

Research News Quarterly

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Letter from the Editor

Welcome to the inaugural edition of the *ATS Research News Quarterly*! This new publication will provide updates and announcements from all of the research programs that the ATS monitors, including the National Institute of Health (NIH), Centers for Disease Control and Prevention (CDC), the VA Research program, the Agency for Healthcare Research and Quality (AHRQ) and the Environmental Protection Agency (EPA). The quarterly is a collaboration from the ATS Washington office and the Research Advocacy Committee, which I chair.

This edition features a personal interview with the new Director of the National Heart, Lung and Blood Institute (NHLBI), Gary Gibbons, M.D. In this interview, Dr. Gibbons lays out his vision for the institute through a balanced scientific portfolio across basic, translational, clinical, and population research and articulates key goals on addressing health disparities and his commitment to sustaining “the largest and most talented biomedical workforce in the world.” Dr. Gibbons also challenges the research community to become more strategic, efficient, and effective in delivering the return on the NIH investment as a response to the tightening fiscal climate.

The long-awaited release of the report on the status of VA laboratory infrastructure is another feature story, along with the news on the newly-established Office of Emergency Care Research at the National Institute of General Medical Sciences. Finally, we urge you to respond to our call to action for ATS members to mobilize advocacy to avert implementation of budget sequestration funding cuts that would devastate our nation’s biomedical research and public health systems.

We hope you enjoy the first *ATS Research News Quarterly*!

Sincerely,



Augustine Choi, M.D.
Editor



Interview with new Director of the National Heart, Lung, and Blood Institute, Gary Gibbons, M.D.

1) What is your vision for the institute over the next five years?

As I begin guiding this great institute, I consider it important to build upon the enduring principles that have made the NHLBI such a successful and respected steward of the public's resources and health for nearly 65 years. These foundational principles include maintaining a balanced portfolio that recognizes the value and synergy of basic, translational, clinical, and population research; applying new knowledge toward improvements in public health outcomes in all communities; elucidating and eliminating health disparities; maintaining a commitment to sustaining the largest and most talented biomedical workforce in the world; training and nurturing a diverse cohort of the next generation of researchers; and engaging and educating the public. We are in a new era of opportunity to innovate, enable collaborative synergies, and apply new scientific tools to confront health problems. As the NHLBI moves toward its 75th anniversary, we foresee opportunities to "bend the curve" of chronic diseases and begin to envision the "remission" of heart, lung, and blood disorders with advances in areas such as predictive health, reparative biology, and systems medicine. It is an exciting time for biomedical research and care, and I am looking forward to both the challenges and the opportunities that lie ahead as we work together with this dedicated community to make a difference on a national and global scale.

2) Lung diseases are now the third-leading cause of death in the United States. As director of the NHLBI, how do you plan to address this shifting burden of disease?

The cornerstone of the Institute's response to the increasing burden of lung diseases is clearly scientific research. We will need to strive continually to assure that the research we support is innovative, is highly relevant to public health, and will have a high impact. As a part of our efforts to ensure that the research we support is productive and is leading toward improvements in patient care, we must keep in mind that most lung diseases are highly heterogeneous. It is because of their heterogeneity that we must maintain the balanced approach I noted previously. The NHLBI needs to keep its lung portfolio broad

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Gary Gibbons Interview *(Continued from page 2)*

and diverse, so that it encompasses everything from basic molecular studies to large-scale genomic efforts, if we are to be able to understand, treat, and cure such complex diseases. Another important step toward reducing mortality from lung diseases is empowering the public by increasing their awareness and understanding of these disorders. Partnering with communities and with organizations such as the ATS is essential if we are to be able achieve that goal. We have seen wonderful progress in this area through our combined educational efforts and health campaigns such as the Learn More, Breathe Better® program and the National Asthma Education and Prevention Program (NAEPP). To cite one success, COPD awareness continues to rise, especially among smokers. Now we need to make sure their increased awareness translates into increased visits to their doctors, so that we can ‘bend the curve’ on the more than 12 million Americans who are estimated to have undiagnosed COPD.

3) What is your vision for promoting translational research, and its application to human disease for diagnostics or therapy - will it rely on NCATS programs or will the institute also unveil new programs?

The NHLBI remains committed to accelerating the translation of basic discoveries to the clinic, and I look forward to continuing to fulfill that responsibility on multiple fronts. We will certainly continue to work with other components of the NIH and especially with NCATS when opportunities arise, but we will also work with the investigator community such as members of ATS to make use of the innovative programs already in place at the NHLBI. For example, we recently initiated the SMARTT program (Science Moving towArds Research Translation and Therapy) to support the pre-clinical testing of potential new therapies for heart, lung, and blood diseases. These tests are critical to establish the safety and efficacy of potential new drugs and transition them from the lab to the clinic. NHLBI has

piloted some innovative new programs including the translational program projects in lung disease, and the centers for diagnostics and experimental therapeutics (CADET) aimed at exploring potential target(s) for validation to determine which are amenable for development of mechanism-based modalities for direct clinical application in the prevention, diagnosis, and treatment of pulmonary diseases. The Phase II Clinical Trials of Novel Therapies for Lung Diseases provides a mechanism for testing promising agents, possibly re-purposed drugs or combinations of drugs.

4) What opportunities do you see for increased collaboration with industry and pharmaceutical companies for the promotion of clinical trials leading to drug development?

As I noted earlier, historically the NHLBI has thrived on collaboration, and I expect to continue that pattern. With such a broad mission we really cannot go it alone, and with such a wide range of potential partners, we should not try. All forms of partnerships that will allow us to leverage our resources and complementary expertise will become increasingly important as we move forward in these fiscally uncertain and potentially challenging times. But let me make clear that financial considerations are not the only imperative for partnering. True partnerships are often the most effective way of coming up with creative ideas about how we can do our research, translation, and education more efficiently and more cost-effectively. One successful model at the NHLBI is the public-private partnership we have with the Foundation for the National Institutes of Health (FNIH) to support research to identify biomarkers for COPD through the SPIROMICS program. The COPDGene study has also been successful in engaging the pharmaceutical industry in partnerships that have also involved a patient advocacy organization, the COPD Foundation. Another example is the collaboration between NHLBI and the Pulmonary Hypertension Breakthrough

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Initiative that has resulted in a new program to support research on human pulmonary hypertension.

5) As you know, federal budget limits and the looming sequestration are likely to impose severe limits on future federal support for biomedical research. What steps do you see NIH taking and NHLBI in specific taking, to ensure continued federal support for research?

The mission of the NIH is foremost to improve human health and well-being, and our commitment to that mission has not and will not be changed by variations in our appropriation. I am encouraged that the public and policymakers are becoming increasingly aware that the United States is the preeminent leader in the biotechnology sector of the global economy and that NIH plays a significant role in promoting innovation, job creation, workforce development and economic growth across every district in the United States. It is important for the NHLBI to work with its investigator community to enhance public's understanding that the advances in medicine that we enjoy today reflect the dividends on investments in NIH made decades ago. The NHLBI and organizations such as ATS are the stewards of the future health of our children. The arc of time that links discovery science to advances in health spans a generation. Our current grant support of fundamental discovery science is the seed from which future medical breakthroughs will grow. The lives and well-being of the next generations will be determined by the investment decisions we make today. We recognize that in the current fiscal environment, our scientific community must be more strategic, efficient, and effective in delivering the greatest return on investment of the public's resources. Given that the NHLBI oversees research on three of the four leading causes of death and disability in the U.S— we still have some 'unfinished business' and much to offer to enhance the future health of the nation. I am excited by the privilege to work with the NHLBI community in the collective effort of building upon a proud legacy of extraordinary

success over the past 65 years, by seizing the unprecedented opportunities in discovery science and emerging technologies to improve health for the nation and indeed for the world. ■

VA Research: Infrastructure Report

VA Releases Report on Research Infrastructure: Persistence Pays Off

For years, the American Thoracic Society and its colleagues in the world of advocacy for the VA research program have been trying to bring attention to the large infrastructure needs in the VA research program. Armed mostly with anecdotes about instances of inadequacies in VA research laboratories, the ATS and its allies were largely unsuccessful in getting Congressional attention, and more important, funding to address VA research infrastructure. Four years ago, a VA Subcommittee of ATS's Research Advocacy Committee was created. The VA Subcommittee identified correcting deficiencies in the VA's research infrastructure as one of its advocacy goals. The Subcommittee held meetings of VA investigators at each of the last four ATS International Conferences. The diminished state of research laboratories was identified as a potential impediment to recruitment and retention of ATS members as physician investigators at some VA facilities.

Congressional Report

In an attempt to advance the issue from anecdotes to hard data, the ATS and its sister organizations were successful in getting report language inserted into the FY2006 Military Construction/VA Appropriations Bill. This language directed the VA to conduct an

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internal audit of the infrastructure needs in VA labs and provided financial support for the review. The hope and expectations were that the VA would conduct the audit, produce a public report that would document the needs of the VA research program, and give Congress the concrete information it needed to begin to fund VA lab infrastructure improvements.

The Wait

At Congressional direction, the VA did engage in an internal audit of VA lab facilities. However, the audit was started by one contractor and then later transferred to another contractor to finish, thus adding delay to completion time of the project. Then the report got stuck within the VA approval process, further delaying its release. At the Research Advocacy Committee's annual Advocacy Days on Capitol Hill, the issue of the need to support refurbishing of VA research laboratories was raised as one of the issues for discussion during numerous meetings between Congressional staff and members of the ATS's Research Advocacy Committee. After several years of effort, the report finally was released to the public in August 2012.

The Report

The report describes surveys of 74 VA campuses and 171 laboratory buildings and documents an estimated \$774 million in critical VA lab infrastructure improvements. Of the \$774 million in documented need, VA currently has budgeted only \$178 million in planned lab improvement projects, leaving a funding gap of \$595 million.

What's Next?

The long delay in the release of this report, and its arrival during a time of looming fiscal austerity, make advocating for VA research funds challenging. However, the ATS, its Research Advocacy Committee, and its sister organizations will use this report to educate Congress on the unmet needs in the VA lab infrastructure. While no one expects Congress to provide all \$595 million in gap funding all at once, the

hope is that over time Congress will provide funding to start tackling the backlog of VA lab infrastructure projects. The report identifies 71 percent of the overall costs as for Priority 1 or 2 needs, that is for deficiencies that should be corrected within two years. This characterization of the deficiencies may assist in persuading Congress that the deficiencies should be addressed soon. ■

RESEARCH FUNDING Looming Budget Sequestration Threatens NIH

As the nation is gripped in the run up to the presidential election, an enormous threat to U.S. leadership in biomedical research is looming--budget sequestration. Sequestration refers to \$1.2 trillion in across-the-board budget cuts to all discretionary programs, including the National Institutes of Health, the Centers for Disease Control and Prevention, and all global health programs that are scheduled to go into effect on January 2, 2013, if Congress and the President do not enact an alternative plan.

The plan for sequestration was enacted as part of last year's deficit control agreement between Congress and the Administration, following the failure of the congressional Super Committee to enact a comprehensive agreement for reducing the deficit. The funding reductions are estimated at 8.2 percent per agency, and many programs may face more than this reduction in order to offset exemptions for other programs. Some agencies and programs are exempt from sequestration. These include Medicaid, Social Security, Food Stamps, Assistance to Needy Families and all Veterans Administrations programs, including the VA Research Program.

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Medicare benefits are exempt but cuts of 2 percent to providers are specified in current sequestration plans.

Sequestration reductions would amount to a cut of up to \$2.5 billion for the NIH, reducing funding from \$30.7 billion in FY2012 to \$28.3 billion, which would put NIH back to FY2006 funding levels. Such a funding reduction would have an immediate and significant impact on NIH, which has already seen its spending power decline over the past two years as a result of increases below the biomedical research inflation rate.

NIH Director Francis Collins has estimated that NIH would have to cut 2,500 – 2,700 extramural project grants, with additional intramural reductions. The cuts would further translate to 33,000 job losses throughout the country and a \$4.5 billion loss in economic activity. This substantial reduction in the NIH budget would follow a 12 percent drop in the number of NIH-funded research grants between Fiscal Year 2002 and Fiscal Year 2010 and the decline in research opportunities, particularly for young investigators, has become a significant concern for the research community. Finally, the potential loss of scientific progression if sequestration is applied to NIH will be keenly felt by patients and their families, who will have to go longer without innovative new treatments, diagnostics to identify diseases earlier and preventative therapies.

The stakes are even higher for other agencies that do not enjoy the level of public and bipartisan support than NIH does, such as CDC, the Agency for Healthcare Research and Quality (AHRQ) and global health programs through the U.S. Agency for International Development (USAID). Because it is predicted that additional programs may receive exemptions from sequestration, CDC and other programs that do not have large support constituencies may have to absorb cuts larger than 8.2 percent. This will come at a time when state public health programs have already been cut significantly, leaving communities vulnerable to flu and tuberculosis outbreaks. In global health efforts, a cut of 8 percent or more to USAID's tuberculosis

program would force the agency to withdraw or substantially cut technical assistance to several highly burdened countries and/or curtail support for clinical drug trials, further delaying the pipeline for a new TB drug.

So what is the likelihood that full budget sequestration will occur? ■

New Office of Emergency Care Research Opened at NIH

In July, NIH Director Francis Collins, M.D., Ph.D., announced the opening of the new NIH Office of Emergency Care Research (OEGR). The OEGR will be housed at the National Institute for General Medical Sciences (NIGMS). The office will coordinate and promote basic, clinical, and translational research and research training in emergency care across all NIH institutes, although it will not fund research grant opportunities.

The OEGR was created in response to recommendations from the NIH Emergency Care Research Working Group and findings from a 2006 Institute of Medicine report that found that the U.S.'s emergency medical system is overburdened, underfunded, and highly fragmented. The NIH Workgroup identified many different emergency research and training opportunities funded at various institutes and determined that a coordinated, trans-NIH approach would advance emergency care.

In addition to working closely with the Trans-NIH Workgroup, the OEGR will organize scientific meetings to identify new research and training opportunities in emergency medicine, coordinate emergency care

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research funding opportunities across NIH institutes and centers and foster career development for trainees in emergency care research. This will include assisting investigators identify grant opportunities. The office will not be supporting research on health care infrastructure, systems of health care delivery or logistical responses to natural disasters, such as planning logistical responses to disease epidemics and natural disasters, as most of these efforts are managed through the Agency for Healthcare Research and Quality.

Walter J. Koroshetz, MD, deputy director of the National Institute of Neurological Disorders and Stroke (NINDS), will serve as acting director of the OECR

while a search is conducted for a permanent director. Alice Mascette, MD, senior clinical science advisor in NHLBI's Division of Cardiovascular Science, will serve as deputy director. A steering committee chaired by the NIGMS Director, Judith Greenberg, PhD, and composed of directors of institutes with a key role in emergency medicine including the NHLBI, NINDS, the Eunice Kennedy Shriver National Institute of Child Health and Development, and the National Institute of Nursing Research will oversee the new office. The office will report annually on progress towards its goals to improve outcomes for patients in emergency care settings. ■