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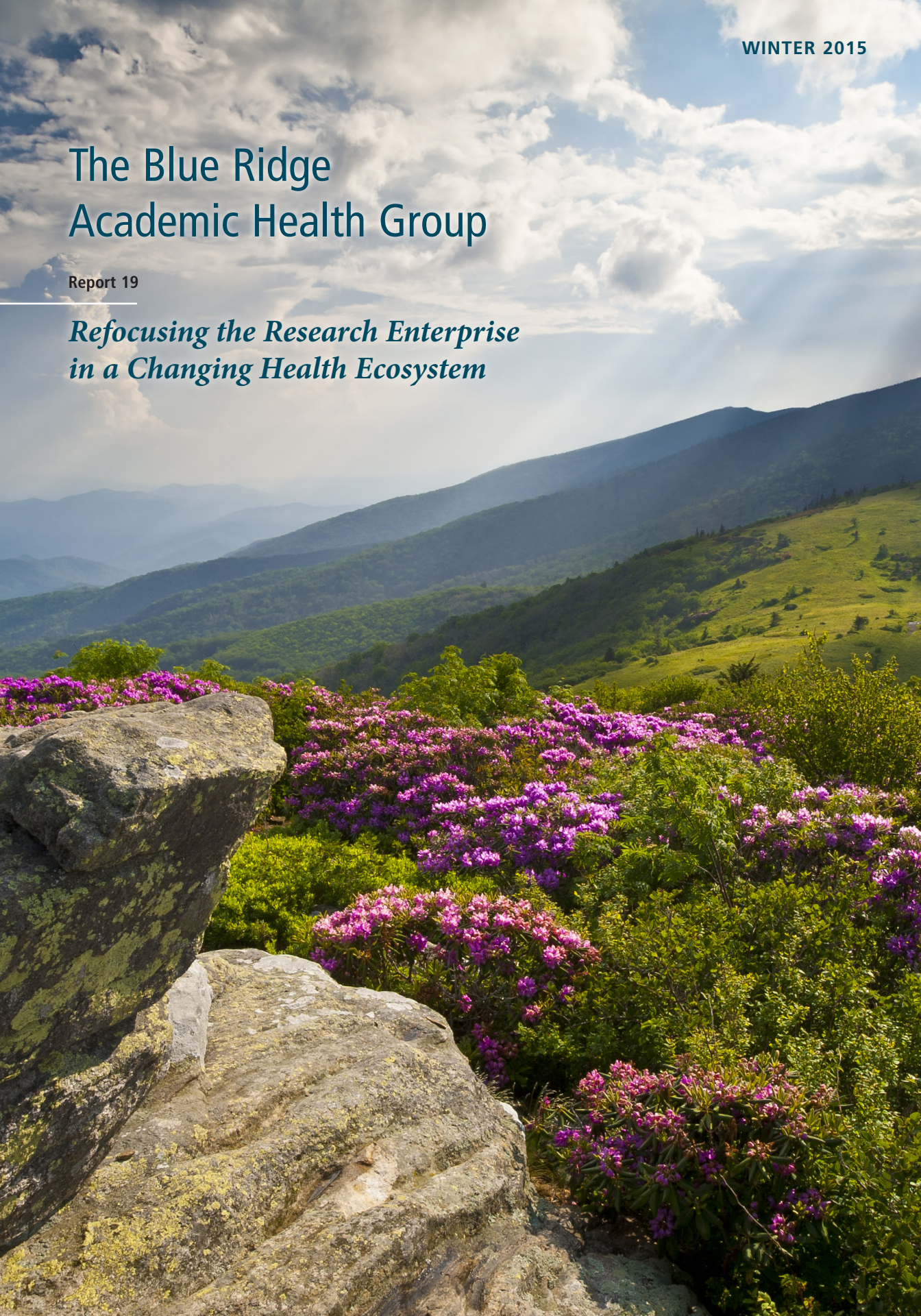
The Blue Ridge Academic Health Group

Report 19

Refocusing the Research Enterprise in a Changing Health Ecosystem



Refocusing the Research Enterprise in a Changing Health Ecosystem *is the 19th in a series of reports produced by the Blue Ridge Academic Health Group. The recommendations and opinions expressed in this report represent those of the Blue Ridge Academic Health Group and are not official positions of Emory University. This report is not intended to be relied on as a substitute for specific legal and business advice. Copyright 2015 by Emory University.*

MISSION: The Blue Ridge Academic Health Group seeks to take a societal view of health and health care needs and to identify recommendations for academic health centers (AHCs) to help create greater value for society. The Blue Ridge Group also recommends public policies to enable AHCs to accomplish these ends.

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(August 2014 meeting)

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Report 19. Refocusing the Research Enterprise in a Changing Health Ecosystem

Executive Summary

The research enterprise in academic health centers (AHCs) must respond with energy and creativity to a new set of challenges and opportunities related to cost, effectiveness, and accessibility of health care—even while academic medicine's traditional mainstay of budget support from the federal government is flat or declining. Academic health leaders must find ways to maintain their commitment to the strong base in curiosity-based science that has made America the world leader in biomedical research. At the same time, they must accept that many of their historical assumptions about funding and organizational structure may be subject to fundamental change.

Against this backdrop, the Blue Ridge Academic Health Group (Blue Ridge Group) believes AHCs will best serve society and honor the academic values and commitments that have made them the pacesetters for world science by following these measures:

- Taking advantage of opportunities in clinical, translational, and health services research, while preserving and continuing to invest in basic science research.
- Aligning the research enterprise across departments, centers, and divisions within each AHC, being responsive to its distinctive mission, culture, and strategic priorities, and building on institutional strengths and commitments.
- Honoring and rewarding the distinctive skills, educational pathways, and career trajectories that reflect these new realities, even where such approaches may differ from the traditional models of success for researchers.
- Understanding that one significant key to innovation in this new era will consist in partnerships and collaborations. Metrics of competition will need to give way to new measures of collaboration and service, as AHCs look for ways to leverage society's investment in research across traditional dividing lines between disciplines, schools, and even entire institutions.

Implementing the changes proposed in this year's report may represent a departure for some AHCs; however, some institutions are taking initial steps along this path, and their experiences are described as case studies in this report.

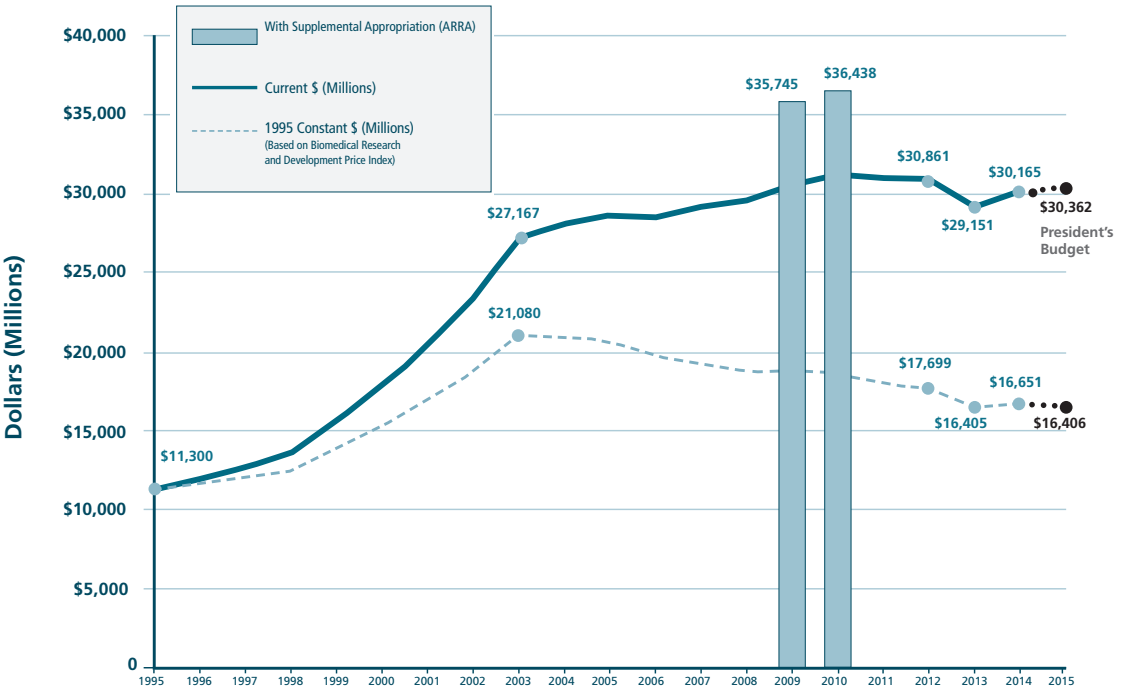
The Case for Change

The appetite for discovery, capacity for invention, and vision for improvement that are embodied in the American research enterprise all remain as vital as they were in the years immediately following World War II, when Vannevar Bush, director of the Office of Scientific Research and Development, wrote his seminal monograph, *Science: The Endless Frontier.*[1] With a provocative declaration that the federal government should commit itself to supporting both basic research and directed research on specific goals, Bush helped set the stage for half a century of unrivalled, university-based, federally financed biomedical research that became the envy of the world. Addressing a charge from President Roosevelt to make recommendations about how best to support science in the postwar world "for the improvement of the national health, the creation of new enterprises bringing new jobs, and the betterment of the national standard of living," Bush made the case for sustaining research in defense of national security and the war against disease. He told Roosevelt's successor, President Truman, that

> The responsibility for basic research in medicine and the underlying sciences, so essential to progress in the war against disease, falls primarily upon the medical schools and universities. Yet we find that the traditional sources of support for medical research in the medical schools and universities, largely endowment income, foundation grants, and private donations, are diminishing and there is no immediate prospect of a change in this trend. Meanwhile, the cost of medical research has been rising. If we are to maintain the progress in medicine which has marked the last 25 years, the Government should extend financial support to basic medical research in the medical schools and in universities.

Figure 1.

NIH Appropriations in Current and Constant Dollars[2]



Source: *NIH Office of the Director, Office of Budget: http://officeofbudget.od.nih.gov/*
REPRODUCED WITH PERMISSION.[2]

A half-century of extraordinary growth followed, but now, there is no denying the diminishing support for research dictated by the current state of economics and politics. Facing big deficits and anemic economic growth, the engine of big science has stalled. AHCs have felt the chill and are catching cold, if not yet pneumonia.

In real dollars, there has been an actual decrease in NIH funding for research, amounting to an approximately 25% reduction since its 2003 peak (figure 1).[2] And within that total, the focus on finding clinical applications for basic science has increased.

Compounding the decline in external funding, careful analysis at a wide range of AHCs, both large and small, public and private, shows that every dollar of funded research must be matched and supported by institutional subsidies of 25% to 40%. A proprietary study of 38 members of the Association of Academic Health Centers who voluntarily furnished financial data about their research budgets revealed that all of them, regardless of size and level of funding, needed substantial subsidies from other sources, chiefly the clinical enterprise and philanthropy, to cover the gaps in research support—and that is even with indirect cost recovery.[3] In short, while vital to excellence, reputation, and continual improvement, research is not a self-supporting activity for any AHC. It can be sustained only by a substantial institutional commitment and funds from other sources.

Within this context, the Blue Ridge Group believes the academic health research enterprise must reinvent itself. The current system is unstable and uncertain. Partly as a function of health care reform, partly from competitive pressures, AHCs by and large anticipate diminishing margins from their health systems to support their academic mission, including research. Knowledgeable and senior observers are talking about how to find new pathways to "sustainability" of the biomedical research system, recognizing that substantial changes will be required from

all major parties—the government, academia, and private industry—if meaningful progress is to be achieved.[4, 5]

AHCs: Organization and Support

The scale of the research enterprise is a significant asset, but that very size also poses significant financial risk for AHCs. In most AHCs, the research enterprise is several times the size of the educational enterprise. For example, extramural research funding in the 50th ranked medical school (based on NIH rankings) was more than $100 million in 2014, while it exceeded $500 million among the most research intensive medical schools. In comparison, undergraduate medical education represents only a $25-50 million budget for most medical schools (Chartis Group analysis). More important, the research enterprise requires significant financial support. In addition, as noted earlier, careful analysis finds few economies of scale in research, with the deficit typically growing in proportion to the size of the research enterprise.

The research enterprise has generally not been managed as a strategic investment despite its scale and economics. For example, consider the following:

- Alignment of the research enterprise with the AHC's overall strategy is often limited, despite the significant funds invested to support research; economic performance is often suboptimal and is generally worsening because of funding constraints. A recent review of basic science departments at one AHC found that about two-thirds of the basic science faculty's research was in areas that were identified as one of the AMC's strategic program priorities. However, most of the faculty members whose research is in the priority programs were not actively involved in those programs; there was no discussion among those doing research in a specific field across departments, e.g., all the neuroscience researchers, and little or no discussion with clinicians (Chartis Group, proprietary client research, 2013).
- Research economics often are not well understood by the faculty, including department chairs. Many faculty and chairs believe the research enterprise is self-sufficient, and they are unaware of the broader financial commitments institutions incur to support this research. Senior AHC leaders generally recognize that their research enterprise does not break even, though the magnitude of the loss is not well documented or understood. For them, it is sufficient that research investments generate ample "social return," even if they do not net positive returns on a balance sheet.
- The ways in which research deficits are funded also generally are not well documented or understood. Most AHCs provide financial support for the research deficit with explicit transfers from clinical, philanthropic, and other funding sources. However, numerous implicit subsidies typically are provided as well by the departments, the dean, and from endowments. A better understanding of the costs and funds flow within AHCs and increased transparency about this funds flow are essential to ensure effective use of the funds invested in research.

Given the many pressures on AHCs, this funding gap must be addressed. Federal funding streams for the research enterprise are under extreme pressure, at least partially as a result of calls to direct funds to competing national priorities. The ability of AHCs to fund deficits is expected to become more difficult because of growing financial challenges for funding clinical care and education, uncertainty about federal support for disproportionate share hospital and graduate medical education payments, and the challenge of providing care to the newly insured.

At the same time, there are opportunities for growth and new resources, but success in the coming years requires that we change strategies, structure, and interrelationships (both organizationally and academically). We can and must use the tools of "Big Data," statistics, and informatics to support new kinds of research and become more effective and efficient.

The development of the Clinical Translational Science Awards and the genomic sciences themselves are refocusing academic institutions from being isolated research universities to becoming much greater collaborators. Advances in information technology and "team science" also are driving this transition. As methods for collabora-

tion improve and inter-institutional partnering increases, however, the additional burdens of federal and state regulations are becoming very apparent. This is particularly true for sharing and managing patient data needed for research. In addition to burdens and costs associated with Institutional Review Boards, which have differing institutional practices, state laws intersect with federal policies and procedures. Conflicting and burdensome federal regulations involving multiple agencies increase administrative overhead, at a minimum, and can preclude some research efforts altogether.

Some researchers continue to feel a tension between HIPAA, passed in 1996; the potential for improving health from the Human Genome Project, which was not even concluded until 2003 but has made great progress since then; and maturation of the Internet from its development in the mid-1990s onward, which now allows large health-related databases to be studied on a scale that was impossible previously. NIH efforts to improve policy relating to human subjects has been incremental, rather than looking at what would support scaling of databases while also offering appropriate security for the data.

The ability to capture and reallocate just a few percentage points of total revenue at the margins would make a tremendous difference for the research enterprise at most centers.

Until recently, there was little appetite in either Congress or the Department of Health and Human Services to do anything about these barriers. However, the 21st Century Cures Initiative of the Energy and Commerce Committee in the House of Representatives introduced in 2014[6, 7] and a few other efforts within Congress seek to enhance the research enterprise through sensible changes to policy and regulation. These efforts deserve great attention and support from AHCs as legislative proposals come forth in Congress. All research institutions should read these documents carefully and identify where additional regulatory clarity and/or relief would result in less expensive and more efficient research operations.

One Person's Waste

The U.S. health care system embodies a tremendous amount of inefficiency. In a widely noted study,[8] PricewaterhouseCoopers found that the U.S. wastes about $1.2 trillion in health care spending every year, slightly more than half of the total $2.2 trillion spent on health care. And despite spending more per capita than any other developed nation, the U.S. achieves only about the 27th-greatest life expectancy at birth.[9] To be fair, this must be understood against a relatively lower ranking among developed nations in the social determinants of health. As analysts at the Organisation for Economic Co-operation and Development put it,

> The slower progress in life expectancy in the United States is due to gaps in health insurance coverage and proper primary care, poorer health-related behaviours and poor living conditions for a significant proportion of the U.S. population.[9]

This crucial context for understanding our nation's health indicators was addressed in the Blue Ridge Group's Report 14.[10]

The research enterprise must help solve the problem of waste in health care through organizational and cultural change.

Three specific subcategories alone added up to more than half the total waste: defensive medicine ($210 billion), inefficient claims processing ($210 billion), and caring for the preventable conditions of obesity and overweight and their health consequences ($200 billion).[8 (p 1)]

Reducing waste, in this sense, is highly congruent with the aims of health services research itself and also with value-added health care. Whether a given AHC's combined academic and clinical budget is $500 million, $5 billion,

or somewhere in between, there are tremendous opportunities to use creativity and courageous leadership to re-envision its strategy and operations. That is our challenge and our necessity. The ability to capture and reallocate just a few percentage points of total revenue at the margins would make a tremendous difference for the research enterprise at most of our centers. It is the thesis of this report that this is both feasible and imperative. And by leveraging the opportunity, we have the capacity—or can develop the capacity—to do so while investing in our own ability to perform health services research.

Health services research reflects the growing necessity to examine what we do and how we do it, so that we may produce improved outcomes for the betterment of our patients, our communities, and society as a whole. AHCs must embrace and ensure funding for the complete spectrum of research, from discovery to implementation, to accelerate improvements in human health and address the drivers of excess cost. A recent article in *JAMA* by Moses and colleagues,[11] argues that the relative neglect of health services research, amounting to $5 billion per year overall in a total U.S. research base of $116.5 billion,

> represents a major missed opportunity to improve many aspects of health, especially as the burden of chronic illness, aging populations, and the need for more effective ways to deliver care are appreciated.

However, the study also finds that such funding has grown 37% over the past decade.

Supporting the Full Spectrum of Research

The growing emphasis on the complementary role of health services research provides considerable opportunities for AHCs. However, taking advantage of the growth areas may require AHCs to recruit faculty with new and different skills. It will also require significant cultural change, along with supporting infrastructure for a different type of research, in some ways resembling engineering or business analysis more than it does the health sciences as traditionally defined. AHCs must have the courage of purpose and the clarity of mind to understand the seismic shifts that are occurring and the agility to move with them. For example, in many cases, the capacities and perspectives we need will be found in engineering schools, which typically have expertise in systems thinking.

At the same time, AHCs cannot abandon basic research, which will remain a defining component of university-based research, as compared with free-standing institutes, national laboratories, and private industry, to name three. Fundamental discovery research is the foundation for breakthroughs that translate into clinical innovations. The heart and soul of America's decades-old supremacy in biomedical science and research has been the close inter-relationship of the best research with the most intense education at the undergraduate, graduate, and professional levels, and we must never relinquish that understanding—both for the sake of AHCs and for the sake of the nation.

Expanding the research budget has historically had strong bipartisan backing. However, AHCs must acknowledge the reality that the current congressional climate is marked by disagreement on how to reduce deficits and provide resources to support the essential federal role in research. This environment necessitates ongoing, nonpartisan advocacy for federally funded research based on economic vibrancy, medical advances for all, and international competitiveness—values that historically have polled strongly across both parties and a wide range of American voters. This also underlines a continuing obligation for AHCs and research universities in general to effectively communicate the value of research findings and their impact.

See "Principles" (page 7) for a summary of conclusions in making the case for change.

Principles Underlying the Case for Change

- Research is an indispensable part of the academic health center's tripartite mission of improving health through research, educating health professionals, and providing care to patients. Discovery science is embedded deeply in the DNA of every academic health system (AHC). Indeed, discovery-based science and innovation is the principal justification for creating and maintaining AHCs in the first place. A sophisticated, ongoing program of research is inextricably linked and woven into all teaching of health professionals that is worthy of the name, and equally so, into all clinical care that represents the state of the art of health science.
- Accordingly, AHCs must continue to prioritize research as part of fulfilling their social contract. Each AHC will need to determine the optimal balance of basic science, translational and clinical science, and health services research based on their unique capabilities and resources. All discovery science that improves care, leads to greater efficiency and effectiveness, and enhances the utility of AHCs to patients and the greater community is important and worth doing.
- Every AHC must be engaged in some program of active research at a level and with a focus commensurate to its mission. The scale, mix, and focus of research programs at various AHCs will naturally vary with their age, heritage, level of funding, capabilities, and community expectations and needs.
- AHCs' funded research programs must increasingly include a focus on their own operations, efficiency, and effectiveness. As large, critical, and indispensable engines of discovery, AHCs' domains of inquiry must include themselves. We must continually interrogate the proposition that society's investment is being well spent, patients are being well treated, students are being well educated, researchers are being well supported and directed, and the future is being well primed with the seeds of advancement, even if some of those seeds may not bear fruit for years or decades.
- Greater transparency should be the default position for AHCs. Building a well-earned reputation for candor, beginning with finance and operations, will enhance the ability of AHC leaders to engage in the kind of strategic decision-making that is necessary to focus and sustain the research enterprise in an era of limits. Transparency with internal constituents, especially with faculty, is essential.
- AHCs must model and embody the changes they recommend. AHCs educate and train the health professionals of the future and are usually among the largest health care providers in their region or state. They must not only share their research findings and recommendations with others, they must build meaningful feedback loops into their own education, training, and health care delivery activities so that they exemplify the very best practice standards in quality, safety, care, and access that they recommend to others. This requires seamless and continual interaction between "academic" and "clinical" sides of the AHC enterprise.

The Case for Convergence

The research and clinical enterprises need to converge to speed the translation of discovery to clinical application and better meet the social responsibility of AHCs to do the following:

- Accelerate value-driven health care
- Create new, more effective therapies
- Improve outcomes
- Improve the health of our communities
- Enhance our societal impact

Obviously, this has major implications for organization and systems: the status quo must change. Convergence should help AHCs maintain strong economic performance and achieve greater efficiency by demonstrating better outcomes and clinical improvements for managing episodes of care and complex conditions. See table 1.

Table 1.
Comparison of Perspectives on Common Challenges Encountered in Fostering Convergence[12] (pp 5-7)

Common Challenge	Multi-Institution Report* (2004)	National Research Council Report (2014)[12]	Blue Ridge Report (2015)
Establishing effective organizational cultures, structures, and governance	■ Institutions should explore alternative administrative structures and business models that facilitate interdisciplinary research (IDR) across traditional organizational structures; institutions should develop equitable and flexible budgetary and cost-sharing policies that support IDR. ■ Allocations of resources from high-level administration to interdisciplinary units, to further their formation and continued operation, should be considered in addition to resource allocations of discipine-driven departments and colleges.	■ Alternative structures must harmonize with the existing culture of investigator and laboratory autonomy. Convergent science fields provide a starting point to organize around compelling scientific and societal challenges. ■ Factors such as differences in cost recovery models among schools of science, engineering, and medicine can complicate intra-university partnerships. Laboratories and core facilities are expensive to start up and maintain.	■ High-performance cultures are needed to select, promote, and reward both faculty and staff for the right qualities and achievements in this new environment. ■ New organizational structures—such as centers and institutes—must be developed to facilitate collaborative interaction, and they must be supported with core/shared facilities and open environments designed to foster interaction across disciplines and groups.

**Facilitating Interdisciplinary Research* (From the National Academy of Sciences, National Academy of Engineering, Institute of Medicine.)

Table 1. (continued)

Common Challenge	Multi-Institution Report* (2004)	National Research Council Report (2014)[12]	Blue Ridge Report (2015)
Addressing faculty development and promotion needs	■ Recruitment practices, from recruitment of graduate students to hiring of faculty members, should be revised to include recruitment across department and college lines. ■ The traditional practices and norms in hiring of faculty members and in making tenure decisions should be revised to take into account more fully the values inherent in IDR activities.	■ Promotion and tenure is still obtained through a primary departmental affiliation for many faculty members undertaking convergent research or associated with convergence institutes. ■ Differences in faculty research and service expectations among science, engineering, and medical faculty may complicate collaborations, although multiple journal authors and diverse research contributors are already a norm within many science fields.	■ Departments or divisions remain the basis of disciplinary integrity, but centers and institutes may be equally important in hiring, promoting, and retaining faculty and talented teams focused on largest-magnitude research questions and areas of need (such as quality, safety, and personalized or precision medicine). ■ Tenure must be recognized and understood as entailing bidirectional obligations between faculty and institution and substantive contributions to the work of teams. ■ Faculty must have career paths that allow meaningful transitions to mentoring, lab management, community outreach, and other forms of service as research productivity wanes.
Creating education and training programs	■ Educators should facilitate IDR by providing educational and training opportunities for undergraduates, graduate students, and postdoctoral scholars, such as relating foundation courses, data gathering and analysis, and research activities to other fields of study and to society at large. ■ Institutions should support interdisciplinary education and training for students, postdoctoral scholars, researchers, and faculty by providing such mechanisms as undergraduate research opportunities, faculty team teaching credit, and IDR management training.	■ Curricula at the undergraduate level need to meaningfully integrate relevant physical, mathematical, computational, and engineering concepts and examples into life science courses and vice versa in order to provide a solid foundation for undertaking convergence. ■ Opportunities are needed to effectively fill in gaps in training and expertise or to learn fundamentals of a new area to foster a common language and understanding. These opportunities are needed at the graduate, postdoctoral, and faculty levels.	■ University-wide or trans-school courses can foster understanding of convergence and holistic comprehension of issues at the undergraduate and graduate level. ■ Internal impediments relating to calendar, credits, and prerequisites may need to be addressed. ■ Student interests, enthusiasm, and creativity are important institutional drivers of change.

Table 1. (continued)

Common Challenge	Multi-Institution Report* (2004)	National Research Council Report (2014)[12]	Blue Ridge Report (2015)
Forming stakeholder partnerships	■ Academic institutions should develop new and strengthen existing policies and practices that lower or remove barriers to interdisciplinary research and scholarship, including developing joint programs with industry and government and non-government organizations. ■ Continuing social science, humanities, and information science–based studies of the complex social and intellectual processes that make for successful IDR are needed to deepen the understanding of these processes and to enhance the prospects for the creation and management of successful programs in specific fields and local institutions.	■ Establishing extramural agreements is complex and may be affected by factors such as different leadership, funding, and cost-sharing models, or different traditions and expectations around issues such as patent development and intellectual property protection. ■ Taking full advantage of the possibilities enabled by convergence increasingly draws upon contributions from fields such as the economic and social sciences, which have their own cultures and norms that must be considered.	■ Great opportunities lie in closing the gaps between academic and clinical sides—schools and health systems—within the AHC to focus on the largest questions of health services research—patient/community engagement, quality, safety, cost and access. ■ Equally great opportunities lie in pooling efforts of AHCs, both within states and in multi-state compacts. AHCs and industry can collaborate to their mutual benefit in areas of AHC expertise and industry need or market opportunity.

**Facilitating Interdisciplinary Research* (From the National Academy of Sciences, National Academy of Engineering, and Institute of Medicine.)

Columns 1 and 2 reproduced with permission from the National Academy of Sciences. Courtesy of the National Academies Press, Washington, DC.[12]

The success of the transformations outlined in table 1 will hinge on strong and sustained leadership and an ongoing commitment to organizational change that recognizes the scale of the challenge and the vital need for shared information, analysis and timely communication at all levels. A recent report from the Association of American Medical Colleges (AAMC)[13] reminds us that the challenges faced by AHCs will by no means yield to top-down decision-making alone, no matter how firm the hand on the tiller might be. Rather, coordinated leadership at many points and levels in our organizations is required, including at the department chair level. Also critical are several new or enhanced positions that must translate, guide, and implement the changes needed to achieve meaningful integration between the academic enterprise and the health system as well as enduring changes and improvements in patient care. They include the positions of chief quality officer, system chief medical officer, group practice president, and chief medical information officer to lead physicians, nurses, and other health professionals and direct clinical processes across hospitals and networks.[13-18]

See "Findings and Observations" (page 11) for a summary of conclusions in making the case for convergence.

Table 1. (continued)

Common Challenge	Multi-Institution Report* (2004)	National Research Council Report (2014)[12]	Blue Ridge Report (2015)
Obtaining sustainable funding	■ Funding organizations should recognize and take into consideration in their programs and processes the unique challenges faced by IDR with respect to risk, organizational mode, and time. ■ Funding organizations should regularly evaluate, and if necessary redesign, their proposal and review criteria to make them appropriate for interdisciplinary activities. ■ Congress should continue to encourage federal research agencies to be sensitive to maintaining a proper balance between the goal of stimulating interdisciplinary research and the need to maintain robust disciplinary research.	■ Government support is one component of obtaining funding for convergence. Many convergence programs have also obtained critical support from sources such as private philanthropists and foundations interested in advancing science. ■ Income from start-up companies and venture capital investors, which may be part of convergence ecosystems, may also provide support.	■ AHCs must continue to work through AAU, AAMC, and others to press the case for sustained basic research funding, which can come in sufficient quantities only from the federal government. ■ AHCs must enhance their own efficiency and effectiveness to maximize their value to government and industry sponsors in areas of mutual interest. ■ AHCs must continue to work hard and creatively to identify and cultivate philanthropic sources of funding—both individuals and foundations—who can help supply critical missing margins and jump-start new initiatives. ■ AHCs should continue to aggressively pursue technology transfer and licensing opportunities to sustain their research enterprise and to maximize their contributions to their communities and to society.

Findings and Observations

- Government, industry, and the public all look to university-based researchers to continue their distinguishing enterprise of basic science. Everyone wants the AHC's goose to keep laying golden eggs. The debate is over who pays for food, drink, and shelter.
- However, the golden age of the "endless frontier" that followed World War II and continued for about half a century is over and will not return in the near future. Funding from all sources has plateaued, at best, and will remain flat or decline in real dollars.
- The traditional funders of basic science are varying their approaches, requiring adaptation on the part of institutions and researchers. While capacity expands for clinical and translational research, implementation science, and health services research, our collective commitment to the basic science which fuels breakthroughs must continue. The pharmaceutical industry cannot replace large-scale public investment in research and, in fact, is becoming less likely to fund broad-gauged institutional grants.
- Private philanthropy cannot replace large-scale public sector investments in research—though

Findings and Observations, continued

it may provide an indispensable margin. First, the scale of philanthropic contributions is approximately an order of magnitude less significant. Second, and equally important, many of the new mega-philanthropists will insist on directing their investments to research, diseases, and causes that are important to them and, in any event, generally will not invest in the requisite indirect cost base to keep the lights on and the heating bill paid.

- Across all AHCs, small and large, research costs the institution money above and beyond what any outside payer will support. AHCs must find sources for the significant cross-subsidy that is needed at every size of institution, according to careful analysis.
- Clinical margins and health care cross-subsidies of research are at risk and in some degree already diminishing in the new competitive landscape of health care and given the new pressures on graduate medical education and other missions. While some specialties currently remain highly profitable, the enterprise increasingly is balancing its budget by the positive margins of just a few key specialties. This cannot be regarded as sustainable for the long term.[13]
- AHCs accordingly must look to their own organization, culture, and administrative overhead to find new efficiencies and become more competitive. The fact that AHCs are often too slow and cumbersome to produce results on the time scale industry can achieve[18] leads to the growing industry preference for striking one-off deals with individual researchers focusing on specific molecular targets or pathways.
- Talent management is a critical part of the research continuum and must be done more efficiently and more strategically at every stage of the process. AHCs must improve hiring, promotions, and strategic direction across the active lifespans of faculty, and they must improve processes for admitting, training, supporting, graduating, and placing students and trainees. These critical investments of time and money are increasingly too important to be left exclusively to departments in a time of global resource constraint. Every hire into a tenure-track position is an institutional commitment and must be made with a clear recognition of institutional opportunities, needs, and strategies. Similarly, the student-to-postdoc-to-first-grant pipeline is far too long and costly and must be shortened and made more efficient.

The Continuum of Research

Government, industry, and society all look to AHCs for "basic" discoveries. New drug/vaccine development timelines are decades long, but all start with fundamental discovery (e.g., Gleevec, Gardasil).[19] While there is a growing belief that computational biology will shorten the lag time between discovery of a genetic marker and its effective targeting by a therapy, it is nevertheless true that serendipity plays a large role in some of our most important advances, and the progress of science is not linear. As Bush[1] pointed out 70 years ago:

> One of the peculiarities of basic science is the variety of paths which lead to productive advance. Many of the most important discoveries have come as a result of experiments undertaken with very different purposes in mind. Statistically it is certain that important and highly useful discoveries will result from some fraction of the undertakings in basic science; but the results of any one particular investigation cannot be predicted with accuracy.

It is sobering to consider that the health and livelihood of our descendants in the 22nd century may depend in ways we cannot imagine on findings being made in obscurity by unknown researchers in university labs today.

However, support for "basic" sciences—whether from NIH or industry—is stagnating, if not diminishing. Researchers and AHCs must increasingly be opportunity-driven to collaborate with industry (e.g., J&J Innovation Centers—see Johnson & Johnson Case Study, this page). NIH funding for basic science amounts to more than $15 billion but has declined by 16.8% over the past decade.[20] The Blue Ridge Group strongly supports maintaining the baseline of national investment in basic funding. No other single actor has the capacity or the ability to wait years, if necessary, for tangible returns, to the degree that the federal government does.[21] Everyone who participates in biomedical R&D needs a robust foundation of serendipitous, curiosity-driven discovery science, which will pay off in unpredictable but dramatic ways, years or decades from now, just as it has historically. As analysts from the Federation of American Societies for Experimental Biology said recently, referring to the impact of sequestration on the research community: "For biomedical research, 2013 was a terrible year to have a great idea."[2]

Case Study: Doorways to Collaboration with Johnson & Johnson

With more than $71 billion in annual sales, Johnson & Johnson (J&J) is the world's largest health care company, divided into three chief divisions: consumer products, medical devices, and pharmaceuticals. In a transition that is typical of the pharmaceutical industry in general, J&J is changing the way it has traditionally done business with universities and academic health centers.

The era of the institutional mega-grant is giving way to a new approach in which J&J strives to build close collaboration with individual investigators working in areas of specific interest. The company will continue to look to academia for basic research, especially research that identifies molecular targets that look promising in defined disease areas such as oncology, immunology, neuroscience, cardiovascular research, metabolism, and infectious disease, according to J&J's chief medical officer, Joanne Waldstreicher.[22]

J&J believes it shares common challenges and goals with academia, especially when it comes to serving patients and bettering society. But the company also believes it can meet its vision of "transformative innovation" more effectively by working with specific investigators who have deep expertise and interests, rather than with institutions. The company has increased its funding for externally conducted basic science, looking for the creation of "win-win" collaborations with external scientists around the world.

"We still have some big academic collaborations, where we give money to an institution to collaborate in an area of mutual interest, but we may do fewer of those," says Waldstreicher. "We have some good lessons learned. We have learned the real value of working with individual researchers, working on specific problem statements or targets we are interested in, more so than with the big institutions."

Asked why, she says: "We found that with big grants, there might be less accountability, collaboration, and shared vision for the outcome and sometimes a misunderstanding in the concrete deliverables."

One notable successful academic collaboration is the Yale Open Data Access (YODA) project in which J&J is collaborating with Yale to make anonymized clinical trial data accessible to researchers unaffiliated with either institution in an effort to serve independent evaluation and outcomes assessments.[23, 24] The researchers at YODA have a specific passion for and expertise in transparency and data sharing, a common passion of researchers at J&J.

In J&J's new approach, the company has opened four Innovation Centers—in California, Boston, London, and Asia-Pacific. These centers each have satellites, along with some associated incubators for early-stage biotech and other science companies. "We want working with us to be a win-win," says Waldstreicher. "We are very flexible. If you have an interest, we want it to be beneficial for researchers to work with us—so that it can lead to financial returns for both of us, and importantly, so we can turn their discoveries into products that meet unmet medical needs."

Worldwide, J&J is currently involved in hundreds of early-stage R&D projects with external collaborators. Although more than half are with

academic or biotech partners, academic collaborators alone are only about one-quarter of the total. How should universities or AHCs interested in working with J&J proceed? "Visit or contact our innovation centers," says Waldsteicher. "Understand what our targets are. They would be happy to see you; or they can come and visit you."[22, 25]

* * *

AHCs increasingly must focus their research enterprise so that they differentiate around their strengths, reflecting their individual histories, mission, opportunities, scale, and scope. Not all AHCs will be expert in multiple areas of research. Researchers, in turn, must align with their AHC's overall strategic direction and priorities.[18]

What role remains for disconnected, fundamental, curiosity-driven research? The future will depend on constructing "win-wins" that protect a vital margin for basic science. However, the limited availability of external funds for fundamental, discovery-based research will necessarily result in greater selectivity and focus around strengths and areas of strategic opportunity.

Supporting Basic Research in a Transdisciplinary Frame

We are in an era of unlimited discovery potential in the biological and biomedical sciences, the result of decades of fundamental research. A seeming paucity of advances in the 1990s was, in retrospect, partly attributable to industry chasing "blockbuster" drugs instead of systematically capitalizing on what basic science is making possible in terms of the acquisition of new targets. Now, a new alliance between industry and academia, revolving around these new understandings, promises to accelerate new drug development—against the conventional wisdom that the Human Genome Project has largely come up dry.[26]

New therapies have emerged as the product of a long pathway or pipeline of discovery, in some cases stretching back decades to early-stage, basic research insights. Evidence suggests we are now at a time of quickening change in the discovery model.

- Innovative therapies require validated molecular targets—typically genes or proteins.
- Academic research labs can accomplish these molecular discoveries.
- Pharmaceutical/biotech funding can contribute to the development of new molecular-based therapies.[19]

This ongoing revolution, or evolution, is being driven by new and powerful techniques that allow for molecular-level analysis and precise genetic manipulation of organisms, from microbes to man. Molecular biologists and physician-scientists now collaborate with engineers, mathematicians, statisticians, chemists, physicists, and computer scientists to address the great questions in science and medicine that run the gamut from basic discovery to the development of new treatments to sustain health and treat disease.

Team-based science can accelerate discovery and, in fact, will increasingly be the bellwether of advances. AHCs must support this new reality by developing new organizational structures to facilitate collaboration. Appointment and promotion standards must be able to recognize the team contribution of faculty, and physical space must be designed to accommodate collaborative, team-based science.

But the elephant in the room is that our historical organizational structures and our metrics of pre-eminence continue to be anchored in siloed approaches and assumptions.[18] Convergence (a desired approach) will continue to be impeded by AHCs' guild identity, administrative and organizational structures, reward/recognition systems, and departmentally based revenue incentives and resource controls.

In order to meet the extreme demands of the rapidly dawning new era, AHCs cannot afford to accomplish convergence at the margins while maintaining traditional structures and cultures, including unaligned incentives. We must keep pushing for the changes that will make convergence the assumption of those committed to research, discovery, and application. Sustained and profound organizational change will require clear vision, bold leadership, and motivational communication. Indeed, as Enders and Conroy[13 (p 7)] put it,

Leaders must become agents of change rather than protectors of the status quo. The broad gap in readiness to operate as a system, the lack of well-established primary care systems, troubled histories of engagement with local communities, limited experience in managing risk contracts, relatively high cost structures and inexperience with partnerships combine to create a significant handicap for even the most far-sighted and determined leaders. The added complexity of aligning an expanding clinical enterprise to educational and research programs also in need of re-engineering creates a further challenge for leaders.

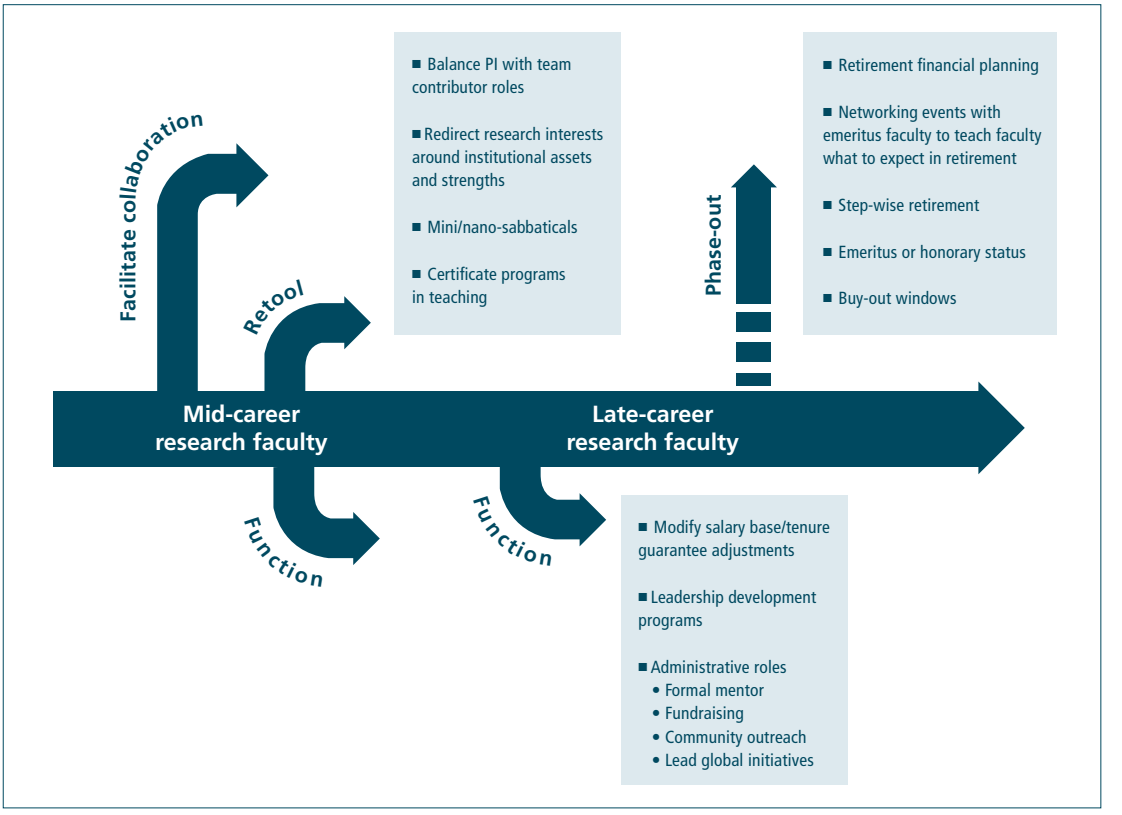
One critical marker of convergence must be defining career pathways for faculty that honor academic values, including the core value of tenure, but construct models at each phase of a lifetime that are economically sustainable, flexible, and humanly feasible. Figure 2 illustrates one such construct, thanks to the AAMC's Advisory Panel on Research.[27]

Changes in the funding climate make it unrealistic to use the same calipers for individual achievement going forward that have been historically applied in the post-war period. Consider the implications of figure 3,[2] for example, at a time when the size, scale, and staffing of the typical AHC have all increased.

Note in figure 3[2] that the number of competing R01 awards has actually *decreased* by nearly 15% across the 20-year period, and consider the implications for traditional criteria of promotion and tenure. Consider also a recent study that found less than 1% of all scientists published at least one research paper every year from 1996 to 2011.[28] Clearly the terrain has shifted and is con-

Figure 2.

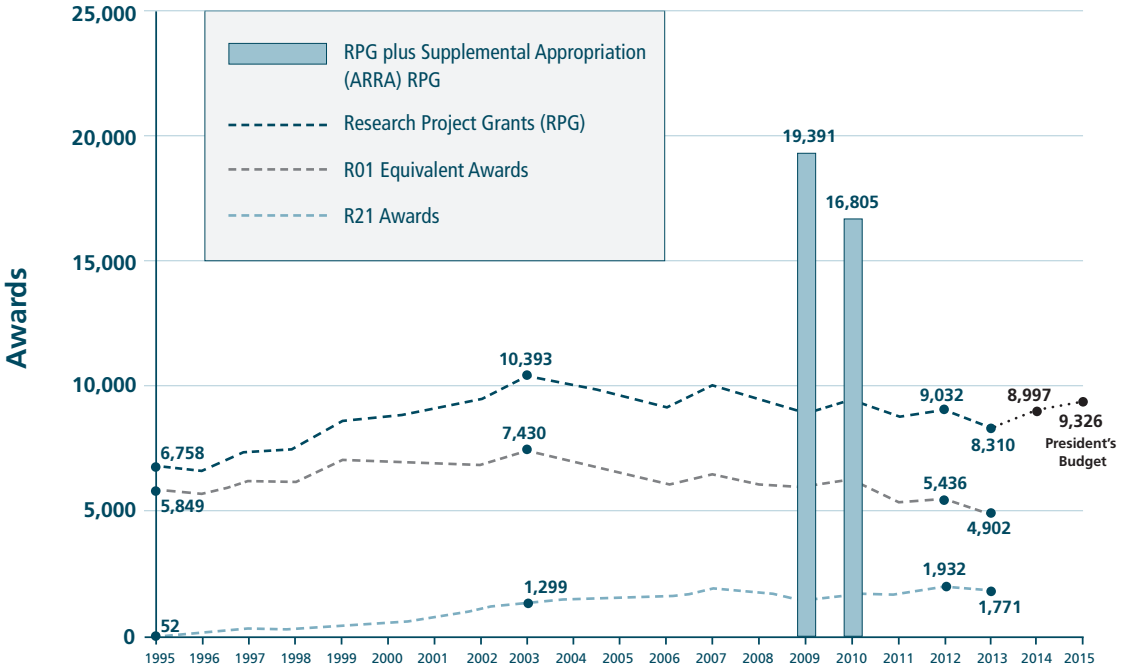
Research Faculty Career Development Pathways: Respect, retool, change function, adjust salary[27]



Source: *AAMC Advisory Panel on Research: Research Issue Briefs, 2013-2014*
REPRODUCED WITH PERMISSION.[27]

Figure 3.

Number of Competing Awards (with Breakout of R21)[2]



Source: *NIH Data Book: http://report.nih.gov/nihdatabook/index.aspx and supplemental tables available in RePORTER*

REPRODUCED WITH PERMISSION.[2]

tinuing to change for what were once considered career norms.

Of equal concern, from the standpoint of career pathways and talent management, is the success rate for first-time NIH grant applications. Across the board, they are down significantly from 1995, and only about half of what they were in 2000 (figure 4).[2]

AHCs must be mindful of what is ideal and what is feasible as they look to their educational, hiring, and tenure pipelines in an era of funding constraints and the changing variable of large research groups and team science, both within and across institutions. Again, the ecosystem for researchers is changing, and we must continue to adapt.

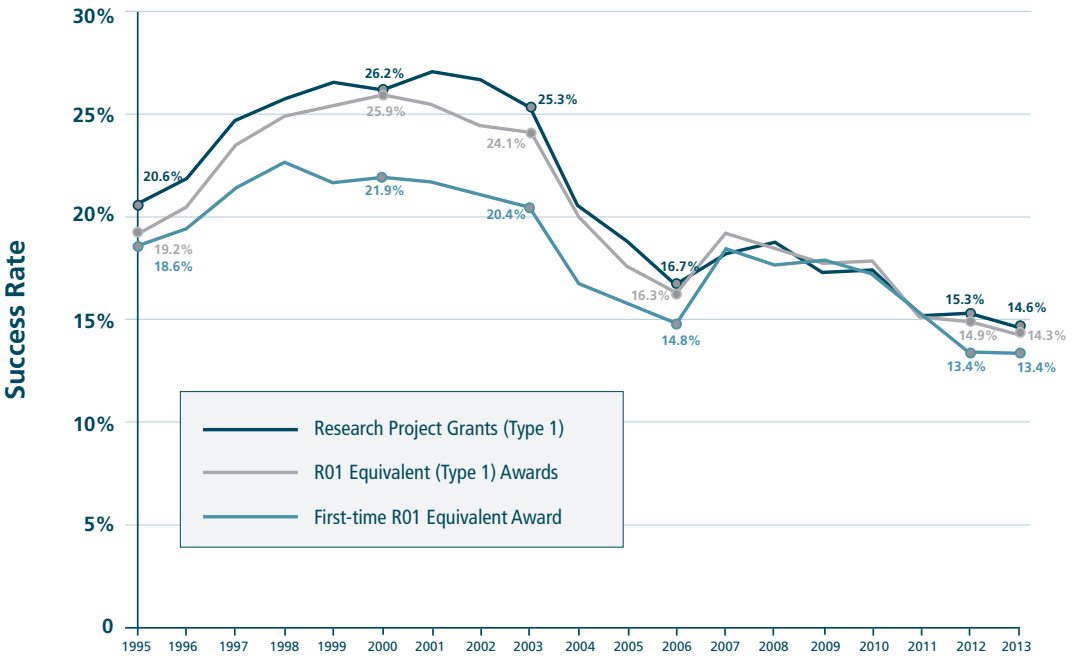
Changes are needed to measure and promote success for faculty across the career path:

- Front end: shorten postdoctoral fellowships and time to first independent research.[19]
- Mid-career: focus on respect, recognition, promotion paths for faculty serving institutional priorities (such as cross-cutting health services research and QI implementation) that do not necessarily result in sponsored research grants and traditional publication.
- Late-career: redefine tenure; find productive models for researchers with slowing productivity to contribute institutional service, mentoring, community outreach; or identify other mechanisms to improve the financial viability of the overall enterprise and provide the resources to invest in strategic priorities.

Fortunately, there is evidence from AAMC that many institutions are beginning to recognize these realities and are in the early to mid phase of responding appropriately, as shown in a faculty personnel policies survey from 2012 (figure 5).[27]

Figure 4.

Success Rates for New (Type 1) Applications, Including First-time R01 Awards[2]



Source: *NIH Data Book http://report.nih.gov/nihdatabook/index.aspx and supplemental tables available in RePORTER*

REPRODUCED WITH PERMISSION.[2]

Extending the Continuum

Persistent gaps within and without AHCs must be closed—especially the gap between the academic (research- and teaching-oriented) and clinical (patient-oriented, clinical revenue-generating) sides of the house. To do that effectively, academic medicine must look to other parts of their own universities—including business and engineering schools. Academic leaders within AHCs need to explicitly recognize and embrace the engineering science base underpinning health system performance improvement.

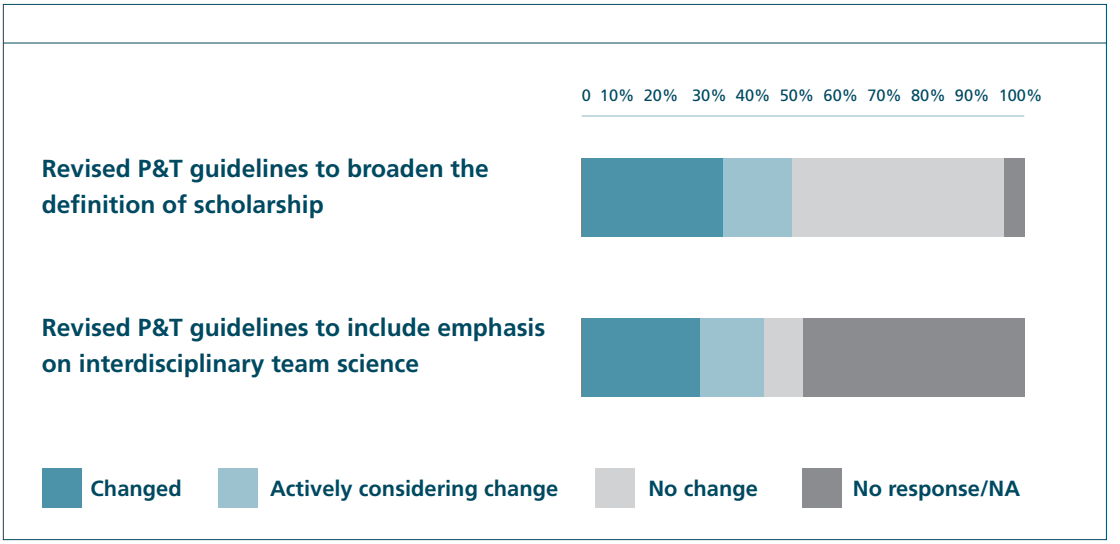
In addition to the many other aforementioned considerations mentioned, the out-year prospects for health care reimbursement make it clear that academic health systems will come under increasingly intense pressure. Their ability to shift revenues from a few remaining high-premium, subspecialty areas is expected to disappear. A recent AAMC report,[13] warns of the "collapse" of clinical margins under unremitting pressure from Medicare and Medicaid,

> putting enormous tension on the component parts of the AMC [academic medical center] to compete for scarce resources and limiting the ability of clinical services to cross-subsidize the academic missions.[13 (p 3)]

In this environment, the study warns, AMCs will face only four options: form a system, join collaborative networks, merge into a system, or "shrink in isolation."[13 (p. 5)] The bottom line will be to find creative ways to become leaner and more efficient, better at providing care, more effective at managing chronic diseases, adept at using advanced information technology, and capable of improving the health of communities.

Figure 5.

AAMC Data: Changes to Promotion, Tenure 2008-2012[27]



Source: *AAMC 2012 Faculty Personnel Policies Survey Recent Changes Report.*
Data from LCME accredited institutions (112 respondents)
REPRODUCED WITH PERMISSION.[27]

Case Study: Emory-Georgia Tech Healthcare Innovation Program

Now entering its fifth year, a novel program founded on a partnership between Emory University and Georgia Tech has made surprising discoveries—and resulted in gratifying, unexpected achievements. Fred Sanfilippo, MD, PhD, executive director, gives credit to the rich health care and research ecology of Atlanta, as well as the strong appetite of researchers within and across participating institutions to find others with whom they can partner and collaborate.[29] That's a need that the Emory-Georgia Tech Healthcare Innovation Program (HIP) was designed to fulfill.

Institutional goals were to expand the quality, scope, impact, and recognition of health services research, without creating an expensive new operating unit at either institution. Health services research was defined simply and elastically as any research designed to improve the cost, access, and quality of health care.

Like the proverbial mustard tree, HIP began with a seeming pittance—less than $150,000 a year in operating budget and one-half FTE staff support. Much has grown from that kernel.

The first step was to inventory existing grants at both Emory and Georgia Tech to see what lines of health services research already existed. Surprisingly, although there was much relevant activity in Emory's Rollins School of Public Health, there were even more health services research grants at Georgia Tech than there were at Emory. These were based largely in the College of Engineering, in the discipline of industrial and systems engineering. The entire canvass turned up more than 250 funded projects with more than 200 participating faculty.

A data-rich website, hip.emory.edu, was developed to promote information sharing and networking. An external advisory board was appointed, representing nine AHCs and other groups from outside the state of Georgia. External members were generous with their time, information, and advice. Other members came aboard. HIP university participants now include Morehouse School of Medicine and Georgia State University; health systems include Emory Healthcare, Children's Healthcare of Atlanta, Grady Health System, and the Atlanta VA Medical Center; and other organizations include the Atlanta Clinical & Translational Science Institute (ACTSI), the American Cancer Society, Kaiser-

Permanente, and the Centers for Disease Control and Prevention.

Within institutions, HIP brought together schools and disciplines in a new way. For example, at Emory, liaisons were drawn from all the health professions schools but also from arts and sciences, business, and law, as well as Emory Healthcare. Significantly, HIP became an information-sharing bridge for quality improvement efforts in Emory Healthcare and academically based health services research.

Another major form of outreach and activity was creating student activities and symposia and identifying representatives from each participating institution. "You can get a lot done with students," says Sanfilippo. "Students drive a lot of these activities." HIP offers them not only a chance to meet and collaborate with each other within and across institutions but also the opportunity to identify and reach out to faculty members in relevant research areas.

In addition to holding annual symposia on the subject "U.S. Healthcare: What's Broken and How to Fix It," the HIP has held six rounds of grants competition and awarded 14 $25,000 seed grants to date. The grants are being funded by ACTSI and participating institutions. Awards have gone to cross-institutional teams that involve 220 faculty from Emory, 51 from Georgia Tech, 23 from Georgia State, 12 from Morehouse School of Medicine, two from Duke, one from the University of Georgia, and one from Northwestern. Hospital staff from all four participating institutions have been awarded grants.

Metrics of effectiveness are elusive, but two types of measures seem promising.

One metric is the number of people who have been engaged in the work of HIP. More than 1,750 persons from more than 50 institutions have been involved in HIP's various programs in some way. In addition, since 2011 HIP's website has had more than 56,000 visits from all 50 states and 155 countries.

And although it is difficult to prove causation, the work of HIP over the past four years is correlated with a dramatic upsurge in externally funded health services research at Emory. From FY11 to FY13, health services research funding increased by $22.9 million, even while all other sponsored research was declining (see table 2). The bulk of the health services funding is from NIH, and the bulk of the *increase* is from NIH.

"A 150K annual budget that is associated with a $23 million increase in funding two years later is probably a good return on investment," says Sanfilippo.

* * *

The Blue Ridge Group believes it is past time for AHCs to engage in a comprehensive and sustained critique of their own research enterprises and health systems (as they regard their academic

Table 2.

Emory FY 2011 versus FY 2013 Health Services Research Funding[29]

	FY 2011	FY 2013	Change	
Health services research	$27.4M (5.1%)	$50.3M (9.9%)	$22.9M (84%)	p<0.0001
Other	$512.2M (94.9%)	$456.8M (90.1%)	-$55.4M (-11%)	
Total	$539.7M	$507.1M	-$32.6M (-6%)	

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"partners")—to wit, our institutions can be too slow, too expensive, and too inefficient in their use of outside dollars as applied to the needs of society.[18]

However, in every crisis there is opportunity. In this case, we are awash in new potential to apply academically rigorous health services research—defined as research focused on improvements in the functioning of the health system itself—to our own institutions. Subjects of this research can include administrative structures and services; systems support; and structural, functional, cultural, and operational separation of health care and research, even within the same institution.

Strengthening the whole enterprise bolsters basic science and research at every stage of the continuum. Health services research itself is increasingly being funded by internal and external sponsors, but often the rigor and benefits of health services research are not being applied systematically to the health systems in the same institutions where the researchers are found. To close this circle, right in our own backyards, would undoubtedly be transformative for the provision of health care in America.

As we witnessed the debate over a relative handful of Ebola cases in the United States in 2014, who could not be struck by the fact that this health crisis—which riveted the White House, the national media, the governors of leading states, and the mayors of large cities—reflected two crucial dimensions of biomedical research? Each seemed as important as the other in terms of how health care is ultimately received and experienced by the individual patient and by society at large:

1. The failure of the R&D pipeline to provide us with adequately tested vaccines and drugs—even though at least one promising vaccine candidate had been brought to the point of clinical trials nearly 10 years ago, when it had to be put on the shelf for lack of money.[30]

2. Striking disparities in a patchwork of guidelines, protocols, training, and preparation that resulted in early expressions of confidence by public health authorities being undercut by cases of illness occurring inside the U.S. When health care workers contracted Ebola despite—allegedly—following recommended protocols and wearing the prescribed protective gear, governors responded by ordering quarantines that were neither medically supported nor politically popular with many Americans.

Writing in JAMA online about the Ebola epidemic in West Africa, Boozary and colleagues[31] make the case for understanding "quality as a cure" in health care, with three important aspects: safety, effectiveness, and respect for the dignity of individuals. Failing to maintain focus on these three elements leads to distrust of the health care system, which in turn causes behavior that helps perpetuate epidemics in places like West Africa, they say. Extending the argument, who is to say responses in the U.S. would be so different if we in this country were ever to witness an outbreak of a high-mortality disease with hundreds of new cases per week (much less thousands)? They observe:

> Ensuring that systems are built or rebuilt centered on basic principles of quality assessment and improvement is imperative. Moreover, this must be done in ways that build trust with the local communities by treating patients with dignity. When people receive care that is unsafe or ineffective, or they are not treated with respect, it is little surprise they avoid further care. Preventing such "betrayals of trust" through a systematic focus on quality is crucial, for both the current epidemic and the next.

Case Study: University of Michigan Institute for Healthcare Policy & Innovation

Now in its third year, the Institute for Healthcare Policy & Innovation (IHPI) at the University of Michigan, ncrc.umich.edu/research/initiatives/ihpi, has become one of the leading university-based generators of health services research—for both the private and public sectors.

IHPI exemplifies how transdisciplinary institutes can work within a school- and department-based academic setting, with strong central support and unceasing communication aimed at magnifying its impact on university colleagues and external constituencies alike.

Launched in 2011 when Michigan took over a site adjoining its campus that had been previously

owned by Pfizer, IHPI has the mission of studying how health care works; improving quality, safety, affordability, and equity; and advising policy makers. Today, IHPI has more than 400 faculty members. Slightly more than half, 58%, come from the medical school, while the remainder come from 11 other schools and colleges and a handful from local groups outside the university.

John Z. Ayanian, director and the Alice Hamilton Professor of Medicine, says IHPI was founded by the university with strong backing from the Regents in order to have an impact on the provision and improvement of health care and population health.[32]

Reporting directly to the dean of medicine and with a national advisory board, IHPI has a strong core in health services research, including a strong data analytics hub, and it is organized for outreach so research findings move quickly into the public discourse.

With its own communications and government relations staffing as well as support from the university in these key domains, IHPI created an "impact accelerator," led by a professor of medicine with communications staff support, that is "focused on helping members communicate research more effectively to policy makers, the public and private sector, and the media and general public so work we are doing is used by decision makers in the health care system," said Ayanian.

The institute is located in 77,000 square feet of space, representing an investment of about $12 million, with an additional 10,000 square feet of newly renovated space being added in September 2015. It was backed with annual appropriations in the $2.5-$3 million range for its first five years.

So far, the investment is paying off handsomely. IHPI researchers garnered more than $82 million in health services research funding during FY13 and published 1,980 articles in 807 journals—including 138 articles in high-impact journals such as *JAMA* and *NEJM*.

IHPI's policy efforts, though, are going well beyond the theoretical. Michigan is one of the 27 states that opted to expand Medicaid under the Affordable Care Act, and the state legislature mandated modifications that required a waiver from CMS. However, as one of the conditions of the waiver, the state was required to commission an independent evaluation of the expanded Medicaid program. Seeing an opportunity to engage in high-impact work, IHPI applied for the job and was awarded a five-year contract by the Michigan Department of Community Health.

Additionally, a number of IHPI faculty participate in collaborative quality initiatives funded by Blue Cross Blue Shield of Michigan designed to analyze care and improve outcomes at hospitals across the state. Data is pooled on a confidential basis, and Michigan faculty oversee collection and analysis.

Going forward, Ayanian says, IHPI anticipates major new forms of collaboration with its own University of Michigan Health System, once the health system completes a multi-year implementation of the Epic electronic health record that began in 2010. That looming prospect points to the challenges as well as the opportunities in marrying academic research capacities to clinical services business, in academic health systems housed under the same roof.

Other issues, faced by many cross-campus centers and institutes, include how to account for indirect cost recovery on IHPI grants brought in by researchers who work both in and out of IHPI-assigned space and how to recruit, promote, and tenure researchers who have their academic homes in departments but spend much of their professional lives in transdisciplinary team activities in IHPI. An important challenge is how to measure and communicate the impact of faculty members' research on health policy and health care delivery.

Constructing New Metrics for Success

It is increasingly obvious that current gauges of reputation and ranking are unsustainable for all but a few universities and AHCs. The corrosive effects of a *U.S. News & World Report,* "Top Ten" mentality as applied to 141 medical schools are being widely felt. Just as it is painful and inappropriate for institutions to all try to squeeze through the neck of a funnel, so it is with individuals.

Grant-getting and high-impact journal publication are increasingly difficult for individual researchers as well. Collaborations and partnerships directed to defined needs and outcomes must be the hallmark of the new order (see table 3).

AHCs must develop new metrics for their own ratings, to reflect their own missions, values, and achievements against meaningful measures of patient outcomes, community health, and societal impact. A side-by-side measure of "traditional" and "forward-looking" metrics is provided in table 3. An analogy could be drawn to developments in the area of undergraduate education. *U.S. News & World Report* pioneered "beauty-contest" rankings that reward richly endowed, highly selective institutions. *Washington Monthly* has responded with what it calls "a different kind of college ranking," one that turns the *U.S. News* ranking on its head:

> Instead of lauding colleges for closing their doors to all but an elite few, we give high marks to institutions that enroll low-income students, help them graduate, and don't charge them an arm and a leg to attend.

One promising example in the area of academic health is that of the Quality Leadership Awards given by the University HealthSystem Consortium (UHC) to recognize member achievements in performance improvement.[33, 34] Experience suggests that these awards can be locally significant in enhancing the perceived credibility of member AHCs. Other such efforts could be developed, connecting institutions with the needs and goals of their internal and external communities of interest.

Conclusion: Collaborate and Conquer

Growth in the unfunded costs to sustain the current models of research will require AHCs to do the following:

- Focus their research investments in the areas of greatest strategic opportunity.
- Redirect resources away from areas that are not aligned with strategy or are less productive.
- Reduce inefficiencies in the current model.
- Improve the depth and breadth of expertise required to provide core services (e.g., shared services in such areas as research administration that historically have been departmentally controlled).

Greater collaboration will be required to make best use of scarce resources within each institution and as a sector. That will be true across

Table 3.

Academic Metrics		Metrics that Matter to Others[27]
■ **Bibliometrics** ■ **Funding received** ■ **Publications** ■ **Citations** ■ **Patents/licenses/start-ups** ■ **"National/international prominence"**	+	■ **Impact on institution** ▪ Reputation ▪ Changes to clinical workflows, cores, policies, vision ■ **Impact on education and training** ▪ Student, resident outcomes ▪ Collaborations ▪ Graduate questionnaire responses ■ **Impact on patients, other persons, and communities** ▪ Outcomes ▪ Quality metrics ▪ Engagement

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departments and schools within universities and also across institutions.

Five CEOs of leading AHCs, writing recently for the Institute of Medicine, concluded as much,[35] as they considered essentially flat NIH research budgets from 2010 to 2020, amounting to a projected 25% shrinkage in purchasing power:

> AHSs [academic health systems] will need to forge partnerships with each other and with those holding private sector research resources. New research capacities and funding streams can take advantage of patient care and related data systems as tools in developing novel and accelerated clinical research and knowledge translation strategies.

Underlining the point, the CEOs added:

> In addition, the financial constraints that come with shrinking NIH research support compel the AHS community to look to alliances within the commercial community for the sponsorship of research on clinical interventions. Emerging recognition of the multifactorial nature of disease processes and treatments compels the engagement of partner investigators across disciplines and institutions.

These are some of the salient considerations that led to the establishment of PCORnet—the National Patient-Centered Clinical Research Network—which is a major initiative of the Patient-Centered Outcomes Research Institute (PCORI).

Case Study: Leveraging the Electronic Health Record for Clinical and Translational Research at Vanderbilt

An early investment in electronic health records, along with one of the country's largest groups in bioinformatics, numbering approximately 70 faculty members, is beginning to pay off in changed medical practice patterns at Vanderbilt University Medical Center, says CEO Jeff Balser.[36]

As an application of crossover health services research that moves seamlessly from academic study to health system application and back again, the Vanderbilt experiment illustrates both the potential for improvement and some of the inherent tensions as Big Data interacts with physician practice.

To begin with, Vanderbilt starts with an advantage, Balser acknowledges: its hospital, clinics, and medical center are all university-owned; there is not even a separate faculty practice plan. Therefore, decisions can be made and implemented in an integrated fashion.

That allows Vanderbilt to run nimble experiments in attacking some of the biggest embarrassments in health care—with hundreds of deaths from adverse drug reactions every day (the equivalent of a loaded Boeing 747 being lost every 24 hours) and an estimated $1.2 trillion in waste[8] caused in part by doing wrong and unnecessary things. For instance, while genomic testing to ensure the suitability of drugs for individual patients is recommended by the labels for more than 200 drugs, the FDA mandates such testing for only four of them.[36, 37]

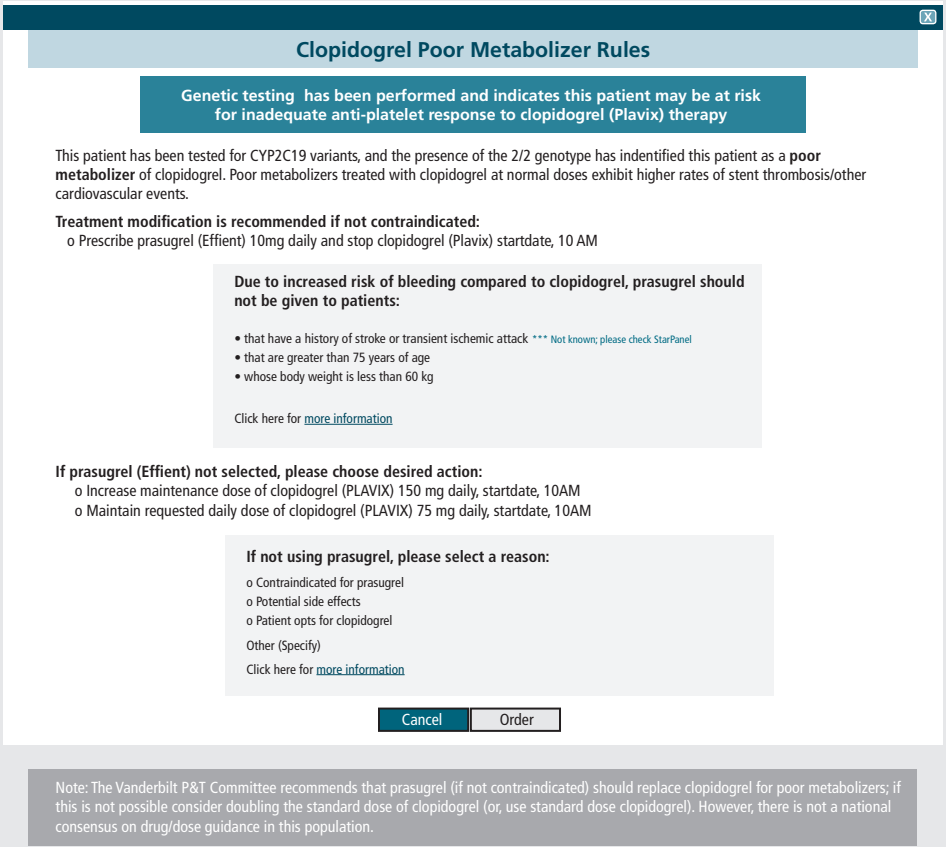
"There is a growing disconnect between what we know from basic science and what we actually implement in care," says Balser. "There is a big opportunity here."

By implementing enhanced electronic health records, along with IRB-approved DNA testing for up to 200,000 outpatients and counting, Vanderbilt is beginning to build an extensive de-identified research resource (BioVU) for identifying new genomic biomarkers for drug efficacy and toxicity, as well as disease risk. In a related project (PREDICT), patients are being tested preemptively for a panel of individual genetic variants that warrant prescribing different drugs from those most commonly used.

For instance, one gene variant, occurring in about 2.5% of all people, means standard anticoagulant therapy with Plavix (clopidogrel) will not work. Patients at risk for heart disease are preemptively tested for this genetic variant, and the information is stored with their electronic health record. Coupled to this, VUMC physicians have decision support that automatically notifies them at the time they order a drug for a patient having the genetic variant, so that doctors see a "red box" when they attempt to prescribe Plavix for such patients (see figure 6). Doctors are free to override it. "There are times when they still decide to give Plavix because there are contraindications to the other drugs. It's not 'thou shalt';

Figure 6.

Decision Support for Clopidogrel/CYP2C19[36, 38]



it's 'please be aware,'" Balser notes.

This is, self-avowedly, an experiment in progress. One patient had stents placed at five different hospitals, racking up $500,000 in medical bills, before she came to Vanderbilt and doctors realized she had both recessive genes that made her a poor candidate for Plavix. They sent her home with a different anticoagulant, successfully treating her at long last. "That's one patient, and you can't base medical practice on one case," said Balser. But an outcome study is now under way to determine cost savings and medical outcomes in about 1,620 patients who received stents, 32 of whom were genotyped as "poor metabolizers" of clopidogrel and 305 of whom were classified as "intermediate metabolizers." Some were prescribed Plavix anyway; how did their outcomes compare? Rigorous data analysis is needed.

Sometimes common sense is wrong. For instance, Vanderbilt invested in one nurse who would be charged with preventing pressure ulcers. Algorithms were applied to all patients in the hospital to determine which ones were most at risk of pressure ulcers, and the nurse worked specifically with them and other nurses to prevent ulcers. At the end of a year, to everyone's surprise, there was no demonstrable difference in outcomes, despite the intervention.

Because of Vanderbilt's expertise in bioinformatics and its ability to handle large volumes of data, it has become the center of a clinical data research network (CDRN), one of 11 in the country funded by PCORI pursuant to the Affordable Care Act. The Mid-South CDRN[39] includes Vanderbilt University Medical Center, with its owned hospitals, more than 100 clinics, 2 million patients, and the Vanderbilt Health Affiliate Network, bringing together eight health systems, 45 hospitals, 350 clinics, and more than 3 million patients in five states. It will also network, eventually, with Greenway Medical Technologies, representing more than 24 million patients nationwide.

In the case of Vanderbilt, its Mid-South CDRN will serve distinct regional needs as well as advance science generally and abstractly. Initially, the network will focus on three disease groups:

- Sickle cell disease (SCD),
- Coronary heart disease, and
- Overweight/obesity.

SCD patients will be recruited through the Comprehensive Sickle Cell Center (a joint effort of Vanderbilt and Meharry Medical College), which sees about 90% of the pediatric/young adult SCD patients in middle Tennessee.[39]

What about getting paid for all this—or some of it? Evidence shows that both the federal government and private payers recognize the potential impact of prospective genotyping on their bottom lines and are beginning to reimburse for it. Balser says Vanderbilt is getting paid "about half the time," with Medicare/Medicaid reimbursing about $85 for genetic tests and commercial payers, about $145.

And payment has also come in the coin of the realm in academia—Vanderbilt researchers have gotten about 150 publications and more than $75 million in grants directly attributable to BioVU.

* * *

Mentioned in the J&J and Vanderbilt case studies were two kinds of major, institutional collaborations that will fuel advances in the 21st century—advances made possible by Big Data, bioinformatics, cooperation across industry sectors and state lines, and wise investment by all payers—commercial, governmental, and nonprofit.

Figure 7 illustrates one way in which basic (but most definitely "mission-driven") research in the new era will be conducted and begin to pay off through novel partnerships:

Increasingly, it is clear that the mantra of success in the 21st century will have to be "collaborate and conquer." The half-century from the 1950s through the 2000s was the era of a spirited arms race among institutions, each vying for bragging rights on research dollars, velocity of change, Nobel Prize winners and like markers of achievement. Limited as it may have been, the competitive spirit embodied in that approach could be sustained and harnessed to national good by the rapidly growing resource pool that nourished it.

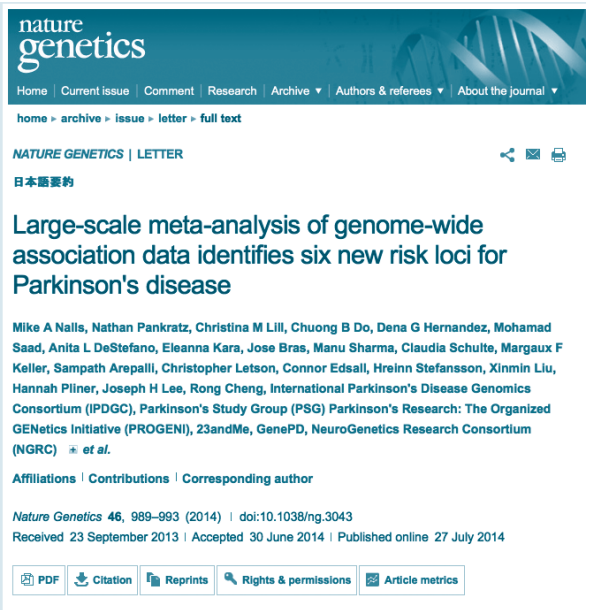
Competition is, after all, an American virtue. But in a steady-state era for AHCs, it is increasingly clear that differentiation around mission and collaboration around strategy will be the approaches most needed by the American society and economy.

Collaborations and partnerships directed to defined needs and outcomes must be the hallmark of the new order.

Metrics of achievement will have to be chosen differently and communicated both internally and externally. Faculty, staff, and students will have to be chosen for different sets of characteristics, nurtured along new pathways of development, and rewarded for unique kinds of accomplishments. Money saved, tests avoided, disparities narrowed or eliminated will be badges of honor—and those wearing them will, ironically, help to free up scarce money and other finite resources to engage in every kind of research, from "curiosity-driven" to "mission-driven."

Figure 7.

Example of a Breakthrough



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NATURE GENETICS | LETTER

日本語要約

Large-scale meta-analysis of genome-wide association data identifies six new risk loci for Parkinson's disease

Mike A Nalls, Nathan Pankratz, Christina M Lill, Chuong B Do, Dena G Hernandez, Mohamad Saad, Anita L DeStefano, Eleanna Kara, Jose Bras, Manu Sharma, Claudia Schulte, Margaux F Keller, Sampath Arepalli, Christopher Letson, Connor Edsall, Hreinn Stefansson, Xinmin Liu, Hannah Pliner, Joseph H Lee, Rong Cheng, International Parkinson's Disease Genomics Consortium (IPDGC), Parkinson's Study Group (PSG) Parkinson's Research: The Organized GENetics Initiative (PROGENI), 23andMe, GenePD, NeuroGenetics Research Consortium (NGRC) ✳ *et al.*

Affiliations | Contributions | Corresponding author

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First of its kind collaboration:
234 institutions, including
21 US medical schools and
14 teaching hospitals

- NIH
- GSK
- University of Miami Health System/ Miller School of Medicine/ John P. Hussman Institute for Human Genomics
- U.S. Department of Defense
- The Michael J. Fox Foundation for Parkinson's Research
- Federal Ministry of Education and Research
- 23andMe
- PDGene
- Cohorts for Heart and Aging Research in Genomic Epidemiology

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Recommendations

- The academic health community must continue to partner with and advocate for the NIH to sustain the federal investment in basic research. This investment, particularly in basic science, will come from nowhere else in the magnitude that is required to maintain the world's foremost research base in the life sciences. In our system, only AHCs, supported by the federal government, have a sufficiently rich pipeline of human capital, research infrastructure, scientific expertise, and cultural memory required to perform the basic research that will lead to new drugs, therapies, and health advances in 10, 50, or 100 years. Absent a robust continuing federal commitment, all of this is at risk because the requisite funding is not coming from other areas.
- The academic health community must be prepared to rethink any and every traditional structure or totem that prevents the most effective use of finite research dollars. The golden age has ended. Even while advocacy is critical and must be maintained, it is unrealistic to believe we will soon return to the sustained upward trajectory of the first half-century following WWII. It is now incumbent on AHCs to adapt and reinvent themselves to maximize the productive use of any and all funding available.
- Institutional leadership must be recognized, reinforced, and supported by boards and national leadership in making transformative decisions to respond to the new realities of steady or declining funding for research (at least in the near term). But leadership from the top, though necessary, will not be sufficient for the challenges of the 21st century. Leadership from all levels is critical as well, particularly at the department chair and laboratory director level.

- Universities and AHCs should develop new rubrics for evaluating impact based on metrics that are meaningful to all stakeholders. Quality and safety metrics, such as those developed by UHC, are one example, as opposed to *U.S. News & World Report*-style beauty contests that encourage wasteful "arms race" spending. Institutions should promote, publicize and encourage these alternative and more informative metrics for rating institutions and gauging their quality and impact, helping to educate internal and external publics about how to measure excellence in more socially meaningful ways than by counting and ranking research dollars.
- Private philanthropy is a critical source of support and must be vigorously and creatively pursued by every institution. Institutions must look for areas of convergence between their own needs and opportunities and the expressed goals and visions of philanthropists, including individuals and foundations. However, institutions must also be realistic with themselves and others about the indirect as well as direct costs associated with running a university-based research enterprise. Each institution must ultimately direct its own research priorities in ways that are consistent with its mission and strategic plan.
- Academic and clinical services businesses—universities and health systems—can no longer afford the operational abyss and arm's-length decision-making that have often characterized their relationship in the past. Meaningful integration of the academic and clinical sides, which we have defined as convergence, is required. While health systems have always generated revenue that supports their medical school partners, this is not enough going forward. Academia needs to learn from health systems by becoming less cumbersome, and health systems need to open their arms to academia to infuse high-quality research into every aspect of their operations, from clinical trials to health services research. Forces of cultural resistance and operational autonomy cannot be underestimated as this process occurs. Convergence will require strong leadership and ongoing, systematic, two-way communication to lead a process of thorough, consistent, and ultimately transformative organizational change. System-based quality-improvement programs must cooperate and collaborate with academically based health services research programs, and vice versa.
- Meaningful collaboration between and among institutions—both within and across states and regions—must become the new norm. Multi-center clinical trials are a well-established concept, but higher-level and strategically designed institutional collaborations must now become just as common. That's true both for positive reasons (research opportunities that are made possible by pooling and analyzing massive volumes of patient data) and negative (waste reduction, taking total cost out of the system, which is only possible by system wide changes).[8]
- AHCs must specialize and differentiate around areas of research, even if this has the effect of seeming to limit institutional ambition. There must be no embarrassment in admitting what an era of constraint now impels. No institution can do everything. Especially at the level of basic research, institutions will gain effectiveness and impact by recognizing their strengths and building on them. Leveraging institutional strengths by combining with partners to magnify areas of excellence and infill areas of need will increasingly be the norm, expected by board leadership and political stakeholders alike.
- AHCs must do a better job of educating their own constituencies, beginning with faculty, but also including senior staff, students, and others in the university context about their financial realities. This must be rooted in greater degrees of transparency about funds flow within AHCs, including between the academic and clinical sides of the enterprise and between the AHC and the rest of the university community. There must be a substantial commitment to internal communication and education so that the faculty in particular better understand the internal flow of resources and all of the direct and indirect costs of the research dollar. Out of better understanding will come

Recommendations, continued

heightened strategic alignment as well as more realistic expectations and, quite likely, more innovative solutions to the problem of using all our institutions' dollars to greatest effect. This involves greater insight into the distinctive advantages and very real limits of all forms of institutional income, from tuition payments to research grants to foundation and individual philanthropy to endowment income.

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About the Blue Ridge Academic Health Group

The Blue Ridge Academic Health Group (Blue Ridge Group) studies and reports on issues of fundamental importance to improving the health of the nation and our health care system and enhancing the ability of the academic health center (AHC) to sustain progress in health and health care through research—both basic and applied—and health professional education. In 18 previous reports, the Blue Ridge Group has sought to provide guidance to AHCs on a range of critical issues. Previous reports identified ways to foster a value-driven, learning health care system for our nation; enhance leadership and knowledge-management capabilities; aid in the transformation from a paper-based to a computer-based world; and address cultural and organizational barriers to professional, staff, and institutional success while improving the education of physicians and other health professionals.

Reports also focused on updating the context of medical professionalism to address issues of conflict of interest, particularly in the relationship between academic health professionals and institutions and their private sector partners and sponsors; quality and safety; and improved care processes and innovation through the use of informatics. One key report explored the social determinants of health and how AHCs could reshape themselves to address this critical dimension of improving health. The group also issued a policy proposal that envisioned a new national infrastructure to assure ongoing health care reform, calling for a United States Health Board; identified opportunities and the most critical challenges for AHCs and their partners as the Accountable Care Act (ACA) was implemented and examined ways in which AHCs could leverage their unique characteristics and capabilities through the ACA to improve health care, research, and training systems.

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Notes

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