIH has a target success rate of 30 percent. The K99 and K01 are the only NICHD career award programs that are available to most individual scholars with non-clinical PhD degrees, and the K01 is limited to 3 specific fields. The K99 is the only mechanism for which non-US Citizens are eligible. Inadequate commitment to the K99 program creates a serious gap in the career pipeline for these groups of individuals. The rates for K99s can be controlled more effectively by establishing a separate pay line, as was done for FY2015.
- Modify K08 and K23 salary and research expense allowances To make career awards more attractive, the PSW committee recommended increasing the IC salary contributions to \$100,000 per year and the research expense contribution to \$50,000 per year. Those changes will indeed make the awards more attractive, but the financial commitments will result in major decreases in numbers of awards and success rates. The Task Force recognized that NICHD would need to follow NIH's requirements, but suggested finding

ways to at least partially preserve the numbers of individual K08 and K23 awards. Two ways of accomplishing that goal would be to 1) place an upper limit of total post-doctoral experience; 2) shift funds from institutional career award programs (K12) to individual K awards.

- Focus K08 and K23 awards on investigators at more junior levels Many applicants for the K08 and K23 programs are beyond the stage where mentored awards can be justified. Such individuals are often advised by their departments and colleagues to seek mentored support even though their experience and track records are better suited to research project grants. This tendency keeps physician-scientists in training status far longer than necessary. The Task Force members were in agreement that NICHD should take steps to shorten the period of career-level training and focus its support on more junior investigators rather than those who are beyond the early assistant professor stage. NICHD should therefore continue its current 6-year limit on aggregate career-level funding (institutional plus individual). The institute should also establish an upper limit on the number of total years of post-doctoral research experience.
- Modify the categories of research eligible for K01 funding K01 awards are now restricted to 3 program areas: child abuse and neglect, population sciences, and rehabilitation medicine. The branches that utilize the K01 certainly find those awards valuable, and their constituents may not be eligible for other career programs by virtue of not having a clinical degree. The Task Force recommended more detailed assessment of whether those areas continue to need stimulation. In addition, NICHD should consider adding one or two other high-priority research areas in need of stimulation, with phase-out or rotation provisions. Targeted individuals would not include clinical scholars who are eligible for K08 or K23 awards.

Institutional Career Development Awards

NICHD supports a far larger number of institutional career awards than any of the other NIH institutes. These programs are largely designed for late-stage clinical fellows or early faculty. One of the most important advantages of the institutional K12 programs is the ability to attract and provide research training for clinicians with little or no research experience, namely, individuals who would not yet be competitive for individual K or research project grants. Some of the shorter K12 programs encourage or expect scholars to apply for individual K awards in order to complete their research training. Longer duration K12 programs are intended to bring scholars to point where they can apply for independent research grants by the time the K12 appointments are finished.

Although the outcomes of scholars supported by K12 programs are generally very good, the Task Force had concerns about supporting long-established programs in a period of tight fiscal constraints. There were also concerns about duplication of support across institutions, multiple awards to single institutions or single PIs, inadequate competition among applications for RFAs, and potential conflict of interest of peer reviewers who are funded via the same programs but

in different cohorts. The primary conclusion reached by the Task Force was that NICHD should strategically and gradually moderate its commitment to institutional K12 programs.

- Shift a portion of K funds from institutional K12 to individual Ks Review existing K12 programs and reduce NICHD commitments for national awards with large numbers of slots or reduce the number of awards for programs based on the single-institution model. Set a minimum number of slots for all K12 programs, with 3 slots as the recommended minimum.
- **Consider establishing expectations for the duration of K12 appointments** The Task Force recognized the importance of sufficiently long K support in order to prepare scholars for independent grants. A number of successful K12 institutions encourage appointments for clinical K12 scholars of no less than 2 years in duration, with a third optional year depending on progress of the scholar. After the second or third year, these programs transition scholars to individual K awards or to research project grants. NICHD should consider establishing general expectations for the duration of K12 appointments along these lines.
- **Reduce investment in underperforming K12 programs** Identify and reduce investment in programs or awardees with higher than average unfilled slots, low rates of former scholars continuing in research, or FOAs with relatively low numbers of applications and correspondingly high success rates (lack of competition).
- **Create multi-thematic institutional K12 programs** Task Force members felt that some scientific areas were over-represented or overlapping, and those programs should either be reduced in number or merged. One suggestion was to create multi-themed programs across much broader disciplines instead of issuing multiple RFAs for narrower subject areas. Another suggestion was to issue a single "parent K12" funding opportunity announcement (PAR) and review all of the applications together in the Scientific Review Branch.
- **Consolidate reviews of K12 programs** Task Force members were concerned with variability in K12 application success rates and insufficient competition for some of the review cycles. All of these programs are competed via RFAs. Consolidating reviews would raise the standards for all programs. NICHD may consider a model of soliciting larger numbers of applications across multiple disciplines so more programs are reviewed together.
- Continue to monitor and analyze the impact of training programs, used alone or in combination, at various career stages -- The long-term outcomes for the cohorts of trainees examined varied somewhat across training field, degree, and mechanism. For example, as a group, MDs who were supported under the T32 program had considerably fewer subsequent NIH applications compared with other trainees. Key limitations in these types of long-term outcome analysis, however, pointed out the need for more real-time monitoring and assessment of intermediate and long-term outcomes across trainees by degree background, field, mechanism, and institution.

R25 Grants for Short Courses

The T15 and R25 programs involve a wide variety of educational activities, including short courses and workshops in research approaches and methodologies, summer long intensive research experiences, and outreach/dissemination activities. The Task Force members felt that many of these programs were valuable to their respective fields, but were sensitive to budgetary pressures posed by large programs or programs of especially long duration. There was general agreement that institutions sponsoring the programs or nominating participants should support a greater share of the costs.

Recommendations:

- Select programs/courses based on programmatic need rather than strictly by pay lines applied to priority scores. The Task Force concurred with NICHD's practice of limiting awards, and also recommended selecting awardees based on programmatic need rather than strictly by pay line.
- Consider moderately raising the minimum direct cost, but set a high standard of justification for costs above a standard amount.

Mentoring the Community

The Task Force discussed the important need for mentoring of individuals at various stages of training. NIH has always encouraged mentoring by program staff and by senior investigators within the extramural community. Despite such efforts, there continue to be important gaps in knowledge of NIH and NICHD programs. This lack of knowledge, or even misinformation among trainees and mentors, can result in unsuccessful applications or even decisions of individuals to leave research altogether. In the case of individuals who have already received some training support, such consequences may sacrifice the effective use of the Institute's limited resources. The Task Force strongly urges the institute to invest in traditional and novel forms of mentoring to communicate funding opportunities and areas of research need. At the same time, the committee questioned the value of the K24 award for mentoring in patient-oriented research.

- Commit more travel funds for program and review staff to present at scientific meetings.
- Structure NICHD staff mentoring opportunities through webinars or other media
- Host more meetings at NIH that target trainees, new investigators, and PIs seeking their first renewal.
- Create staff mentoring opportunities and more intensive follow-up for recipients of diversity awards (Diversity F31, diversity supplements)

Reduce or refocus K24 program – NICHD supports the Midcareer Investigator Award in Patient-Oriented Research (Parent K24) program to provide protected time for established investigators to devote to patient-oriented research and to act as research mentors primarily for clinical residents, clinical fellows and/or junior clinical faculty. Based on the publications and grant applications of K24 awardees and the individuals they mentor, the Task Force had serious reservations about the value of this program. Many K24 awardees are highly acclaimed faculty with multiple grants. Progress reports indicate that many of these senior investigators are receiving substantial salary support for mentoring obligations or collaborations they would normally have already as part of their professional responsibilities. The Task Force suggested reducing this program and/or focusing on specific areas of need such as diversity. Possible ways of limiting the number of awards or reducing their cost include: 1) reduce the number of awards (tight pay line); 2) limit professional effort to 25 percent (FOA allows 25-50 percent effort); 3) limit eligibility to PIs with only one R01-equivalent grant (K24 awardees often have multiple research grants); 4) establish one or more focus areas, such as diversity mentoring.

Peer Review

Peer review is essential in assuring the quality of fellowships, training grants, and career awards. Scoring patterns of review groups have the potential to unintentionally bias the portfolios in certain directions. The Task Force members discussed a number of issues that often complicate the ability of reviewers to accurately and fairly assess scientific and technical merit of applications. The following recommendations were proposed to facilitate the peer review process.

- Modify SF424 and/or FOA instructions for presenting program data (mentors, trainees, progress) to improve consistency among applications There is minimal flexibility for the Parent T32, but more flexibility for RFA/PAR for T32 or K12 custom criteria. Staff should review the new SF424 and FOA instructions scheduled for release in FY 2016, and consider whether additional modifications to the instructions can improve consistency among applications.
- Improve the effectiveness of the Data Tables, which are unwieldy and make applications excessively long – T32 Data Tables are being converted to electronic form and reduced in number, effective for the May 25, 2016 application deadline. Staff should review the new NIH training Data Tables and consider whether to recommend that K12 applications use a subset of the standard table set.
- Improve/Streamline Review Criteria for T32 and K12 applications There is minimal flexibility for Parent T32 because the review criteria are fixed on the training FOA template; custom criteria are not allowed. NICHD has more flexibility for T32 or K12 review criteria with RFAs or PARs.

- Maximize competition for institutional training and career awards solicited by RFA To the extent possible, review cycles for institutional applications should be synchronized so competition can be optimized.
- Facilitate collaboration between SRO and PO in crafting review criteria at an earlier stage of FOA production
- Reduce unnecessary review questions and remove redundancy
- Conduct a detailed analysis of peer review group coring patterns for major career awards: K99, K01, K08, K23 Differences in scoring patterns across committees in the Scientific Review Branch can potentially favor some disciplines or mechanisms versus others. An analysis would show whether this is occurring and provide data to suggest recommendations for improvement, if needed.