Decline of clinical research in academic medical centers

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ABSTRACT

Marked changes in US medical school funding began in the 1960s with progressively increasing revenues from clinical services. The growth of clinical revenues slowed in the mid-1990s, creating a funding crisis for US academic health care centers, who responded by having their faculty increase their clinical duties at the expense of research activities. Surveys document the resultant stresses on the academic clinician researcher. The NIH provides greater funding for basic and translational research than for clinical research, and the new Patient-Centered Outcomes Research Institute is inadequately funded to address the scope of needed clinical research. An increasing portion of clinical research is funded by industry, which leaves many important clinical issues unaddressed. There is an inadequate supply of skilled clinical researchers and a lack of external support for clinical research. The impact on the academic environment in university medical centers is especially severe on young faculty, who have a shrinking potential to achieve successful academic careers. National health care research funding policies should encourage the right balance of life-science investigations. Medical universities need to improve and highlight education on clinical research for students, residents, fellows, and young faculty. Medical universities also need to provide appropriate incentives for clinical research. Without training to ensure an adequate supply of skilled clinical researchers and a method to adequately fund clinical research, discoveries from basic and translational research cannot be clinically tested and affect patient care. Thus, many clinical problems will continue to be evaluated and treated with inadequate or even absent evidence-based knowledge. **Neurology® 2015;85:1171-1176**

GLOSSARY

AAN = American Academy of Neurology.

The 1910 Flexner report revolutionized medical education in the United States.¹ Among Flexner's major tenets were that all medical schools should be involved in original research and that the critical method of research should dominate all teaching.^{1,2}

Dramatic changes in the funding sources of US medical schools began in the 1960s, as revenues from clinical services increased progressively. Initially this was related to the introduction of Medicaid/Medicare, but it later expanded to broader patient groups, including those with commercial insurance. From 1960 to 2009, expenditures for US medical schools increased by 2,492% (adjusted for Consumer Price Index).³ During this time frame, the percentage of US medical school revenues from clinical service markedly increased while the percentages from all other major sources decreased (see table 1).

In the mid-1990s, the growth of clinical revenues slowed in relation to efforts to contain expanding US health care expenditures. This reduction created an increasing funding crisis for US academic health care centers, which had expanded in large part based on the clinical revenues. Given the difficulties of increasing other revenue sources, US academic health care centers responded by having their faculty further increase their clinical activities. The result has been decreased time for medical university physicians to pursue clinical research and other academic activities, as evidenced by a study comparing the activities of academic physicians from 1984 to 2001.⁴ Effort in patient care increased from 23% to 40.7% while research activities fell from 29% to 14.7%.⁴ A 29% effort for clinical research across academic medicine faculty is probably marginal, but 14.7% is clearly inadequate and indicates an imbalance in the roles of research, education, and patient care in medical universities.

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Table 1 Percent contribution of different revenue sources for US medical schools^a

Funding source	Year, %	
	1960	2009
Clinical service	6	52
Federal research	31	19
Other federal	10	3
State/local	17	8
Tuition/fees	6	3
Other sources	30	15

^aData abstracted from Miller et al.³

The impact of these changes is reflected in a survey conducted in 1998–1999 of senior research administrators and chairs of 5 different types of departments from 122 medical schools assessing their perceptions of the status of clinical research in academic medical centers.⁵ The pressure on clinical faculty to see patients was perceived as a moderate-to-large problem by 93% of respondents. In addition, 75% of respondents noted an inadequate supply of clinical researchers, and 70% noted a lack of external support for clinical research. The authors concluded that the clinical research workforce and infrastructure needed to be expanded and strengthened.⁵ There is no indication that this has occurred.

The above conclusion is supported by a survey of life sciences faculty conducted in 2007 at the 50 universities with medical schools that received the most NIH funding.⁶ Not surprisingly, those faculty without funding spent significantly less time on research activities and more time in patient care. Compared to researchers with MD degrees, those with PhDs or MD-PhDs were nearly 3 times as likely to be funded. While 22% of all faculty were unfunded, MDs make up 69% of this group.

The problems with MD-directed research are multifactorial. Previously, young faculty had protected time to develop clinical research skills, but there is an increasing number of new young faculty being hired with little protected time for academic pursuits, including clinical research. Many young faculty are hired with such a large portion of their effort required for clinical care that their purpose seems primarily to feed the monetary needs of the medical university, and they are unlikely to ever achieve successful academic careers. Further, clinical research has become more complex in conduct and regulatory requirements. High-quality clinical research requires the same focused training as basic science research. However, most medical schools, residencies, and fellowships do not adequately teach clinical research

methodology. This is reflected in the poorer quality of research applications to the NIH and other agencies by MDs compared with PhDs.

Organizations like the American Academy of Neurology (AAN) and the American Epilepsy Society have recognized this problem and have sought to fund clinical research fellowships and establish mentoring networks. For example, the Susan S. Spencer Clinical Research Training Fellowship in Epilepsy is named after one of our colleagues who was committed to clinical research and recognized the emerging problem. The NIH has mentored clinical training K23 grants for T32 programs, K12 programs, and Clinical & Translational Science Institute–funded programs to accelerate training in clinical research. The National Institute of Neurological Disorders and Stroke specifically has embarked on funding 3 clinical trial networks (NETT, NeuroNEXT, and StrokeNET) that have provisions to assist in study design and to support training of investigators. However, the number of clinical research fellowships remains woefully inadequate to address the need. Further, there is evidence that the situation is worsening, with a fall in K award funding across neurologic diseases.⁶ For example, K award funding for epilepsy fell from more than \$9 million to less than \$6 million from 2008 to 2013. Furthermore, most of these K awards support basic research, and only 15% of the K awards were made to MDs without PhDs.⁶

Traditionally, a large portion of clinical research has not been externally funded, but the demand to produce clinical service income has reduced time for such activities. In recent years, nearly half of MD research funding is from biopharmaceutical and medical device sponsors.⁷ This large proportion of industry funding may be due in part to the lack of other funding sources, but it is likely that this disparity is largely because many MDs lack the clinical research skills to conduct investigator-initiated research. Although there is a role for industry-funded health care research, there are many important clinical issues that will not be addressed via industry funding.

Advances in health care in the last century have resulted in improved life expectancy and quality of life for Americans, which have also resulted in economic benefits for our society. Biomedical research in the United States has led the world in innovations and discoveries. This progress would not have been possible without the NIH. However, funding of the NIH in the past decade is not keeping pace with inflation and the rising cost of conducting biomedical research.⁸ There is a need for increased funding in basic, translational, and clinical research. However, the NIH presently provides much more funding for basic and translational research than for clinical research investigations. This disparity has been

exacerbated by the reduction in clinical research previously underwritten by academic centers and the increasing complexity of clinical research, which requires formal training. Simply increasing clinical research funding without addressing the quality of applications will not work. There has been a failure to adequately train MDs in clinical research methodology, and there is an inadequate number of clinical research mentors. Addressing these issues is critical to the future of clinical research in the United States.

The new Patient-Centered Outcomes Research Institute was created to fund comparative clinical effectiveness health care research, but it is inadequately funded to address the scope of needed clinical research. Thus, there has been inadequate compensation for the financial pressures that have led to decline in support for clinical research in academic centers. The declining support for clinical research and the inadequate training of MDs in clinical research methodology will become increasingly impactful because the effect of scientific discovery is cumulative over time. Ultimately, the present course will threaten the predominance of the United States in biomedical research.

The above data and surveys document the stresses on the academic clinical researcher. Concerns over the status of clinical research have been raised since the mid-1990s,^{9,10} but the status has not improved. This issue is not being adequately addressed across academic medicine. The revenue sources for medical schools were listed annually in prior educational editions of the *Journal of the American Medical Association* but have not been included in more than a decade, even though the crisis continues. The failure to routinely monitor and publish data on the status of

clinical research is a major obstacle to addressing the problem. Furthermore, many medical schools do not have policies or mechanisms to address the challenges facing the clinical research mission.⁴

Why is it critical for academic MDs to be engaged in clinical research? Academic physicians appropriately trained in clinical research have the medical knowledge and the clinical context of day-to-day interactions with patients needed to ask clinically relevant questions and assess the clinical effectiveness of technologies, diagnostic methodologies, and therapeutic regimens. Modern clinical research cannot be conducted without adequate training in clinical research methodology. If young faculty have inadequate training, time, and incentives to conduct clinical research, then the advancement of clinical care will ultimately suffer. For example, the development and clinical application of the EEG and of epilepsy surgery were largely achieved without external funding based on a paradigm where such endeavors were underwritten by the environment of academic medical universities. This has also been the primary approach to refine and define the differential utility of new drugs and technologies once released to the market. If this prior environment has evaporated and is not replaced by a viable alternative, then clinical research and ultimately clinical care will be adversely affected.

As a senior faculty member watching this transition over the last 3 decades, I feel that academic physicians are increasingly being treated like shift workers who need to meet relative value unit or dollar quotas. I am concerned about the consequences of the shrinking potential for young faculty to achieve successful academic careers, the fairness of the present process to these young faculty, the quality of clinical research grant applications to funding agencies, and the long-term impact of these changes on the academic environment in university medical centers.

Although the problem is not new, the lack of effective response by academic medicine remains newsworthy. The following specific recommendations are detailed below and summarized in table 2.

1. Every medical university should have policies and mechanisms to address the challenges facing the clinical research mission. The effectiveness of these policies should be routinely evaluated, and the results should be available in a transparent manner.
2. Medical schools should provide training in clinical research methodology and require research by medical students. This is the norm in some countries. Even those physicians who do not enter academic medicine need knowledge of clinical research and its methodology to interpret the literature, understand the science underlying medicine, and provide the best medical care.

Table 2 Outline of recommendations to improve clinical research

1. Clear public policies by medical universities to monitor and improve clinical research
2. Medical universities should provide training in clinical research methodology and require research by medical students
3. Research training and projects should be required components of residency training
4. Accreditation Council for Graduate Medical Education fellowship programs should require research training in clinical research methodology
5. Mentoring programs and protected time for young clinical faculty to develop their clinical research
6. Increased national and foundation funding for clinical research, especially in regards to clinical research fellowships and mentors
7. Financial incentives at medical universities for clinical research
8. Improved use of indirect grant funding to support clinical research
9. Philanthropic efforts focused on advancing the development of clinical research careers
10. Routine monitoring of clinical research on departmental, university, and national levels in order to direct interventions to improve the existing status
11. Improved efficiency of central support by medical universities for clinical research and routine assessment to determine its impact
12. Improved efficiency of clinical service support to improve patient care and income and to increase faculty time for clinical research and other academic activities

This was Flexner's tenet in 1910 and it remains valid today.

3. Clinical research should also be a required component of residency training; there should be didactic lectures on clinical research methodology as well as required research projects.
4. Accreditation Council for Graduate Medical Education fellowship programs have large clinical education and service requirements, but most do not require research training in clinical research methodology or provide enough time for research development. This deficit should be corrected.
5. Every clinical department should have a mentoring program for young faculty, including expert mentoring in clinical research for the clinical faculty. Departments should also offer adequate protected time to young faculty in the first years so that they can develop their clinical research careers.
6. Increased national and foundation funding is needed for clinical research, especially in regards to clinical research fellowships and mentors.
7. Presently, financial incentives for clinical faculty are linked almost entirely to clinical income, which reinforces the relative unimportance of clinical research and other academic missions at medical universities. Human behavior is driven by incentives. Financial incentives are needed for clinical research productivity. There are many types of effort in academic medicine that are not directly funded. Education, other academic activities, and administrative effort (e.g., serving on promotion, tenure, and other committees, designing the curriculum, teaching at the bedside, mentoring junior faculty, writing research articles, reviewing manuscripts and grants, writing grant applications) are not adequately funded by direct sources. I think that some portion of the clinical profits could be directed to not only reward income from clinical activities but also reward clinical research and other academic productivity in order to better balance the missions of academic universities. Incentives should reflect goals. This is true mission-based funding.
8. One obvious source to fund clinical research is the indirect funding related to grants. These funds are to support and enhance the academic environment. Some have questioned whether extramural research funds cover the costs of conducting the research, requiring medical universities to subsidize these costs to maintain a robust research portfolio.³ This claim should be substantiated and the costs justified with an eye to more effective use. The expenditure of indirect funds should be transparent so that the efficiency of their use can be examined and adjusted if needed.
9. There is an important role for philanthropy in supporting the clinical research mission via endowed clinical research fellowships and endowed chairs to allow time for experienced clinical research faculty to mentor young faculty and direct formalized educational programs on clinical research methodology. The push for philanthropic monies to fund bricks and mortar instead of future endowments for clinical research careers has eroded the supply of clinician-investigators. Donors should understand that their name on a building that ultimately crumbles will have less long-term impact than advancing the development of clinical research careers.
10. A critical part of improving the situation is enactment of routine monitoring of clinical research in order to direct interventions. As noted by the prominent 20th century health care expert Edgar Sydenstricker, every health care policy should have a plan to monitor the effect of the policy as an integral component of the policy in order to adjust it if needed to achieve the desired goals.¹¹ The funding of medical universities and the status of clinical research within academic universities have not been routinely monitored. On a national level, detailed comparisons of clinical research (e.g., percentage effort, protected time, number of clinical research fellowships) should be conducted across specialties. The results of the surveys should be analyzed and considered at departmental, university, and national levels to determine whether changes in policies are needed and to direct actions to improve the status of clinical research.
11. Medical universities should provide better central support for clinical research. There has been a marked increase in the complexity and bureaucracy in clinical research to meet legal and regulatory concerns. The effectiveness of these measures and the time burden on faculty have not been adequately assessed. Simply funding a large bureaucracy at medical universities is not sufficient and can even be detrimental to efficient clinical research. Medical universities need to actively seek ways to improve the efficiency of these processes and reduce undue administrative burden on clinical researches at their institutions. Each requirement should be assessed to determine whether it is effective in its goal and whether it can be accomplished with greater efficiency, less faculty burden, and less cost. Clinical faculty are routinely assessed in terms of clinical income, patient satisfaction, grant income, and publications. In contrast, the performance of the

medical university in contract negotiations, central research support, and clinical care support to faculty are not rated on efficacy or ease of use for faculty and are not compared across institutions. For example, the contracting process at academic centers is consistently more complex and longer than at private groups.

12. The provision of clinical services at medical universities is inefficient, which increases faculty effort needed to provide clinical care, further reducing the time for clinical research and education. Some procedure-rich specialties maintain enough income to provide support (such as electronic health data entry by patients and assistance from health care auxiliary staff and physician extenders), which creates more efficient outpatient clinics. Many academic neurology clinics have inadequate auxiliary staff to support the physician, leading to poor patient flow and increased burden on the physician. For example, physicians frequently have to enter documentation into the electronic record for medicines, allergies, past medical history, family history, and social history. This could be done more efficiently and at less cost by patients or auxiliary staff and reviewed by physicians. Medical universities should actively seek ways to improve the efficiency of clinical care and assist physicians in reducing their personal documentation burden. This will improve patient care and clinical income and provide additional time for clinical research.

This problem is not isolated to neurology and cannot be solved in isolation. However, there are actions that neurology can take as a subspecialty. The last publication on this issue in the neurologic literature was in 2004, when the Clinical Research Subcommittee of the Science Committee of the AAN reviewed the status of patient-oriented research in neurology.¹² The present status is uncertain, but there is no indication that the situation has improved. The AAN, American Neurological Association, and neurologic subspecialties should conduct routine surveys on the status of neurologic clinical research, including comparisons across neurology departments. Neurology student rotations, residencies, and clinical fellowships should include didactic lectures on clinical research methodology, and neurologic residencies and clinical fellowships should include requirements for research. Young clinical neurology faculty should be hired with protected time to develop their clinical research careers, and they should be in active mentoring programs. Neurology programs should also encourage development of skilled clinical research mentors and support them financially in this role. Existing mentoring networks for clinical research should be

expanded. The AAN and neurologic subspecialties should continue to lobby for additional research funding for neurologic diseases across basic, translational, and clinical areas. However, given the special pressures on clinical researchers, this effort should include attention to the importance of clinical research, especially the need for more support in training and career development of neurologic clinical researchers.

National health care research funding policies should encourage the right balance of life-science investigations.⁶ Medical faculty, societies, and universities should lobby to improve the present situation. Medical schools should balance their research, education, and patient care missions, and they need to improve education on clinical research methodology for students, residents, fellows, and young faculty. There should be a national plan to replace funding to support time for clinical research, that has been reduced by increasing clinical effort of faculty, to compensate for reduced funding of medical universities. Charitable donations should play an increasing role in underwriting clinical research and clinical research fellowships. Without training to ensure an adequate supply of skilled clinical researchers and a method to adequately fund clinical research, discoveries from basic and translational research cannot be clinically tested and ultimately affect patient care. Thus, many clinical problems will continue to be evaluated and treated with inadequate or even absent evidence-based knowledge, leaving patients vulnerable.

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