Infectious Diseases Research Recommendations for the 120th Congress

Infectious Diseases Society of America

Introduction: America's medical research enterprise has delivered tremendous progress in preventing, diagnosing and treating infectious diseases. As new pathogens are constantly emerging and "old" pathogens continue changing, our nation needs a well-coordinated, adequately resourced medical research enterprise capable of meeting patients' needs today and anticipating and preparing for tomorrow's threats. The way research is supported should be modernized to meet public health needs and better leverage scientific opportunities to maximize the impact of federal investment. The ideas below to achieve this overall goal offer critical starting points that could be pursued collectively or individually and are not intended to be exhaustive.

1. **Prioritize stable and sufficient infectious diseases research funding**

Our nation needs to maintain its infectious diseases workforce and pipeline of trainees. Uncertainty about the availability of research funding is a major barrier that deters many interested individuals from pursuing careers in ID research. Delays, lapses and cuts in funding slow the progress of research, lead to job losses and reduce the return on investments in science.

Recommendations

Appropriations: Allocate consistent annual funding for the National Institutes of Health (NIH), including the National Institute of Allergy and Infectious Diseases (NIAID), with increases that are, at a minimum, commensurate with increased costs of conducting research. Increases should be sufficient to incentivize and support early-career researchers and address emerging infectious diseases threats and scientific opportunities.

Congressional oversight: Monitor NIH and the Office of Management and Budget to ensure that congressionally appropriated funding is allocated to researchers in a timely fashion, aligned with congressional intent and scientific merit.

Facilities and administrative (F&A) costs: Implement the Financial Accountability in Research (FAIR) model to replace the current F&A cost structure. FAIR would utilize a total-project-costs calculation to determine indirect costs to reduce confusion and disparities across research institutions and ensure researchers receive the support they need. The model requires greater accountability from universities to demonstrate that funds provided for essential institutional research support are being spent appropriately.

2. **Modernize grant review to improve transparency, timeliness, health impacts and fairness**

Current grant review processes have not kept pace with changes to academic and medical research systems and the way scientific studies are done. Slow review timelines, lack of clarity

about why a grant is or is not funded, and bias slow the pace of scientific progress and discourage many promising individuals from pursuing research careers.

Recommendations

Expert evaluation of grant review processes: Direct the National Academy of Medicine to assess NIH grant review policies and make recommendations for improvement. Assessment should include the perspectives of researchers across career levels and disciplines, academic institutions of varying size and geographic areas, clinicians and patient advocates. Assessment and recommendations should focus on ensuring the system rewards scientific merit; provides timely decisions and actionable feedback to applicants; balances basic, clinical, translational and implementation science; addresses urgent and emerging health needs impacting Americans; incentivizes early-career investigators; supports researchers throughout their career span; makes research available to scientists and patients in all communities; mitigates bias regarding institutions, researchers and political views; and enables international collaboration to improve the health and preparedness of Americans.

3. **Recruit and retain infectious diseases researchers**

The U.S. is failing to recruit, train and retain sufficient infectious diseases researchers, including physician-scientists, leaving us without the workforce necessary to lead the discovery and development of new strategies and tools to prevent, diagnose and treat infectious diseases. The ID physician-scientist workforce is particularly critical to bridge the gap between research and clinical medicine, ensuring that research is patient-focused and clinically applicable.

Recommendations

Invest in grants and programs to support early-career researchers*:* Increase funding for T32, F31 and K awards and provide direction and oversight to ensure these mechanisms are being used to support early-career investigators, including physician-scientists. Increase funding for R38 Stimulating Access to Research in Residency grants, to help foster physician-scientist careers early in training. Assessments for grants for early-career investigators should focus on potential and commitment to research, rather than past achievement.

Congressional oversight: Request annual updates from NIH regarding increases or declines in funded investigators at all career levels for each institute and center, investments in programs aimed at supporting early-career investigators and physician-scientists, and their impact. This information should inform investments and policies to sustain and grow the scientific research workforce for infectious diseases and other fields.

Expert evaluation of federal recruitment, retention and support for early-career investigators: Direct the National Academy of Medicine to review existing NIH initiatives to recruit, support and retain early-career investigators and identify gaps and make recommendations for improvement. Review should include perspectives from investigators across career levels and disciplines and academic medical centers of varying sizes across diverse geographic settings. Areas for review could include increasing the number of K award applicants who receive funding; simplifying applications for early-career awards; developing nontraditional pathways for research careers; incorporating multidisciplinary training (e.g., clinical trials, computational science), nontraditional

mentors (e.g., statisticians, informaticists), and leadership and communications training into early-career grants; and creating opportunities to strengthen partnerships with academic medical centers and other non-government entities to recruit and retain early-career investigators.

Permit inclusion of foreign medical graduates in NIH training awards: Foreign medical graduates are an essential part of the physician-scientist workforce and should be allowed to receive NIH training and early-career awards, including the National Research Service Award for Individual Predoctoral (F30, F31) and Postdoctoral (F32) Fellowships, as well as Institutional Training Grants (T32). Mechanisms to recruit and train competitive foreign graduates while maintaining funding for American trainees will enhance our biomedical workforce and provide the U.S. with a strategic edge.

4. **Preserve scientific integrity**

Federal scientific research priorities must be established by scientific experts and based upon patient and public health needs and scientific opportunities, not politics. Stability in medical research investments with a focus on the evolving evidence base to support transformative interventions is essential to maintain research infrastructure and enable scientific progress.

Recommendations

Strengthen firewalls between science and politics (such as through the Follow the Science Act): Limit the number of political appointees at NIH and clearly define the parameters of their role to focus on communicating the overall vision of the executive branch to the agency and to coordinate NIH activities with the White House and other Department of Health and Human Services agencies. Maintain independence of NIH career scientific staff with regard to routine scientific communications and activities, such as grant review, distribution and strategic prioritization of funding.

Establish in statute the NIH Grants Policy, which had been in place through 2024, to allow grant cancellations only for the following reasons: failure to comply with terms and conditions of the grant, material failure to carry out the approved project, serious deficiencies affecting public health or welfare, mutual agreement or recipient request. Decisions regarding cancellation should only be made by career scientific staff.

5. **Strengthen infectious diseases research infrastructure for basic, clinical and implementation science**

Strengthening and maintaining a well-coordinated infectious diseases research infrastructure is essential to meeting patient needs and preparing for biothreats. A strong infrastructure is more cost-effective and better able to advance scientific progress and deliver the new vaccines, diagnostics and cures that Americans depend upon. Significant important investments have been made in ID research infrastructure, but not all have been adequately maintained, and there are gaps and opportunities for modernization.

Recommendations

Establish more "core" facilities and repositories: Core facilities and repositories, like those that exist for biodefense and emerging infections, hard-to-make biologic reagents, and materials for

genetic disease research, provide information and materials that investigators at all institutions can access and utilize. This approach is significantly more cost-effective, allows more scientists and labs to conduct research, improves quality control through standardization, and expands data-sharing, as compared to requiring individual academic medical centers to develop their own duplicative infrastructures. Core facilities and repositories should be established to support other high-impact research fields, including research on diagnostic tests for infectious diseases, microbiome therapeutics, and artificial intelligence and machine learning.

Protect basic science: Ensure funding streams are maintained to support basic science in infectious diseases research, recognizing its unique role in underpinning future breakthroughs and its importance in preparing for infections that may emerge and spread in the future.

Strengthen clinical trial infrastructure: Direct the Government Accountability Office to conduct a review of existing infectious diseases clinical trial networks and other clinical trial networks with relevance to infectious diseases (e.g., for chronic conditions that make individuals more susceptible to infections) to identify gaps where insufficient clinical trial infrastructure exists for high-impact infectious diseases, opportunities for improved collaboration and coordination across networks, and barriers to that collaboration and coordination. Given the high risk-high reward nature, basic research is dependent on government investment as it is considered too risky for pharmaceutical investment even though companies benefit from and leverage successful basic research findings for product development.

Create novel financing mechanisms and targeted funding to address antimicrobial resistance and other underfunded major health threats: Antimicrobial resistance (AMR) is a major threat to human health that is undermining the foundation of modern medicine. Increase dedicated AMR research funding at NIAID to support early-stage research on novel antimicrobial therapies, new platforms for antimicrobial development, strategy trials to optimize use of existing antimicrobials, validation and clinical utility studies of new diagnostic tests, development and impact of vaccines for resistant pathogens, and epidemiological studies to understand how patient characteristics may impact outcomes for patients with resistant infections. Enact legislation, such as the PASTEUR Act, to create a new financing mechanism for novel antibiotics and antifungals to address the market failure and ensure sustained innovation and availability of novel antimicrobials.

Better leverage electronic health records for infectious diseases research: Direct the National Academy of Medicine to convene experts across the field of infectious diseases research and health information technology to study and make recommendations on the optimal utilization of electronic health record data for infectious diseases research, including how to make the data appropriately accessible for research questions and quality assessments.

Invest in implementation science, pragmatic research and programs to ensure new interventions reach the patients who need them: Investments are needed to address bottlenecks and difficulties in conducting implementation studies and large, pragmatic studies, including electronic health record integration, automated outcome capture, data networks, simplified consent approaches (where appropriate) and common data standards. Implementation science can significantly improve responses to infectious disease outbreaks in rural communities; antimicrobial stewardship and infection prevention and control in low-resource settings; HIV prevention and care; and pandemic preparedness.

6. **Expand research in rural and other underserved areas**

NIH research dollars are disproportionately allocated to academic medical centers with existing research capacity, and understandably so, as researchers in these settings are best positioned to utilize this funding for maximum benefit to the American people. Researchers at these institutions deliver important lifesaving science, and their work must be maintained. In addition, expanding access to research funding for investigators at smaller institutions can expand opportunities for more to participate in clinical trials and other studies, and while also growing the research workforce. Currently, infectious diseases fellows training at smaller institutions are often unable to receive the additional training necessary to launch a research career as a physician-scientist.

Recommendations

Increase funding for Institutional Development Awards to statewide or multistate networks that build clinical research infrastructure, coordinate studies across institutions and expand the ability to conduct clinical trials.

Establish and test a pilot grant program to foster infectious diseases research partnerships between larger academic medical centers and smaller hospitals to expand the reach of NIH dollars to researchers and patients at smaller institutions. This pilot program should match early-career researchers with more senior investigators and projects at larger institutions and provide sufficient funding to support mentorship.

7. **Preserve and increase global research capacities**

International collaborations are necessary to advance our knowledge of how to prevent, diagnose and treat many infectious diseases that are more common outside of the U.S., but that threaten American travelers and the U.S. military. Increased global travel can easily increase the prevalence of many of these diseases in the U.S., and conducting international research boosts our readiness. Additionally, for many conditions, limiting research to the U.S. adds significant costs to studies, slows recruitment and significantly delays the results and innovations. Finally, many diseases traditionally considered to be uncommon in the U.S., such as dengue, malaria and Chagas disease, are now encroaching on our borders.

Recommendations:

Remove barriers to international research collaborations: Reverse the NIH prohibition on foreign subawards.

8. **Reduce administrative and regulatory barriers to research**

Administrative burdens slow the progress of research and add to its cost, making it increasingly difficult for people to pursue research careers, especially at smaller or lower-resourced institutions.

Recommendations

Direct the National Academy of Medicine to review and make recommendations to reduce administrative burdens for medical research, such as overly lengthy grant application processes and the frequency and detail of progress reports.