The Crisis in Training and Educating a Future Generation of Clinical Investigators

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I appreciate the opportunity to participate in this program today. I should also say that I am a former president of the American Federation for Clinical Research (now the American Federation for Medical Research, or AFMR), and we have been discussing these problems for a long time.

Our ministrations have not been very effective in addressing the workforce issues in clinical research.

I want to discuss 2 issues today: stabilizing the National Institutes of Health (NIH) funding lines so that we have a stable clinical research program and the aging of the medical school faculty and NIH awardees. Is there any room for the next generation of physician scientists?

STABILIZING NIH FUNDING LINES

For investigators who are seeking NIH funding, the success rates are poor and growing worse. Although the NIH received funding from the stimulus package and those funds might temporarily help, NIH will not change as a result of the stimulus funds. The irony of America's situation is that we have never had more opportunity and more promise in biomedicine, nor have we had greater need to translate basic science into clinical benefit. We have had an explosion of valuable information that will be applicable to patient gains, yet we cannot bring this information forward to patients because of this blockade at the level of translational research. In biomedicine, younger scientists may have real innovative and creative ideas and better familiarity with computer use for analysis; these young investigators are better able to use modern tools. To benefit from their innovation and skills, we need to infuse these young people into the system.

In the last few years, the NIH has experienced many changes. In 2003, NIH funding was doubled, per the lobbying of the American Federation for Medical Research, but the victory may have been temporary. Although the NIH has received almost 2 times as many applications (Fig. 1), the success rate of applications has fallen. In the early years, from 1998 to 2003, the NIH increased its applications by 5000, and from 2003 to 2005, the NIH again increased its applications by 5000. The number of NIH applications has accelerated, yet the applicants' abilities to receive funds have fallen dramatically.

In addition, the NIH has seen a change in its applicants' ages (Fig. 2). In 1980, the largest age group of principal investigators on NIH research grants was at the late 30s. Today, the highest percentage of NIH principal investigators is in their late 40s and early 50s. Also, in 1980, the number of principal investigators who had NIH research grant and were older than 65 years was small. Today, we have seen a huge shift in age distribution to older ages (even older than 65 years) of both investigators and medical school faculty.

We learn 2 things from this data. First, the increased age of the medical school faculty may indicate prolonged training time. Second, while we still graduate from college when we are approximately 22 years old, we take much longer to get to the faculty level than we did in 1980. As a result, we are forever infantilized and forever in the training position; an investigator does not get to begin life until he or she joins the faculty and obtains an NIH grant.

Let me illustrate these ideas in another way. In 1980, almost one half of the principal investigators on NIH grants were younger than 40 years. Then, in 2006, that percentage has reduced by 75%. Only 11% of principal investigators were younger than 40 years in 2006. If we project this into the future, the NIH itself predicts that the number of investigators younger than 40 years will be less than 10% by 2020. We can see the commensurate increases in the other age groups. The NIH has shifted away from the young people entering clinical research, which creates a serious problem. In addition, the NIH target for new principal investigators is only 1500 new principal investigators per year, but for the last decade, the NIH has not reached that target. In 2006, the NIH had only approximately 1300 new principal investigators, and the mean age of the new investigators was 42 years. We are really hurting for the next generation of clinical investigators or when we, the Baby Boomers, leave clinical research, no one will be driving the discoveries and bringing those discoveries forward to patients.

The *Journal of the American Medical Association* published an article by the American Association of Medical Colleges.[1] This article showed that, in 2003, the number of investigators who were first-time applicants for R01 grants increased largely in the PhD category. The number of physicians

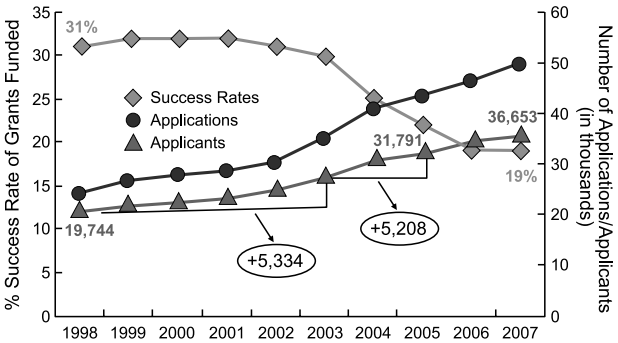

FIGURE 1. Changes in NIH applicants and their fate in the last 10 years. Applicants have nearly doubled; success rates fell by more than one third.

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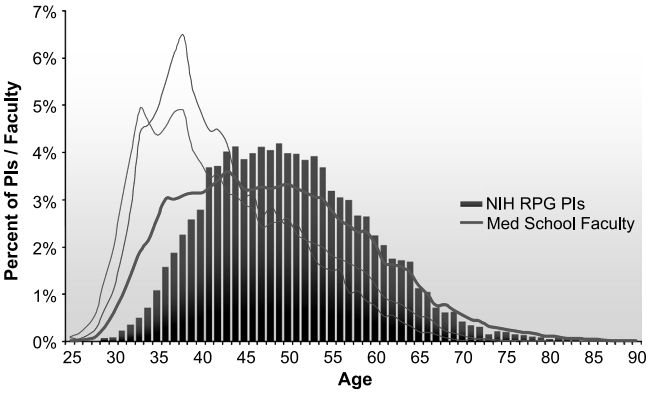


	1980	2006	2020*
Percent of PIs under 40	46.45%	11.34%	9.93%
Percent of PIs 41-50	34.36%	39.27%	35.45%
Percent of PIs 51-60	15.21%	34.25%	31.52%
Percent of PIs 61-65	2.06%	8.36%	9.03%
Percent of PIs 65-80	0.81%	6.63%	11.18%

*Projected by OB Aging Model

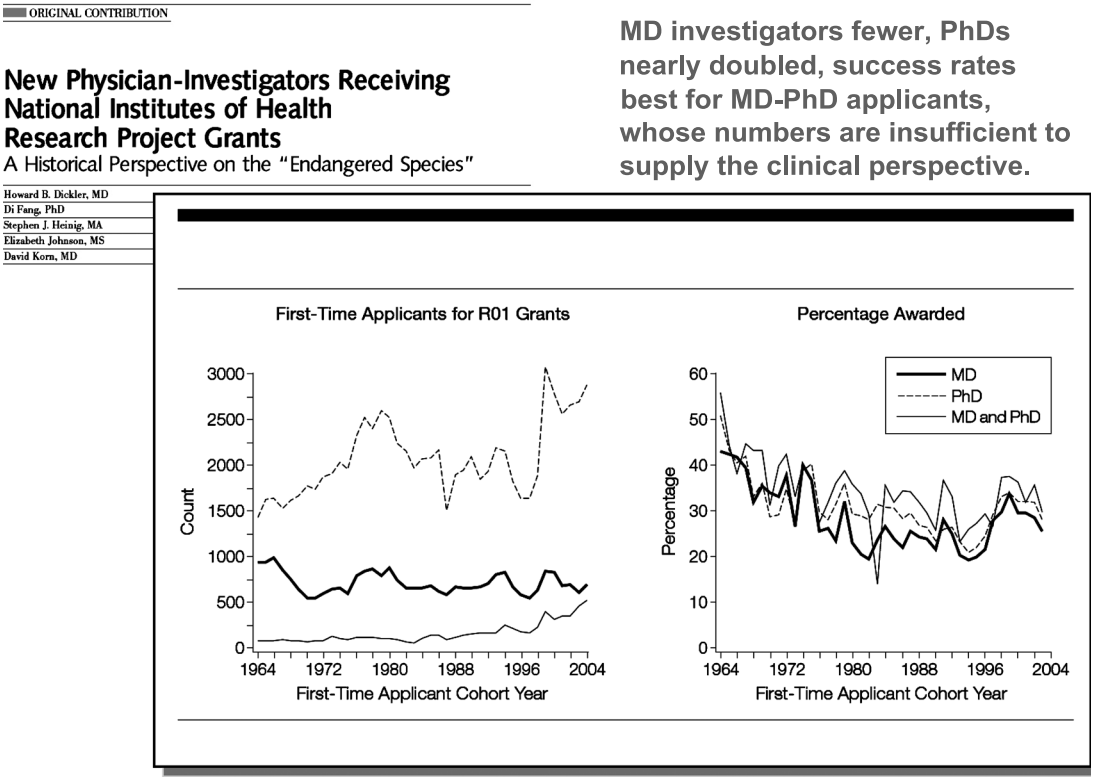
FIGURE 2. The graying of NIH principal investigators in the last 30 years.

as first-time investigators actually fell (Fig. 3). Therefore, the physician investigators have not increased, but the number of the PhD investigators as first-time applicants nearly doubled. The success rate does not differ greatly between MD, PhD, and MD/PhD investigators, which is a surprising figure. Truly, investigators with good training in research who go into the NIH system are the most likely to succeed.

TRAINING CLINICAL INVESTIGATORS

I believe that we should train students early in their education, such as through the STEM programs in high school and then in undergraduate programs. We should expose medical students to research design, and I believe strongly in the Medical Scientist Training Program. When we prepare to launch people—young physicians—into a clinical research career, we should have spent a lot of time on the "guppy model" and we may need to go more into the "mammal model" of training clinical investigators.

In the traditional guppy model, we place physicians into the clinical training program, and many of them receive partial support for their training activities. In general, this model is a "'Swim,' said the momma fishy. 'Swim if you can!'" model, but the mentoring has not been carefully supervised and programs using this model have been of a variable quality. We have seen some wonderful mentors and then some mentors who have said, "I did not have any help when I came through. You are just going


ORIGINAL CONTRIBUTION

New Physician-Investigators Receiving National Institutes of Health Research Project Grants

A Historical Perspective on the "Endangered Species"

Howard B. Dickler, MD
Di Fang, PhD
Stephen J. Heinig, MA
Elizabeth Johnson, MS
David Korn, MD

MD investigators fewer, PhDs nearly doubled, success rates best for MD-PhD applicants, whose numbers are insufficient to supply the clinical perspective.

FIGURE 3. First-time applicants for R01 grants by degree (1964–2004) and percentage awarded (1964–2003). For percentage awarded, $P = 0.03$ for MD vs PhD; $P < 0.001$ for MD vs MD and PhD; and $P = 0.002$ for PhD vs MD and PhD.[1]

to learn and survive on your own." That attitude creates a serious problem.

The body of knowledge that we must know to be a clinical investigator—the didactic—has expanded considerably. We need to know about many fields, not only the specifics of gastroenterology, or pulmonology, or cystic fibrosis—the clinical piece; we also need to know about statistics and epidemiology, and we also need instruction in formal grounding and ethics. We also need to teach people about collaboration—how to work in teams. The complex problems in today's research are not solved in our garages anymore; they are solved by interdisciplinary teams of investigators who work together. The team members are not all physicians: some are nurses, social workers, statisticians—teams are made up of people who come together to work on a common problem.

Our didactic has not been well-coordinated in the guppy model. Also, the guppy model encourages very little community. We put fellows in different projects, and the sense of a community of clinical investigators has not occurred. The result is measured by project grants coming out of training grants (K-to-R transition), which have been disappointing, and that is a difficult transition to make.

The newer mammal model is being promulgated in a number of Clinical and Translational Science Awards (CTSAs) and training programs around the United States. Fewer scholars are supporting this model, and they come from diverse disciplines. Our CTSA has 22 slots for K awardees, and only 13 of them are physicians. The other principal investigators are nurses, dentists, genetic epidemiologists, a stray anthropologist, and a few engineers. The didactics are considerable, and in our training, we include instruction from people at business school who teach leadership, team building, entrepreneurship, and communication because the investigators' teams will require these skills. We have created a community and a critical mass for people who are training in clinical research.

MENTORING INVESTIGATORS-IN-TRAINING

We remunerate our mentors for their work. They must complete their clinical work, and they must also write grant applications. We do not pay our mentors much, but we do give them a small amount of money to obligate them to regularly mentor their trainees. We supervise the mentoring through an advisory committee and require that mentors agree to a mentoring contract, which the advisory committee reviews every 6 months. The review process is a labor-intensive process, but we hope that our program will turn out investigators who are committed. Everybody in our program has at least 2 mentors: a research mentor and a career mentor. We figure that no person can fill the mentor role and be all things to a trainee. In addition, we provide formal career planning: research plans and career plans. We recently started this program, and I am eager to see what happens in 10 years in the careers of these people that we are training.

ENCOURAGING NEW INVESTIGATORS IN THEIR RESEARCH

If we want to assure a steady supply of physician investigators, the NIH, which is our major funder, and the institutions must to work together. The NIH needs to help to assure sufficient funds and some advantages for new physician investigators. For example, the NIH's Heart, Lung, and Blood Institute has given several percentile-points advantage to new investigators.

We also need to increase support for the MD/PhD in clinical and translational science. The MD/PhD program is largely concentrated in basic science, and we now have a clinical and translational scientist training program with 11 slots in 1 of our CTSAs. This program is training PhDs in various clinical sciences. We must attend specifically to the needs of the new MD investigators, and the mammal model may prove appropriate, but I will judge the model when we have data about the program.

We must stabilize NIH funding over time to encourage career investment in research. Nobody wants to go into a career without the assurance that research will somehow be funded. Institutions must develop innovative and validated methods of supporting and training new investigators, especially the physicians, if we expect to capitalize on our investments in basic research.

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1. Dickler HB, Fang D, Heinig SJ, et al. New physician-investigators receiving National Institutes of Health research project grants: a historical perspective on the "endangered species". *JAMA*. 2007; 297:2496–2501.