



American
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Congress of
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March 15, 2021

Walter J. Koroshetz, MD, Director
Nina F. Schor, MD, PhD, Deputy Director
National Institute of Neurological Disorders and Stroke
National Institutes of Health
Bethesda, MD 20892

SUBJECT: Feedback on Draft 2021-2026 NINDS Strategic Plan

Dear Drs. Koroshetz and Schor:

On behalf of the American Academy of Neurological Surgery (AAcNS), American Association of Neurological Surgeons (AANS), American Board of Neurological Surgery (ABNS), Congress of Neurological Surgeons (CNS) and Society of Neurological Surgeons (SNS), representing organized neurosurgery in the United States, we write to thank you and the National Institute of Neurological Disorders and Stroke (NINDS) for the opportunity to provide input into the NINDS strategic plan.

Organized neurosurgery provided extensive recommendations in 2019, following the initial call for feedback (*see* attached letter dated Sept. 30, 2019). After careful review of the new Draft 2021-2026 NINDS Strategic Plan, we appreciate that the NINDS incorporated our previous recommendations into the draft strategic plan, including:

- Funding and support for training of future physician-scientists, mentorship and enhancing workforce diversity;
- Supporting programs that will provide fundamental understanding into nervous system function;
- Funding for programs that will define insights into the basic mechanisms of neurological disorders;
- Supporting developing biomarker and outcome measures that will improve therapies and patient outcomes;
- Funding for personalized therapeutic approaches to treating neurological disorders;
- Improving treatments for neurologic diseases through the support of preclinical development of small molecule drugs, biologics and devices;
- Supporting early/advanced clinical trials, comparative effectiveness research, data analytics, epidemiological studies and preventive measures;
- Advancing health equity through NINDS programs and support;
- Supporting independent and team science research paradigms;
- Providing access to technology and scientific resources across the scientific community;
- Identifying areas to augment the intramural program resources and to increase collaboration extramurally; and
- Promoting communication to propel scientific progress and neurologic treatments.

As the NINDS moves forward with an updated strategic plan, we want to reiterate and emphasize some of the most critical components of the strategic plan for our organizations, including:

- Expanding support for successful in-training and early career support, including the R25, K12, K08 and K23, that have multiplied independent neurosurgeon investigators and neuroscience research impact (see the attached article from the *Journal of Neurosurgery* titled, "Creation of a comprehensive training and career development approach to increase the number of neurosurgeons supported by National Institutes of Health funding");
- Targeting support for device and technologic development for surgical technologies;
- Funding for observational natural history and treatment studies will be transformative to optimizing understanding and management of neurologic disease;
- Creating a pool of expert clinical trialists who use randomized trials and prospective observational database methodologies will be crucial to turning basic and translational discoveries into effective clinical therapies;
- Growing opportunities for NIH, industry and academic partnerships to move device/technologies forward;
- Defining support for regulatory training and new investigational drug/device exemption-enabling studies to provide a pathway to the clinic for promising new technologies; and
- Growing and supporting opportunities for NINDS, industry and academic partnerships to move device/technologies forward.

Because the COVID-19 pandemic had not occurred at the onset of the strategic planning process and the NINDS's initial request for information, we did not have an opportunity to address this critical health care issue in our original letter. Specifically, we believe that funds directed to understanding the acute and long-term impact of this viral illness on the nervous system will be critical in several areas, including the:

- Mechanism of vascular thrombosis and stroke associated with COVID-19;
- Natural history (including long-term effects) of COVID-19 related neurologic findings; and
- Pathogenesis of COVID-19-associated neurologic signs and symptoms.

As the strategic planning process moves forward, we would recommend the following representatives across the various neurological surgery stakeholders:

- One representative (neurosurgeon) that is a member of the NINDS Advisory Council;
- One representative for the Neurosurgery Research and Education Fund (NREF);
- One representative from the Executive Committee of the Neurosurgeon Research Career Development Program (NRCDP); and
- The president/chair (or designated representative) from each of the following national neurosurgical organizations: the American Academy of Neurological Surgery, American Association of Neurological Surgeons, American Board of Neurological Surgeons, Congress of Neurological Surgeons and Society of Neurological Surgeons.

Thank you for the opportunity to provide input into this important process. If you have any questions or need additional information, please do not hesitate to contact us.

Sincerely,



Douglas S. Kondziolka, MD, President
American Academy of Neurological Surgery



John A. Wilson, M.D., President
American Association of Neurological Surgeons



Carl B. Heilman, MD, Chair
American Board of Neurological Surgeons



Brian L. Hoh, MD, President
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M. Sean Grady, M.D., President
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Attachments:

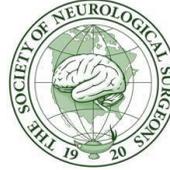
- Sept. 30, 2019 letter to NINDS from national neurosurgical organizations providing input into the NINDS strategic plan
- *Journal of Neurosurgery* article "Creation of a comprehensive training and career development approach to increase the number of neurosurgeons supported by National Institutes of Health funding"

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September 30, 2019

Nina F. Schor, MD, PhD, Deputy Director
Office of the Director
National Institute of Neurological Disorders and Stroke
National Institutes of Health
Bethesda, MD 20892

SUBJECT: NINDS strategic plan planning process input from national organized neurological surgical organizations

Dear Dr. Schor:

On behalf of the American Academy of Neurological Surgery (AAcNS), American Association of Neurological Surgeons (AANS), American Board of Neurological Surgery (ABNS), Congress of Neurological Surgeons (CNS) and Society of Neurological Surgeons (SNS), representing organized neurosurgery in the United States, we are pleased to respond to your request for input on the National Institute of Neurological Disorders and Stroke (NINDS) strategic plan planning process. Below are our collective thoughts and recommendations related to the following points, as defined in the NINDS request for information.

I. Opportunities for, and challenges facing, progress in neuroscience research and neurological health.

Neurosurgeon researchers provide a unique opportunity to advance biomedical understanding and the development of new therapies for nervous system disorders. Neurosurgeons can provide insights into neurobiological-clinical correlations across the continuum of neurologic disease. Neurosurgeon-driven understanding will come from the assessment of patients that can be directly linked to operating room observations and direct response to monitoring and therapy. Traditionally, neurosurgeons form and propel essential collaborations with investigators across scientific fields that have culminated in a deeper understanding of normal and disease pathobiology. These findings have led to new effective treatment paradigms (medical and surgical) for previously untreatable or ineffectively treated nervous system disorders. Neurosurgical access to the nervous system can provide direct and potent insights into nervous system anatomy, biology and physiology. Moreover, neurosurgeons are essential to the use of new surgical therapeutic technology for treatment.

By effectively exploiting the distinctive opportunities that neurosurgeon-scientists use to impact neuroscience research, there are a number of NINDS-related mechanisms that could be employed that would have an immediate and transformative impact in lessening the burden of neurologic disease.

- First, expand the support of successful in-training and early career support, including the R25, K12, K08 and K23, that have multiplied independent neurosurgeon investigators and neuroscience research impact.
- Second, device and technologic development are essential in neurosurgery. Grants targeted at surgical technologies are, therefore, critical.
- Third, growing support for observational natural history and treatment studies will be transformative to optimizing understanding and management neurologic disease.

- Fourth, neurosurgeons can more effectively translate nervous system therapies/technologies through more robust support.
- Finally, the creation of a pool of expert clinical trialists who use randomized trials and prospective observational database methodologies will be crucial to turning basic and translational discoveries into effective clinical therapies.

II. **Emerging scientific or organizational trends, advances, techniques, and perspectives NINDS should account for in this planning process.**

There are emerging scientific trends, advances and techniques in neurosurgery that can significantly and positively impact neurologic disease in a short period of time (3 to 5 years). These will require collaborative efforts across multiple disciplines. Support to expand and/or mature the following nervous system advances will have an impact:

- **Vascular device development.** Endovascular devices are rapidly evolving and improving. These emerging devices will provide more effective and safer treatments for ischemic stroke, hemorrhagic stroke and aneurysms through design and linked therapeutics.
- **Responsive nervous system stimulation.** Closed loop (sensing/responsive) deep brain stimulation devices are emerging for clinical use and may provide more effective personalized stimulation paradigms for the management of neurodegenerative disease, epilepsy, addiction and/or psychological disorders.
- **Gene therapy and gene-editing technology.** Direct genetic manipulation of diseased neural circuitry can have a potent and near-term impact on a wide variety of neurologic disorders that are currently not treatable or ineffectively treated. It is a rich area for collaboration across multiple neuroscience research areas.
- **Robotics.** Cranial and spinal robotics are emerging as opportunities for the more effective and efficient surgical treatment of cranial and spinal disorders. Advances in these devices should improve quality and consistency across a large domain of neurosurgical procedures.
- **Artificial Intelligence and machine learning.** Data analytics are being used in the neurosurgery. These provide an opportunity to enhance understanding and optimal management of neurologic disease, while potentially reducing the number of patients needed to draw conclusions. These analytics permit accurate and personalized diagnoses, as well as management/outcomes across related disease populations. The use of artificial intelligence processes to analyze large, prospective observational databases will be a powerful tool to refine the diagnosis and management of neurosurgical diseases.
- **Wearables and digital phenotyping.** By collecting real-life/activity information, wearables and digital phenotyping provide an opportunity to obtain valuable objective data, understand disease state and/or therapeutic impact. They can also better inform artificial intelligence and machine learning paradigms in the clinical neurosciences.
- **Minimal access technologies.** These technologies include high- and low-frequency ultrasound, stereotactic radiosurgery and laser interstitial thermal therapy for the treatment of neurologic disorders. These technologies continue to expand. Understanding their impact on the natural history of disease and comparing their effectiveness to other management options will determine their therapeutic value.
- **Targeted pharmacologic therapies.** New directed pharmacologic treatments developed through basic mechanistic and pathway studies need to be translated into clinically effective

therapies. This will require a group of well-trained clinical trialists and support for IND-enabling studies.

- **Modulation of the neuro-immune system.** Emerging data indicate that neuroimmune modulation is becoming more critical in the treatment of neurologic disorders. Support for collaborations across research areas that were not previously linked is important.
- **Single-cell genomics.** Single-cell genomics will be essential to define neurologic disorders at the cellular level. Application of these findings is essential to broader disease understanding and the development of target therapeutics.
- **Advanced imaging technology.** Advanced imaging technologies will drive biologic understanding, improvement in non-surgical/surgical treatment and therapeutic assessment in many neurologic disorders. Evolving understanding of disease can be optimized by non-invasive imaging techniques. This will also drive therapeutic discovery and monitoring.
- **Biomarkers for disease.** Developing imaging, blood, cerebrospinal and/or other biomarkers will be essential for early diagnosis (premorbid), tracking disease progression and monitoring of therapeutic effectiveness. Support in this area could rapidly change the scope of disease, diagnostic paradigms and management.
- **Defining the natural history of neurologic disease.** Defining the natural history of a variety of neurologic disorders, including neoplasia, vascular disease, trauma, spinal disorders and neurodegenerative diseases, will have a profound impact on indications for treatment, expected outcomes and comparing the effectiveness of various disease-modifying therapies.

III. Recommendations for steps, actions, activities, and opportunities that will enable NINDS to make rapid progress toward achieving each goal.

Resident, fellow and early career research training support

The R25, K12, K08 and K23 have supported the rapid expansion of neurosurgeon independent investigators over the last four years. The vitality of these programs is critical to growing critical neuroscience discoveries.

- Expand support of in-training (residency and fellowship) and early career (0 to 5 years after training completion) neurosurgeon-scientist awards.
- Define new and innovative mechanisms with national neurosurgical organizations for the funding research training that are responsive to changes in the neurosurgical training environment (e.g., changes in residency requirements are research training and financial complexities of an early career neurosurgeon).
- Creating a robust pool of young neurosurgeon scientists will lead to innovative physiologic, diagnostic and therapeutic strategies across all of the neurosciences.

Define funding streams that support early and late device and technologic development

This is an essential area of need in neurosurgical research. Because the specialty is by definition device and technology-driven, defining innovative strategies that support the early and late stages of device and technology development will be critical to moving device-related technologies forward. Neurosurgeons can effectively translate invasive nervous system therapies/technologies and increasing support of these tools can be foundational. This could be supported in several ways:

- Expansion of intramural-extramural opportunities to drive technology-related trials forward where appropriate.

- Grow opportunities for NIH, industry and academic partnerships to move device/technologies forward.
- Define support for regulatory training and IND/IDE-enabling studies to provide a pathway to the clinic for promising new technologies.

Support for prospective observational studies for comparative effectiveness research and determining natural history

To optimize management and develop new therapies for neurologic disease patients, it will be critical to define the natural history of the diseases we treat.

- Support prospective, observational database studies that include sophisticated biostatistical techniques such as propensity score matching and predictive analytics. These studies will complement randomized, controlled trials to increase participation and knowledge generation in the clinical neurosciences.
- Properly designed prospective observational databases allow meaningful comparative effectiveness research to be done without randomization and include more representative patients and surgeons than is often the case with randomized trials.

Developing a pool of expert neurosurgeon-scientists who are clinical trialists

Funding the creation of a pool of expert neurosurgeon clinical trialists, skilled in designing and conducting randomized trials and/or prospective observational database comparative effectiveness studies, will be essential to developing effective therapies from basic and translational science discoveries.

- Expansion of intramural-extramural opportunities to drive translational research and early clinical trials.
- Define support for regulatory training and investigation new device (IND)/investigational device exemption (IDE)-enabling studies to provide a pathway to the clinic for promising new technologies.
- Grow and support opportunities for NINDS, industry and academic partnerships to move device/technologies forward.

IV. For recommendations you make, please consider indicating appropriate objective success criteria, including quantitative and qualitative benchmarks and milestones for gauging progress in the corresponding domain.

For the recommendations defined above, we provide objective success criteria, as defined below.

Criteria for success of resident, fellow and early career research training support

- Criteria of success for the R25 and K12 awards would be defined by:
 - Conversion rate to K08, K23 or other R01/DP; and/or
 - Conversion rate to other equivalent federal funding.
- Early-career awards (within first five years of completion of training) including the K08 and K23 would be defined by:
 - Successful R01 or DP-awards; and/or
 - Conversion rate to other equivalent federal funding.

Criteria for success of support for early and late device and technologic development

- Increase in the number of NINDS, industry and academic trials supporting early or late device development;
- Development of new targeted training programs with an increase in neurosurgeons involved in IND/IDE-enabling studies; and/or
- Increase in the number of NINDS supported IND/IDE-enabling studies for new technologies.

Criteria for success of support for observational or natural history studies

- Increase in the number of NINDS supported prospective observational database or studies for comparative effectiveness and natural history research;
- Published definition for specific disease natural history; and/or
- Increase in prospective, observational trials that use sophisticated biostatistical methods such as propensity score matching that will complement randomized control trials and increase participation and knowledge generation in clinical neurosciences.

Criteria for success of support for developing a pool of neurosurgeon-scientist clinical trialists with expertise in randomized, controlled trial and prospective, observational database methodologies

- Increase in the number of intramural-extramural opportunities related to translational research and early clinical trials;
- Increase in the number of investigators supported for regulatory training and IND/IDE-enabling studies; and/or
- Increase in the number of NINDS, industry and academic partnerships to move early clinical trials forward.

V. Successes, shortcomings, and impacts of existing NINDS policies, practices, partnerships, strategies, or activities.

Neurosurgery has seen success from the NINDS research training awards. These have led to increases in early career, independent National Institutes of Health (NIH) and other federal funding at a significantly higher rate than those individuals who have not been supported via these awards. This has driven an increase in the number of independent neurosurgeon-scientists.

Shortcomings include the requirements for departmental cost-sharing to support surgeon-scientist, clinical service requirements for residents who elect to spend research time during training and the difficulty associated with translating neuroscience device-related technologies via NIH funding mechanisms.

VI. Stakeholders and experts NINDS should consult in the process of strategic planning and strategy implementation.

We would recommend the following representatives across the various neurological surgery stakeholders:

- One representative (neurosurgeon) that is a member of the NINDS Advisory Council;
- One representative for the Neurosurgery Research and Education Fund (NREF);
- One representative from the Executive Committee of the Neurosurgeon Research Career Development Program (NRCDP);

- The president/chair (or designated representative) from each of the following national neurosurgical organizations: the American Academy of Neurological Surgery, Society of Neurological Surgeons, American Association of Neurological Surgeons, American Board of Neurological Surgeons, Congress of Neurological Surgeons and AANS/CNS Washington Committee,

VII. High-priority objectives that you do not see reflected among the four stated strategic planning goals.

We do not see clinical trial conduct and design reflected in the strategic planning goals. It will be important that a pool of surgeon-scientists is educated in the design and conduct of clinical trials in the neurosciences, including the acquisition of scientific correlates and information from the clinical trials. Similarly, we do not see funding prospective observational studies that will be valuable for comparative effectiveness research and more generalizable to "real-life" clinical practice than traditional randomized control trials.

Thank you for the opportunity to provide input into this important process. If you have any questions or need additional information, please do not hesitate to contact us.

Sincerely,



E. Antonio Chiocca, MD, PhD, President
American Academy of Neurological Surgery



Christopher I. Shaffrey, MD, President
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Linda M. Liau, MD, PhD, Chair
American Board of Neurological Surgeons



Ganesh Rao, MD, President
Congress of Neurological Surgeons



Karin M. Muraszko, MD, President
Society of Neurological Surgeons

Attachment: "Launching Effectiveness Research to Guide Practice in Neurosurgery: A National Institute Neurological Disorders and Stroke Workshop Report"

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Creation of a comprehensive training and career development approach to increase the number of neurosurgeons supported by National Institutes of Health funding

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Kavon P. Rezai-Zadeh, PhD,² Jeffrey G. Ojemann, MD,³ and Stephen J. Korn, PhD²

¹Department of Neurological Surgery, Ohio State University Wexner Medical Center, Columbus, Ohio; ²Office of Training and Workforce Development, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, Maryland; and ³Department of Neurological Surgery, University of Washington, Seattle, Washington

OBJECTIVE To increase the number of independent National Institutes of Health (NIH)–funded neurosurgeons and to enhance neurosurgery research, the National Institute of Neurological Disorders and Stroke (NINDS) developed two national comprehensive programs (R25 [established 2009] for residents/fellows and K12 [2013] for early-career neurosurgical faculty) in consultation with neurosurgical leaders and academic departments to support in-training and early-career neurosurgeons. The authors assessed the effectiveness of these NINDS-initiated programs to increase the number of independent NIH-funded neurosurgeon-scientists and grow NIH neurosurgery research funding.

METHODS NIH funding data for faculty and clinical department funding were derived from the NIH, academic departments, and Blue Ridge Institute of Medical Research databases from 2006 to 2019.

RESULTS Between 2009 and 2019, the NINDS R25 funded 87 neurosurgical residents. Fifty-three (61%) have completed the award and training, and 39 (74%) are in academic practice. Compared to neurosurgeons who did not receive R25 funding, R25 awardees were twice as successful (64% vs 31%) in obtaining K-series awards and received the K-series award in a significantly shorter period of time after training (25.2 ± 10.1 months vs 53.9 ± 23.0 months; $p < 0.004$). Between 2013 and 2019, the NINDS K12 has supported 19 neurosurgeons. Thirteen (68%) have finished their K12 support and all (100%) have applied for federal funding. Eleven (85%) have obtained major individual NIH grant support. Since the establishment of these two programs, the number of unique neurosurgeons supported by either individual (R01 or DP-series) or collaborative (U- or P-series) NIH grants increased from 36 to 82 (a 2.3-fold increase). Overall, NIH funding to clinical neurological surgery departments between 2006 and 2019 increased from \$66.9 million to \$157.3 million (a 2.2-fold increase).

CONCLUSIONS Targeted research education and career development programs initiated by the NINDS led to a rapid and dramatic increase in the number of NIH-funded neurosurgeon-scientists and total NIH neurosurgery department funding.

<https://thejns.org/doi/abs/10.3171/2020.5.JNS201008>

KEYWORDS funding; grant; National Institutes of Health; neurosurgery; training; research

NEUROSURGICAL research has advanced biomedical understanding in unique and fundamental ways.^{1–6} It can provide insight into biological-clinical correlations across the spectrum of neurological disorders,^{7–17} often from an evaluation of patients coupled with direct operating room observations.^{16,18–24} Neurosurgeon-sci-

entists often drive collaborations across scientific arenas that culminate in a deeper understanding of normal and disease neurobiology.^{7,10,18,22,25,26} Neurosurgical access to the nervous system provides direct and powerful insights into neuroanatomy and physiology.^{7,9,16,20,21,23,27,28} Research discoveries by neurosurgeons have led to new treatment

ABBREVIATIONS BRIMR = Blue Ridge Institute of Medical Research; NIH = National Institutes of Health; NINDS = National Institute of Neurological Disorders and Stroke; NRCDDP = Neurosurgeon Research Career Development Program.

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paradigms for previously untreatable and/or ineffectively treated disorders.^{1,12–14,19,25,29–31} Moreover, neurosurgeons steeped in both research and the clinic are essential for the development of new surgical technologies.^{4,10,12–14,19,25,29,32–38}

Despite the historical impact of neurosurgical research, several factors have led to a paucity of National Institutes of Health (NIH)–funded neurosurgeon-scientists during the first decade of this millennium.^{39–43} First, financial influences often drove departments to reward clinical volume over research productivity. This propelled resources away from neurosurgeon-researchers and into high-volume clinical programs. Second, because neurosurgery is a small specialty and researchers are dispersed across the country, broad-based community support for early-career surgeon-scientists was not available. Finally, unlike clinical training, there were no defined expectations or curricula for neurosurgical trainees. These factors made it difficult for individuals committed to research to acquire the skills necessary for success and prevented development of an environment conducive to large-scale specialty research growth.

To reverse this trend and drive discoveries particularly well suited to neurosurgeon-scientists, the National Institute of Neurological Disorders and Stroke (NINDS) developed two comprehensive national research education and early-career development programs. Specifically, the NINDS established a research education program (R25) to support the development of neurosurgeon-researchers during training, and a career development program (K12) to foster early-career faculty neurosurgeon-scientists. These NINDS-funded programs were designed in consultation with academic departments and research leaders to ensure feasibility and acceptance. Besides financial support, these programs provided group oversight, rigorous selection of participants/scholars, organized mentorship (local and national), and annual meetings focused on providing expert guidance and research community building. Since their inception, more than 200 junior neurosurgeons have participated in these programs.

Methods

NIH Funding

Funding data for neurosurgery department trainees and faculty were derived from internal NIH and Blue Ridge Institute of Medical Research (BRIMR) databases. BRIMR data were used to determine the trends in total NIH funding for clinical science departments (2006 [earliest year available] through 2019), the numbers of neurosurgeon-scientists and non–neurosurgeon-scientists in departments, and the contributions by each group (neurosurgeon-scientists and non–neurosurgeon-scientists) to total department NIH funding annually from 2009 (first available data in BRIMR for individual investigators) through 2019. Annual BRIMR data for total NIH funding to clinical science departments (surgery, urology, otolaryngology, and internal medicine) included both clinician/surgeon-scientists and non-clinician-scientists. Funding by mechanisms and funding specifically for neurosurgeons was obtained from NIH databases from 2012 through 2019. To assess

the impact of the programmatic (R25 and K12) changes, we compared annual neurosurgical funding from before 2015 to funding from 2015 to 2019 (2015 was 1 year after the first R25 participant completed residency and the year the first cohort of K12 awardees completed the program). The NIH definitions for new investigator (an investigator who has not previously received an NIH R01 grant) and early-stage investigator (individual who is within 10 years of completing their terminal research degree or clinical training and has not received an R01) were used to distinguish these subgroups of NIH-funded neurosurgeon-scientists. Statistical analysis was performed using SPSS Statistics version 25 (IBM Corp.).

Results

Research Education Program for Neurosurgery Residents and Fellows (R25 awards)

The R25 Award and Awardee Characteristics

Established by NINDS in 2009, the R25 is an institutional award designed to facilitate the research education and training of residents and fellows in neurosurgery and other clinical specialties. Currently there are 19 R25 programs supporting neurosurgeon trainees, including 11 administered by neurosurgery exclusively and 8 coadministered by neurology and neurosurgery departments. Through 2019, support was requested for 185 neurosurgery residents and 87 (47%) were funded. Fifty-three R25 participants (61% of those supported) have completed the R25 award and clinical training. Forty (75%) of these awardees were supported for 1 year and 13 (25%) for 2 years.

Neurosurgeon R25 Awardee Outcome

Of the 53 participants who completed the award and clinical training, 39 (74%) are in academic practice, 13 (25%) are in private practice, and 1 (2%) was lost to follow-up. Fifteen (38%) R25 participants in academic practice have applied for major NIH funding (K, R01, or DP2 awards) and 12 (80%) have successfully obtained funding. R25 participants had more than twice the success rate of those not participating in the R25 program for NIH K-awards (64% vs 31%) and significantly shorter (less than half) time to K-award funding was seen (Table 1).

Support for Early-Career Faculty: The NINDS Neurosurgeon Research Career Development Program (K12 awards)

The K12 Award and Awardee Characteristics

The NINDS K12 program was initiated in 2012 with funding for the first cohort starting in January 2013. Since the program's inception, 83 early-career neurosurgeons have applied and 19 (23% success rate) have been supported by this program. Eighteen different programs are represented by the 19 awardees. Fifty-seven different academic programs (53% of academic programs in the United States) have had a neurosurgical faculty member apply for the K12. Six awardees (32%) have been women or underrepresented minorities. Subspecialty K12 funding corresponded to the number of applications (Table 2).

TABLE 1. Impact of R25 on K-funding success and time to K-award from completion of residency (2011–2019)

Factor	Neurosurgeons w/ R25*	Neurosurgeons w/o R25*
Application success rate (K-award)	41% (7 funded/17 submitted)	20% (18/90)
Applicant success rate (K-award)	64% (7 individuals funded/11 who applied)	31% (18/59)
Mean time from residency to K-award \pm SD, mos \dagger	25.2 \pm 10.1	53.9 \pm 23.0

* Individuals who have completed residency, those who were awarded the R25 in 2015 or before.

\dagger Difference in time to K-award funding from residency completion (Student's t-test; $p = 0.004$).

K12 Scholar Outcome (2013 through 2017)

Outcome of the Neurosurgeon Research Career Development Program (NRCDP) was assessed based on the individuals who received K12 funding from 2013 through 2017, because they have had the opportunity to complete the award and apply for advanced NIH funding. During that funding period, there were 13 K12 scholars (22% of 59 applicants during that time) and all (100%) completed the award. Eleven (85%) have remained in academic practice and have obtained major NIH funding (100%; Table 3).

Outcomes for Unsuccessful K12 Applicants (2013 through 2017)

During the same funding period (2013 through 2017), 46 individuals applied to the K12 program but did not receive funding. Thirty-seven (80%) of these unfunded K12 applicants subsequently applied for NIH funding and 13 (35%) have obtained advanced NIH awards (Table 3). Six have obtained an R01 or U-series grant.

Overall Neurosurgeon NIH Funding Since Inception of Programs

Between 2012 and 2015 (the 4 years before completion of the R25 or K12 program by any individual), the number of neurosurgeons holding R01 or DP-series grants remained stable (30–33 annually; Fig. 1), as did the number of neurosurgeons holding U- or P-series grants (9–11 annually; Fig. 1).

Independent Investigator Grants (R- and DP-series)

Between 2015 (1 year after the first R25 participant completed residency and the year the first cohort of K12 awardees completed the program) and 2019, the number of neurosurgeons holding an NIH R01 or DP-series grant increased from 34 to 72 (2.1-fold increase; Fig. 1). The largest increase was in early-stage/new investigator neurosurgeon-scientists who were targeted by the R25 and K12 programs (from 12 to 34; 2.8-fold increase). From 2015 to 2019, 31 (74% of all early-stage/new investigators) early-stage/new investigator neurosurgeon-scientists were impacted in the R25 and/or K12 programs (Fig. 2). There was also an increase (from 22 to 38; 1.7-fold increase)

TABLE 2. K12 applicants and scholars as defined by neurosurgical subspecialty (2012–2019)

Subspecialty	Applicants (% of total submitted)	Applications Funded (% of total funded)
Functional	27 (33%)	7 (37%)
Neuro-oncology	27 (33%)	6 (32%)
Neurovascular	9 (11%)	2 (10%)
Pediatrics	5 (6%)	3 (16%)
Spine	5 (6%)	1 (5%)
Trauma	8 (9%)	0 (0%)
Socioeconomic	2 (2%)	0 (0%)
Total	83 (100%)	19 (100%)

in the number of established neurosurgeon-investigators holding an R01 or DP-series grant (Fig. 1).

Collaborative Investigator Grants (U- and P-series)

Between 2015 and 2019, the number of neurosurgeons who held U- or P-series grants as principal investigator increased from 10 to 25 (2.5-fold increase; Fig. 1). There were large increases in the number of independently funded neurosurgeon-scientists at both the early-stage/new investigator level (from 0 to 8) and the established investigator level (from 10 to 17; 1.7-fold increase; Fig. 1).

Total Number of Unique Neurosurgeon Principal Investigators

To more accurately define the change in neurosurgeon-researcher workforce subsequent to creation of the R25 and K12 programs, we determined the number of unique neurosurgeon-investigators holding at least one of these major NIH grants (Fig. 1). Following a stable period between 2012 and 2015 (36–40 neurosurgeons with these grants), the number of unique neurosurgeons holding an R01, DP-, U-, or P-series grant increased 2.1-fold between 2015 and 2019 (40–82 neurosurgeons holding major NIH grants; Fig. 1).

Trends in Overall NIH Funding for Neurosurgery

Funding between 2006 and 2014 remained relatively

TABLE 3. Subsequent funding outcomes after individuals complete the K12 program versus applicants not funded (funding period 2013–2017)

Outcome	Unsuccessful K12 Applicants, % (no./total unfunded)	Individuals who Completed K12 Program, % (no./total funded)
Applied for NIH funding	80% (37/46)	100% (13/13)
NIH funding success rate	35% (13/37)	85% (11/13)
Applied for K08 or K23	48% (22/46)	62% (8/13)
K success rate	14% (3/22)	50% (4/8)
R01 or U-series awards	46% (6/13)	78% (7/9)

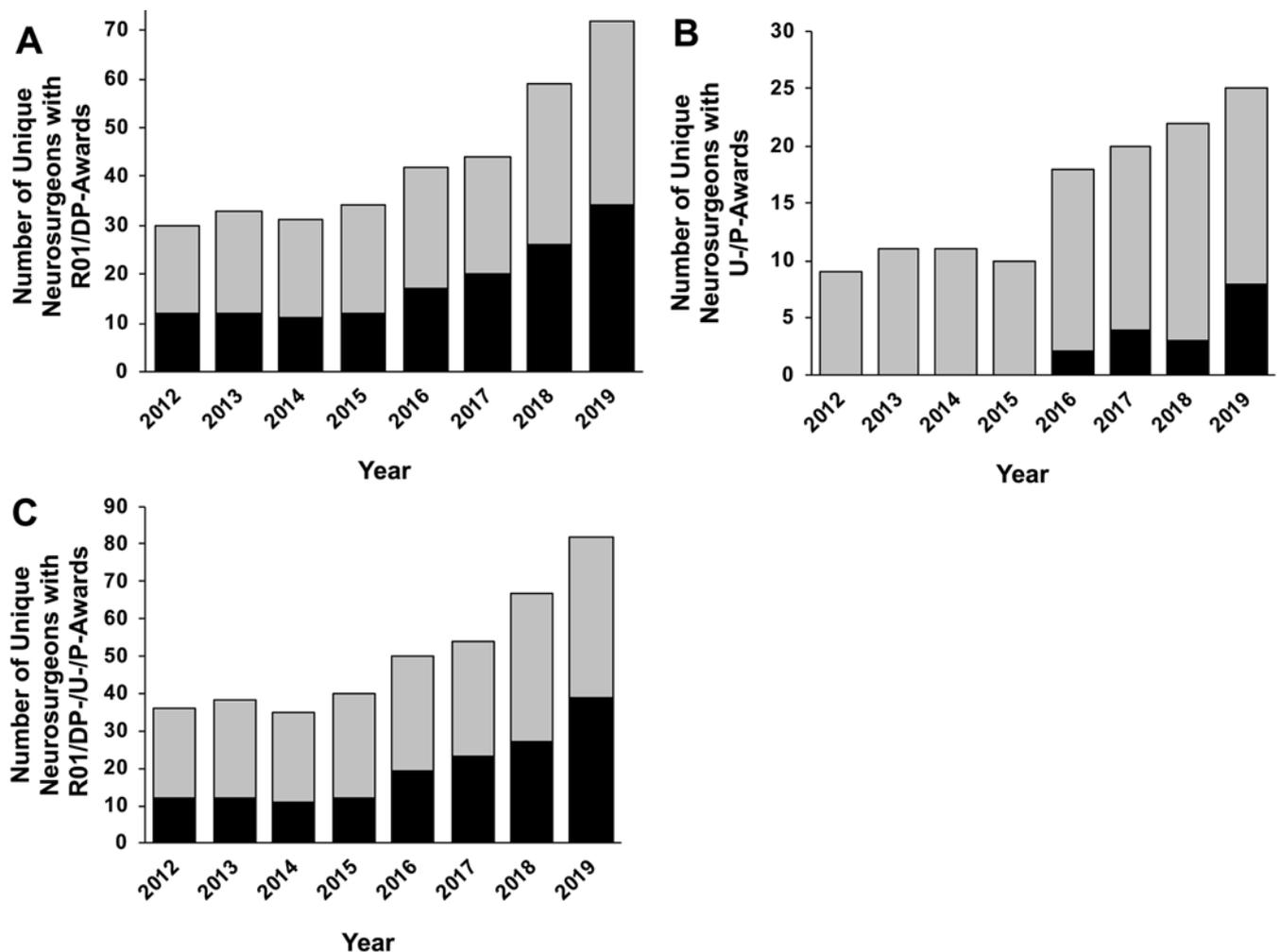


FIG. 1. Annual (2012–2019) number of unique NIH-funded independent (R01 and DP-series) (A), collaborative (U- and P-series) (B), and total (independent and collaborative) (C) neurosurgeon-scientists. A portion of total unique investigators is represented by new or early-stage investigators (black segment of bar) or established investigators (gray segment of bar).

flat for neurosurgery, general surgery, and internal medicine (Fig. 3). Between 2014 and 2019, whereas NIH funding to other surgical specialties remained flat or increased modestly (Fig. 3), funding to neurosurgical departments increased from \$66.9 million to \$157.3 million (a 2.2-fold increase). From 2012 through 2019, the number of neurosurgery department members (clinical and nonclinical) who obtained funding increased from 149 to 248 (66% increase). Although the ratio of neurosurgeons to nonclinician researchers in neurosurgery departments remained stable over that time period (percent neurosurgeons of total funded in neurological surgery departments: mean 33.3%, range 29%–35%; Fig. 4), the percentage increase in funding to neurosurgeon-scientists increased considerably more than funding to non-neurosurgeon-scientists (153% compared to 58%).

Discussion

Research Trends Across Surgical Specialties

Previous data across all surgical specialties indicate that

the overall number of surgeons involved in research is declining, surgeon-scientists are less likely to apply for NIH funding, surgeon-scientists are less successful at obtaining NIH funding than colleagues in medical fields, and funding for the surgical sciences (compared to internal medicine) is diminishing.^{39,40,42,43} Moreover, the impact of these changes has raised concern across the biomedical sciences because of the negative effect they are having on basic, translational, and clinical research, as well as the erosion of the scientific and clinical rigor associated with research training and investigation by surgeons.⁴¹ These findings, combined with reduced/flattened overall NIH funding to neurosurgery in the first decade of this millennium, led to the development of innovative NINDS programs designed to increase the number of neurosurgeon-scientists who are conducting NIH-sponsored research (Fig. 2).

Because it is the most critical period for establishing a sustainable research career, the NINDS program and funding objectives were designed to develop in-training and early-career neurosurgeons into independent surgeon-scientists. To define challenges and feasible approaches,

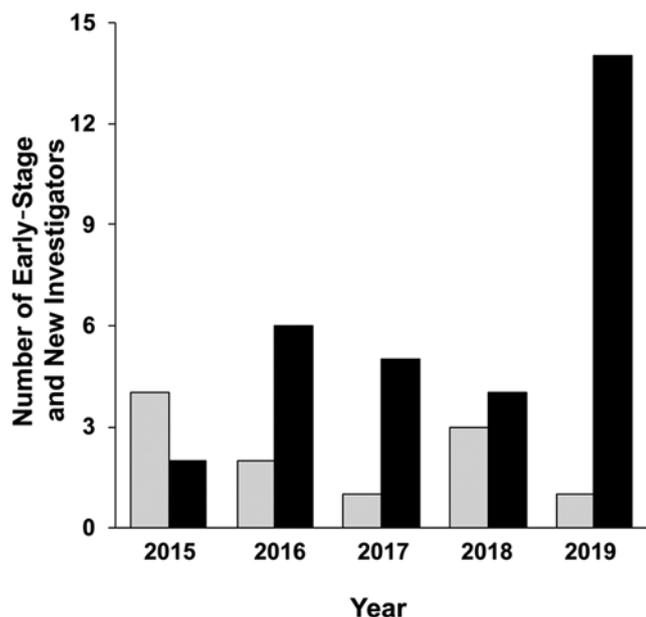


FIG. 2. Annual impact of the R25 and K12 funding and mentoring programs on NIH-funded unique early-stage and new investigators who received R01, DP-series, or collaborative (U- and P-series) awards between 2015 and 2019. Whereas early-stage and new investigators who received R25 and/or K12 funding or who were impacted in R25 and/or K12 programs (i.e., who applied for or received funding from one or both programs, or trained within an R25 residency program) grew rapidly (black bars) over the 2015–2019 time period, those who did not receive R25 or K12 funding (gray bars) remained stable.

these programs were created in consultation with the larger community of organized neurosurgery, neurosurgeon-researchers, and academic department chairs. Sufficient numbers of neurosurgeon-scientists have completed these programs and have had time to apply for major individual

NIH grants to enable us to conduct an initial assessment of the success of these programs.

Program Assessment

The R25 Award

The R25 award was established in 2009 to support institutional research training (up to 3 years) during neurosurgery residency and/or fellowship. This program was designed to select outstanding applicants from R25 institutions who intend to pursue a research path upon matriculation to faculty. This program requires critical institutional oversight of mentoring/training and was designed to cultivate a supportive national community among junior and established researchers. To emphasize the importance of neurosurgical research and provide programmatic guidance, this program engaged national neurosurgical organizations and leaders at an R25 annual meeting with awardees.

The overarching goal of the R25 award is to provide surgeon-scientists in residency (and subsequently fellowship when appropriate) with the necessary scientific skills and a research project to obtain advanced NIH K- or R-series funding upon training completion. Data demonstrate that R25-funded neurosurgeons more effectively and more rapidly obtain K- and/or R-series funding than neurosurgeons without prior R25 support (Table 1). These findings indicate that the R25 comprehensive training approach, which includes early planning, systematic mentorship, strong oversight, and community support, can increase funding success and shorten the time for entry into NIH-funded research.

Seventy-five percent of the R25-supported neurosurgeons who completed the award and training went on to academic practice, and 25% went into private practice. Thus far, 38% of those in academic practice have applied for K-series funding, with an 80% success rate. Enhancement of the success of this program will require efforts

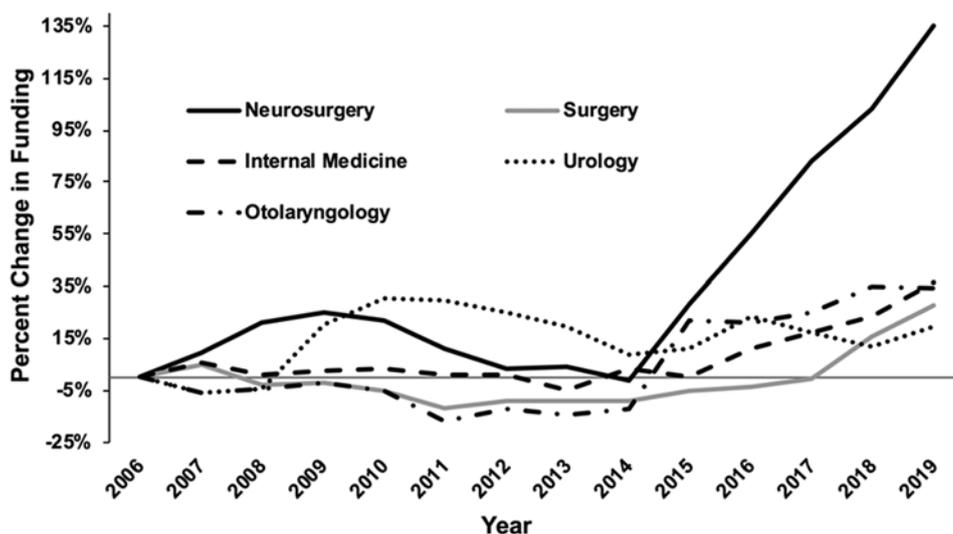


FIG. 3. Comparative trends in percentage change in NIH funding from 2006 through 2019 in neurosurgery (135% increase), urology (20%), otolaryngology (34%), general surgery (28%), and internal medicine (36%). Total annual funding in this panel includes both clinician/surgeon-scientists and non-clinician-scientists.

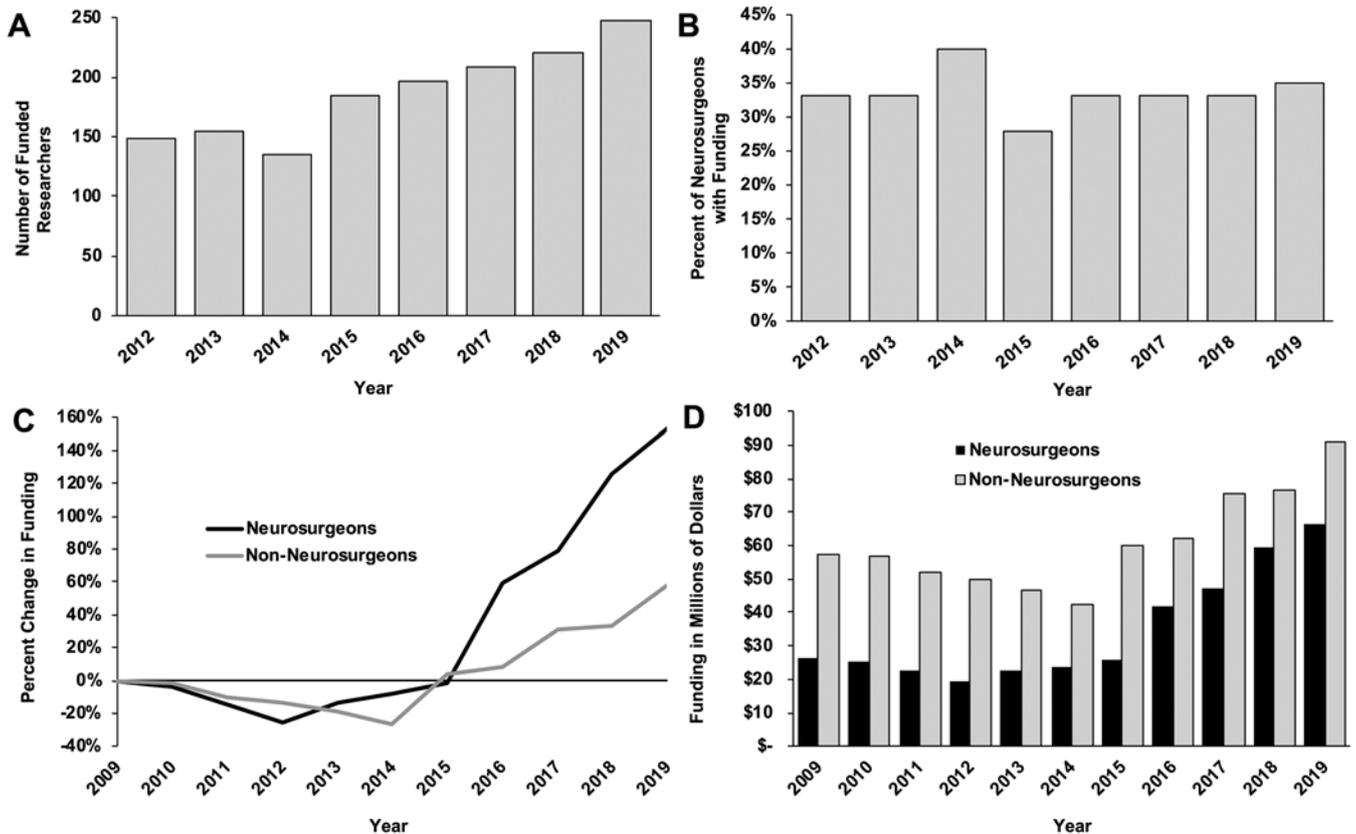


FIG. 4. A: Annual total number of clinician/surgeon-scientists and non-clinician-scientists in neurosurgery departments from 2012 through 2019. **B:** Annual percentage of neurosurgeon-scientists making up the total number of scientists and surgeon-scientists in neurological surgery departments from 2012 through 2019. **C:** Comparative trends in percent change in NIH funding allocation to neurosurgeon-scientists compared to non-neurosurgeon-scientists in neurosurgery departments from 2009 through 2019. **D:** Annual total NIH funding in millions of dollars to neurosurgeon-scientists compared to non-neurosurgeon-scientists in neurosurgery departments from 2009 through 2018.

to further strengthen the early-career research success of R25 graduates and to reduce the number of those funded who transition to private practice. Three key areas have been identified as necessary for achieving this goal: 1) to refine the selection process to ensure that residents chosen for support are firmly committed to a career of research accomplishment; 2) to identify the optimal training year(s) for supported research that will result in an ongoing commitment to and successful entry into funded research careers; and 3) to identify potential approaches that would enable those supported during residency to maintain the viability of an ongoing project while returning to clinical duty in the final year(s) of residency.

The K12 Award (NRCDP)

A significant obstacle to successfully launching a research career is the transition from residency to a faculty position. The NRCDP was designed to bridge this high-risk transition period. The NRCDP is overseen by a large (15–18 members) National Advisory Committee that provides career and research guidance for the first 5 years after training completion. In addition to providing a platform for applying for and potentially receiving research funding in an environment that is career stage appropriate, the NRCDP holds an annual retreat for new NRCDP ap-

plicants, prior or current K12 scholars, neurosurgeon-researchers (junior and established), and department chairs to promote the development of a strong, cohesive neurosurgeon research community that provides both support and mentorship.

The NRCDP is a highly competitive program with a selection process that includes an application, interviews, and detailed planning with a local mentor. It directly supports research for neurosurgeon-scientists in the first 2 years of the faculty appointment with the goal of launching those supported into NIH-funded research programs. The award requires departmental support and a commitment of 50% protected time for research for 5 years. Although initially designed to exclusively support neurosurgeons who left their training institution, the NINDS partnered with the Congress of Neurological Surgeons in 2015 to provide an opportunity for support to neurosurgeons who stay on as faculty at their training institution.

This comprehensive program, which involves not only grant support but also mentorship, oversight, community building, and strong departmental support for launching a research career, has resulted in exceptional success. Eighty-five percent of K12 recipients who completed the award have thus far received NIH and other major federal funding (Table 3). Unexpectedly, through the involvement

of organized neurosurgery, a large number of neurosurgery faculty across the country, and more than 50% of neurosurgery department chairs, the NRCDP appears to have stimulated growth in NIH funding of established investigators (see below).

Although the most common originating subspecialty areas of research included functional/epilepsy (37% of funded awards) and neuro-oncology (32%), applications have been funded proportionally to the application number across the subspecialty areas (Table 2). These data indicate that subspecialty sections and/or departments can increase funding in various areas that have traditionally submitted fewer applications and received less NIH funding (e.g., peripheral nerve, spinal disorders, pain, and trauma) by encouraging investigators in these areas to pursue research, obtain high-quality mentorship, and develop high-quality applications.

The NRCDP has also helped applicants not funded by the K12. Eighty percent of unfunded K12 applicants continue to pursue NIH support. The initial effort to help unfunded K12 applicants achieve research success was pursued exclusively at the K12 annual meeting. In 2018, the NINDS partnered with the American Academy of Neurological Surgery to launch the Emerging Investigators Program, which is designed to complement and expand upon the efforts of the K12 program. These programs provide year-round mentorship and guidance for junior neurosurgeons who continue to pursue research funding and have robust departmental support for this pursuit. Thus far, 35% of the unfunded K12 applicants have secured NIH funding (Table 3).

Growth of Neurosurgeon Research Funding

Factors Underlying Growth of Independent Neurosurgeon-Scientists

The number of NIH-funded neurosurgeon-scientists has grown dramatically since 2015 (Fig. 1). Because those funded by the R25 and K12 programs needed to complete training and/or establish their early faculty research programs, there was an expected lag from inception of the programs to increased funding of early-stage/new investigators. However, the increase in number of NIH-funded neurosurgeons was not restricted to those directly supported by these newly created in-training and early-career programs (Fig. 1).

In the absence of other contributors (e.g., an increase in NIH pay line or NIH research grant initiatives targeted to neurosurgeons), there are specific factors associated with these two programs that are probably responsible for the broader increase in NIH-funded neurosurgeon-scientists. First, a large number of specialty leaders have participated in these programs to create an environment of critical support. More than 70 senior faculty, including more than 30 department chairs, have participated in mentorship activities for the R25, NRCDP, and Emerging Investigators Programs. More than 50 department chairs have endorsed the NRCDP by committing to allowing junior faculty to devote 50% of professional effort to research for 5 years in the event the NRCDP would provide just 2 years of research support. Second, the involvement of national neurosurgical organizations has led

to the development of a large and growing community of neurosurgeon-scientists across the country. The Congress of Neurological Surgeons has supported the R25 annual meeting since its inception and directly supported additional K12 awards by donations to the Foundation for the NIH. The American Academy of Neurological Surgery, through the Emerging Investigators Program, has devoted meeting time and created annual workshops for continuing mentorship and training for early-career researchers who are trying to obtain NIH funding. Finally, attention to NIH research opportunities has been integrated into national neurosurgical meetings. National neurosurgical organization collaboration with the NINDS has markedly increased attention to the importance of research within the field. Research-related sessions have been incorporated into all the national organizations' annual meeting programs, which has led to greater attention to opportunities and facilitated collaborations for both junior and senior neurosurgeon-scientists across the country. Based on the totality of these efforts, neurosurgeons at all career stages have been encouraged (and helped) to pursue NIH-funded research programs.

Overall Funding Growth

NIH funding for neurosurgery has increased significantly faster than for surgery, other surgical subspecialties, and internal medicine over the last decade (Fig. 2). Despite the recent emphasis by surgical specialties on growing nonclinical research faculty to increase NIH funding,^{39,40,43} neurosurgery academic departments have grown overall NIH funding primarily through increased funding to neurosurgeon-scientists (Figs. 1 and 4). Critically, as total NIH funding and the total number of NIH-funded researchers (neurosurgeon- and non-neurosurgeon-scientists) in neurosurgery departments grew, the ratio of neurosurgeon-scientists to non-neurosurgeon-scientists remained stable (mean 33.3%; Fig. 4). However, the funding for neurosurgeon-scientists grew disproportionately faster than for non-neurosurgeon-scientists, underscoring the comparatively larger award amounts granted to surgeons. This growth in the population of neurosurgeon-scientists, and the accompanying growth in federal funding of neurosurgeon research, is critical to the overall research mission of treating and curing disease, because the expertise required to understand the causes and treatment of disease, as well as the development of technologies used to treat patients, will undoubtedly need individuals who have an in-depth understanding of both the science and the clinical issues related to the disease.

Conclusions

The described approach to grow the population of neurosurgeon-scientists underscores the potential for developing clinician-scientists in other specialties, including surgical specialties. Genuine support by departments (during both training and early faculty years), a concerted effort to provide strong scientific mentorship, and a supportive community of practicing clinicians provide the critical tools for committed individuals to become successful NIH-funded scientists.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Lonser, Korn. Acquisition of data: Smith, Tennekoon, Rezai-Zadeh, Korn. Analysis and interpretation of

data: Lonser, Smith, Tennekoon, Rezai-Zadeh, Korn. Drafting the article: Lonser, Tennekoon, Korn. Critically revising the article: Lonser, Smith, Tennekoon, Rezai-Zadeh, Korn. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Lonser. Statistical analysis: Lonser, Smith, Tennekoon, Rezai-Zadeh, Korn. Administrative/technical/material support: Lonser, Ojemann, Korn. Study supervision: Lonser, Korn.

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