

2.03 Recruitment and Nurturing of Clinical Investigators

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Statement of the Problem

- Inadequate pipeline for clinical investigation
- Decline of Physician Investigators
- Disincentives for New Entrees
- “Biomedical Enterprise at Risk”

“...it is the progressive decline in the number of new entries that constitutes the danger to the survival of the species in the numbers and quality needed to maximize the rate of progress against the serious diseases of mankind.”

Wyngaarden JB.

The clinical investigator as an endangered species.

Bull N Y Acad Med 1981;57;415-426

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The Crisis in Clinical Research

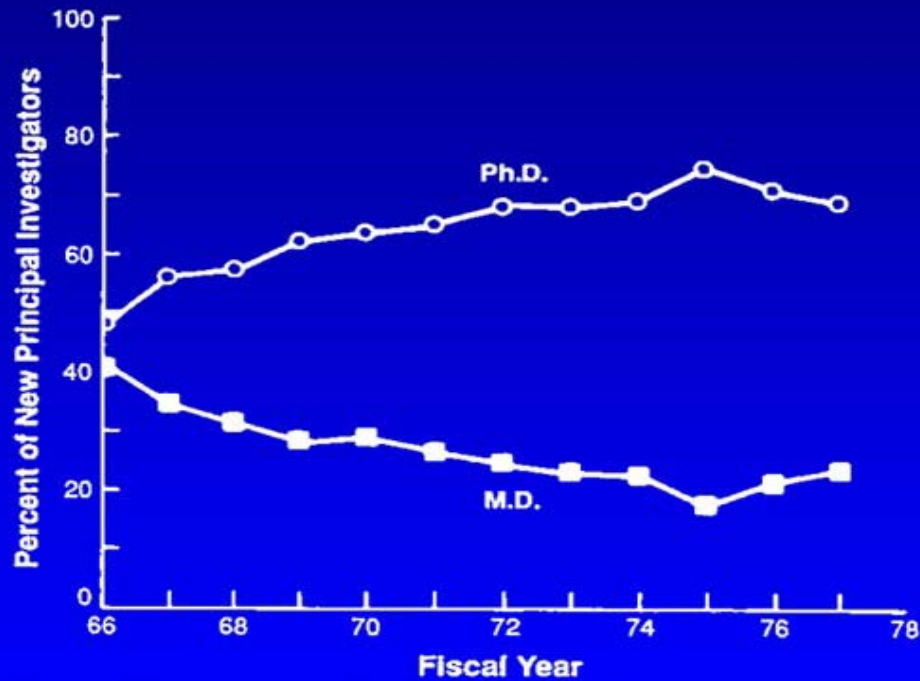


Fig. 7-1 New PIs on NIH research projects by type of earned degree. (Wyngaarden, 1979, Fig. 6)

The Crisis in Clinical Research, Edward H. Ahrens, 1992.

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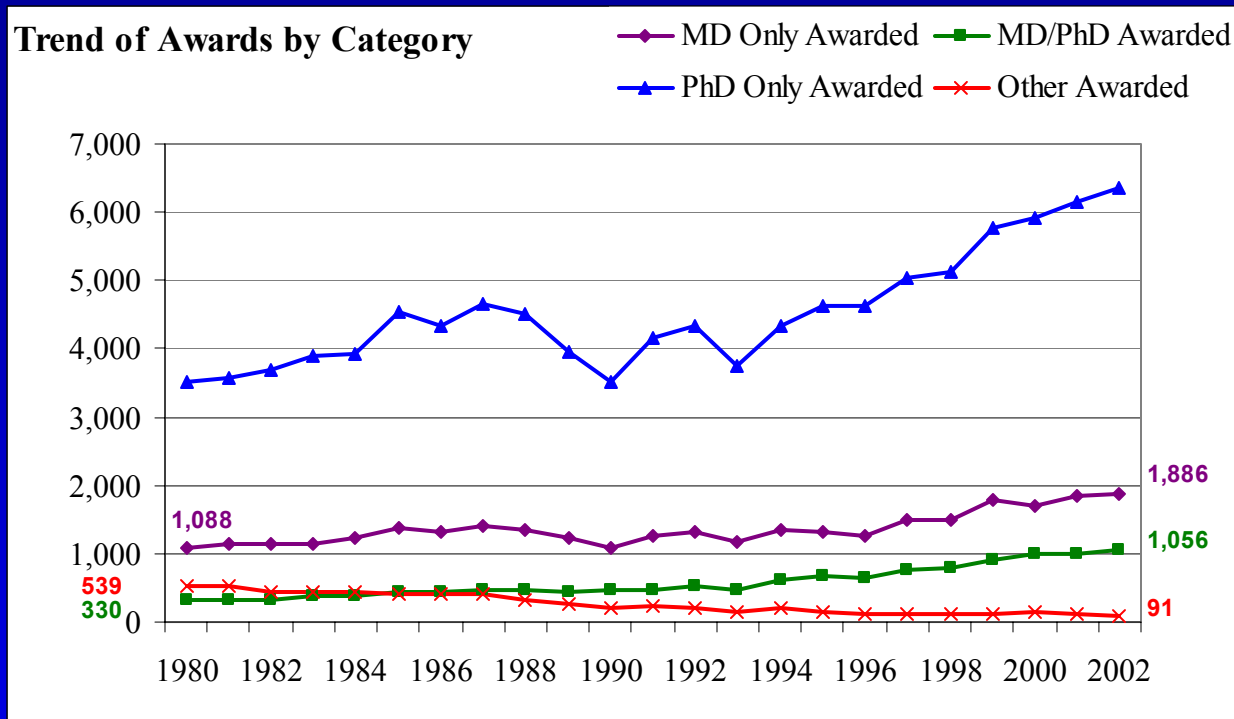
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Reasons for Decline

- Continued changes in economic and social goals (primary care specialties – interventional)
- Instability of grant funding
- Medical School curricula changes
- Perceived lack of research interests of Academic Health Centers
- Dearth of role models

NIH Competing Research Project Applications

FY 1980 - 2002



Walter Schaeffer, NIH, 2004

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Success of Subsequent Type 1 (New) and Type 2 (Renewal) Grant Applications Submitted by Researchers Who Received First-Time Awards in 1996.*

| Applications and Awards | Clinical Research | Nonclinical Research | Total |
|--|--------------------------|-----------------------------|--------------|
| First-time type 1 grants — no. | 255 | 884 | 1139 |
| Renewal (type 2) grants | | | |
| Applications — no. (%) | 49 (19) | 360 (41) | 409 (36) |
| Awards — no. | 26 | 228 | 254 |
| New type 1 grants — no. | | | |
| Applications | 184 | 605 | 789 |
| Awards | 97 | 376 | 473 |
| Total subsequent (type 1 and 2) awards — no. | 123 | 604 | 727 |

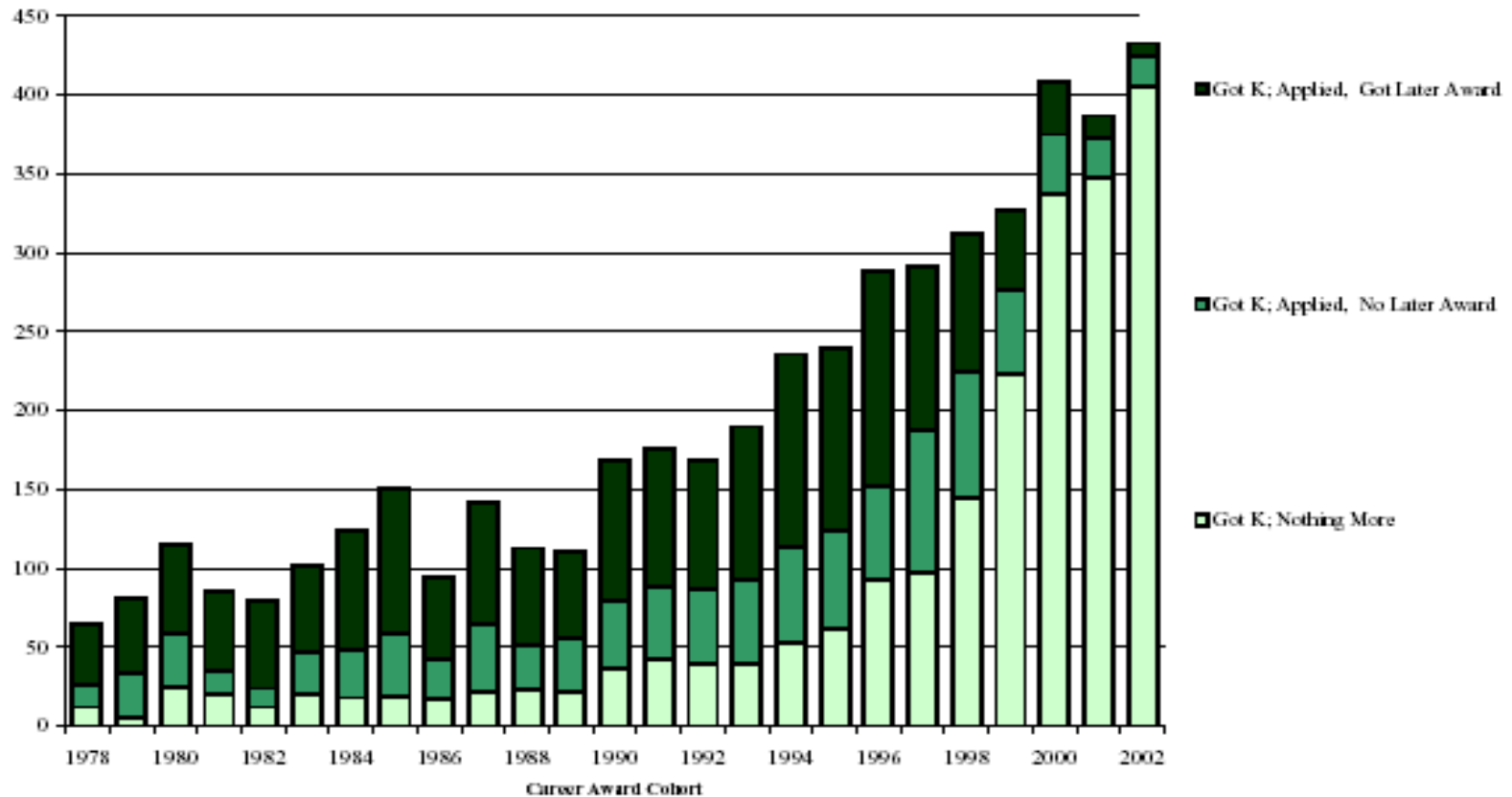
Nathan and Wilson NJJM 2003

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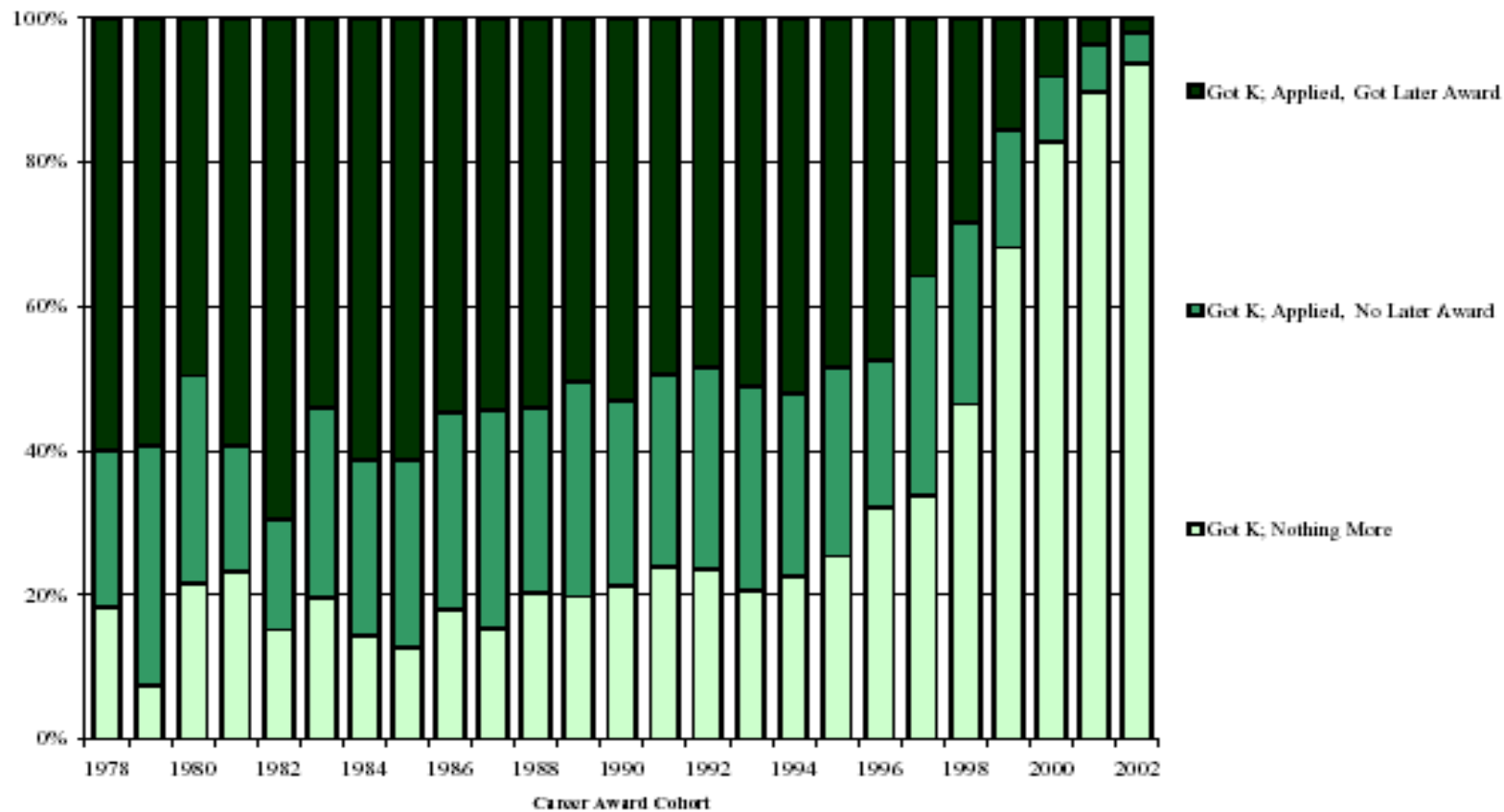


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Outcome Patterns for Selected Career Awards (K01, K07, K08, K20, K21, K22, K23, K25; MD's and MD/PhD's Only)



Outcome Patterns for Selected Career Awards (K01, K07, K08, K20, K21, K22, K23, K25; MD's and MD/PhD's Only)



Careers in Clinical Research Institute of Medicine, 1994 and Present

A decade of limited advancement

- The current level of training and support for health professionals in clinical research is fragmented, frequently undervalued, and potentially underfunded.
- A number of variables make the pursuit of clinical investigation relatively unattractive for medical students and students of the other health professions.
- The voluntary and certifying accrediting bodies have a significant influence over individual career decisions, and in an effort to improve quality in one area, they may create significant hurdles in other areas.

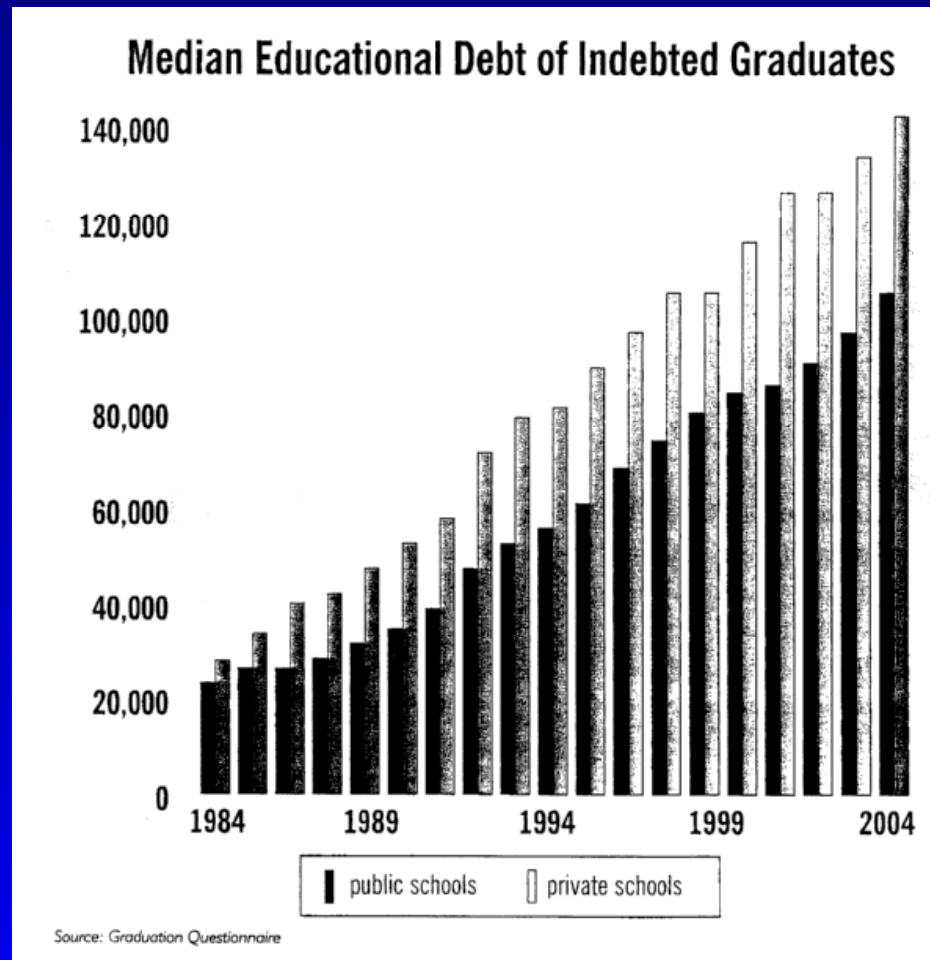
Careers in Clinical Research: Obstacles and Opportunities
Institute of Medicine 1994

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Importance of NIH's Loan Repayment Program



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Careers in Clinical Research Institute of Medicine, 1994 and Present

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Careers in Clinical Research

Institute of Medicine

- Managed competition represents the new paradigm for the funding of health care.
- Funding for investigator-initiated human research is difficult to obtain.
- **Relatively few programs adequately prepare physicians and other health professionals to undertake research involving human subjects, and their successes are unproven.**

Careers in Clinical Research: Obstacles and Opportunities
Institute of Medicine 1994

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Careers in Clinical Research Institute of Medicine

- Responsibility for oversight of the nation's clinical research capacity is fragmented at every level, whether academic or governmental.

Careers in Clinical Research: Obstacles and Opportunities
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1998 Research Summit: AAMC, AMA and Wake Forest University

“Breaking the Scientific Bottleneck”

1. There is not an agree-upon definition of clinical research and its components.
2. Clinical research is not adequately understood or valued by the public. (Need for education)
3. There is a lack of data on clinical research funding and productivity. (Enterprise issue)
4. There is insufficient funding for the conduct of some types of clinical research.

1998 Research Summit: AAMC, AMA and Wake Forest University

“Breaking the Scientific Bottleneck”

5. There is insufficient emphasis on incorporating research findings into clinical practice. (translational research)
6. There is inadequate coordination of clinical research among research entities and disciplines. (roadmap)
7. The ability of academic health centers to conduct clinical research is at risk. (unfunded mandates, protected time)
8. There is a lack of comprehensive, dynamic clinical research agenda. (roadmap)
9. **There are insufficient number of clinical investigators.**

AAMC Testifies at House Hearing on Clinical Research

The House Energy and Commerce Subcommittee on Health March 25, 2004, held a hearing on re-engineering clinical research.

Dr. Braunwald: “a lack of coordination of the clinical research enterprise has led to a fragmented cottage industry of investigators each going in their own separate directions.” He cited several reasons contributing to this lack of coordination, including:

- an enormous regulatory burden,
- information technology systems based on billing needs rather than clinical research needs,
- a need to foster increased integrity in the research process, and
- the shrinking pool of well-qualified clinical investigators.

Association of American Medical Colleges, *Washington Highlights*
Volume 15, number 12: March 26, 2004

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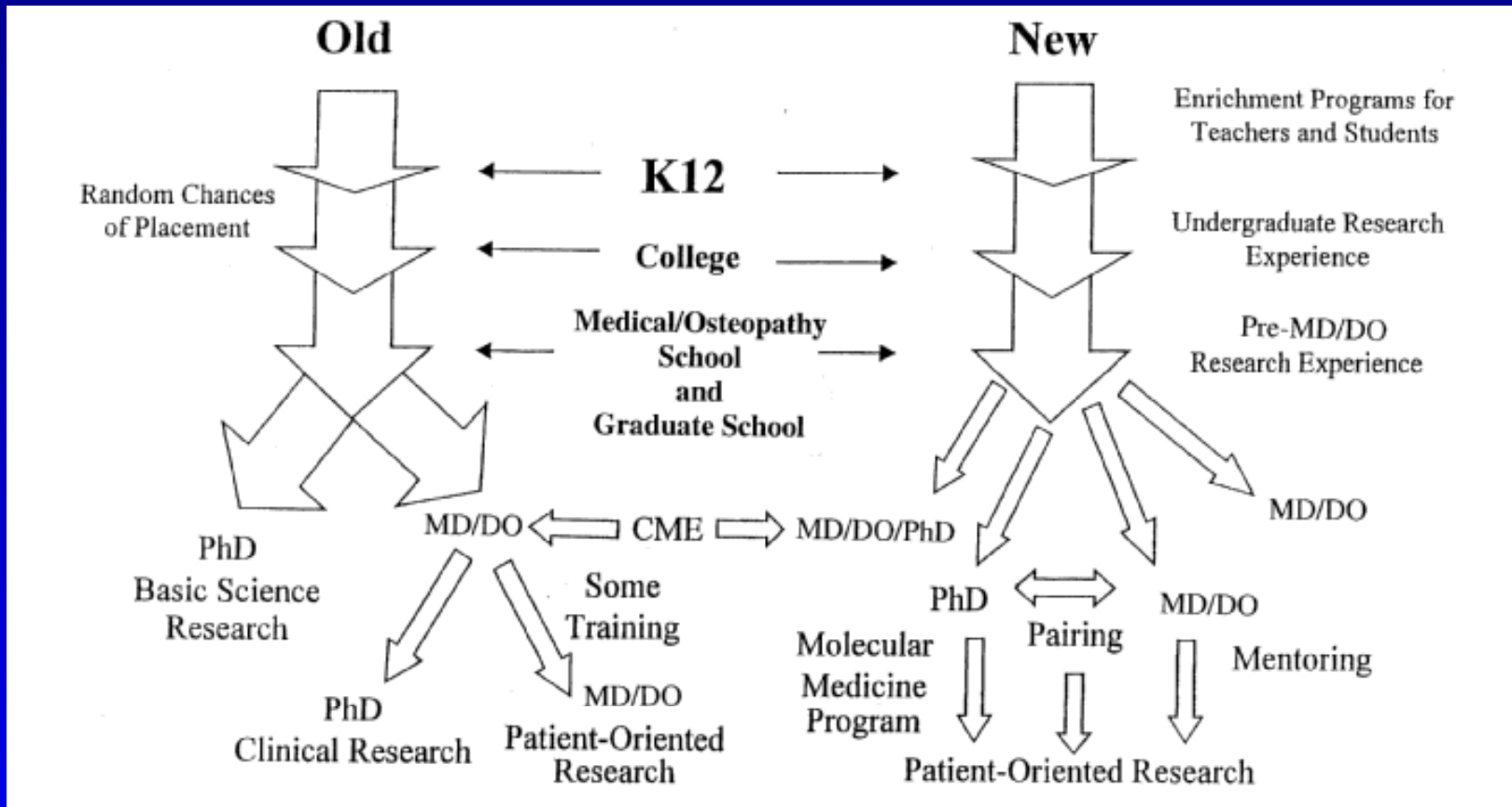
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Potential Solutions

- Reconstruct the Pipeline
- Establish and Fund New Models for Clinical Investigation
- Challenge Academic Health Centers to action

Addressing the Problem

Clinical Research Pipeline

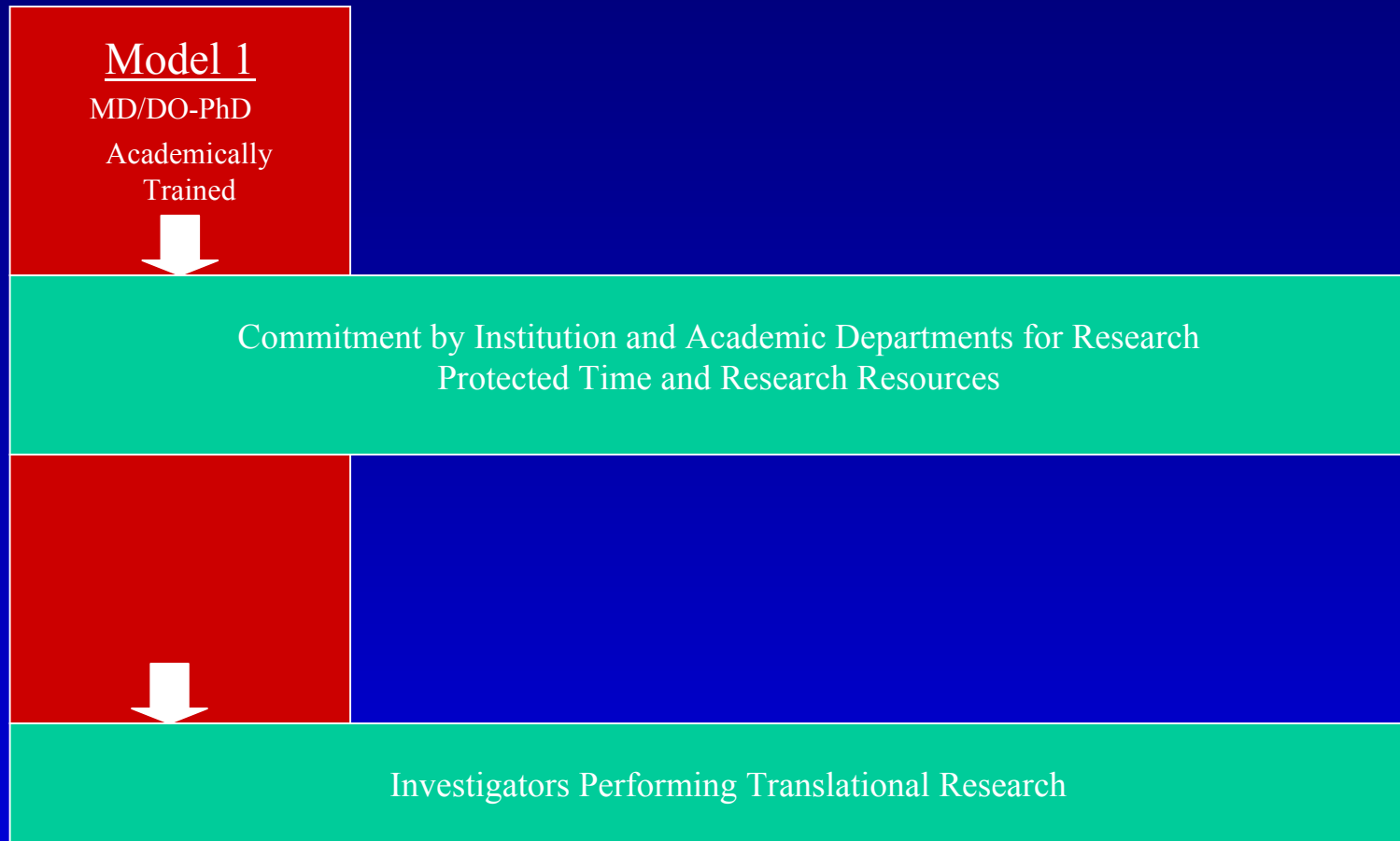


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Addressing the Problem



Estimate of Percentages of Pool of Researchers as Outcomes of Training Method

10%

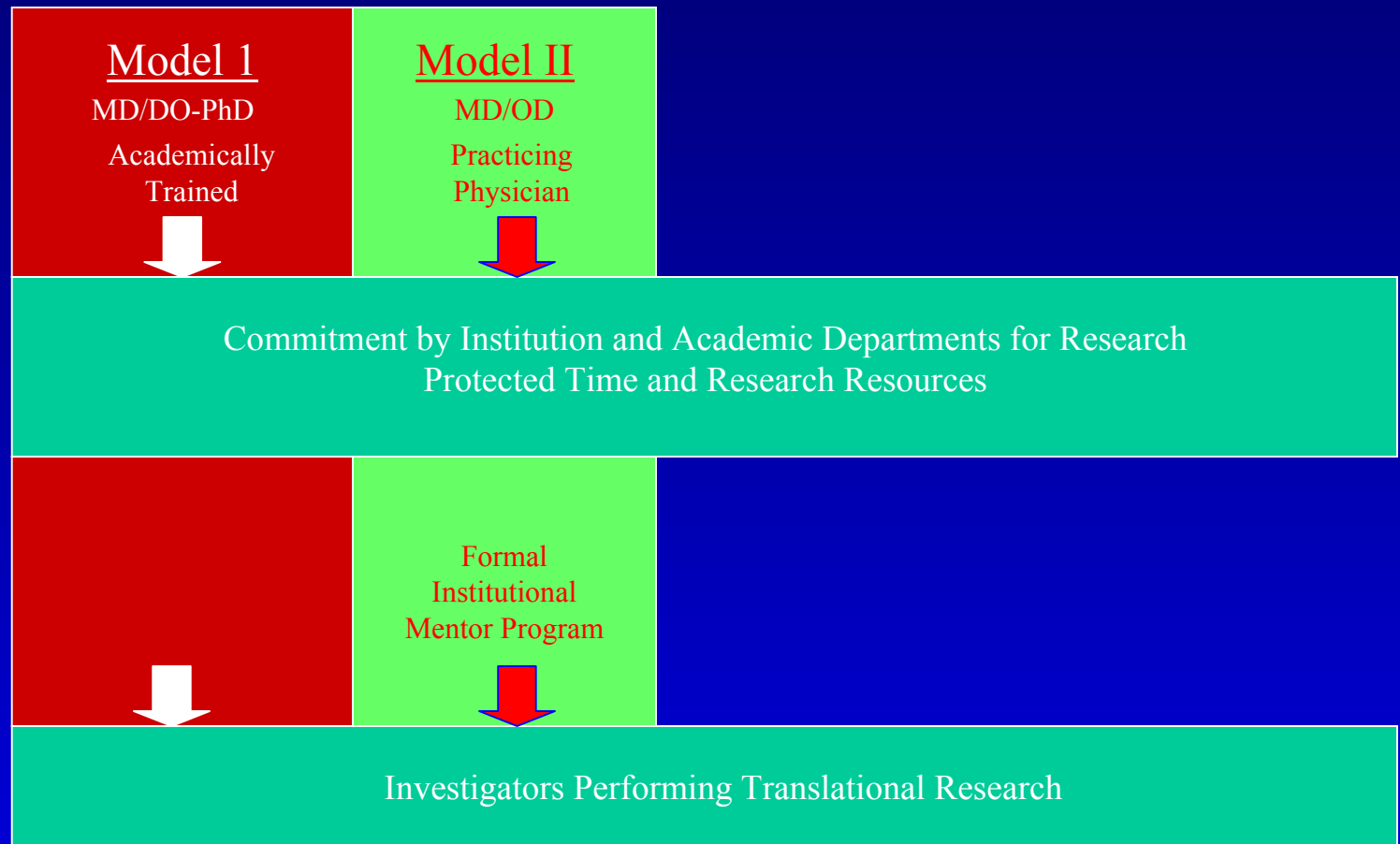
Academic Medicine, Vol. 76, No. 4/ April 2001

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Addressing the Problem



Estimate of Percentages of Pool of Researchers as Outcomes of Training Method

10%

20%

Academic Medicine, Vol. 76, No. 4/ April 2001

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Address the Problem

- Selection of the Mentors
- Mentor the Mentor Program
- Selection of the Mentor Relationship
- Evaluation of Programs

Address the Problem

MD Research Facilitation Awards Penn State Hershey Medical Center

- The Penn State University College of Medicine and the Milton S. Hershey Medical Center announces the availability of “MD Research Facilitation Awards (MDRFA)”.
- These awards are designed to encourage and enhance the productivity of outstanding physician faculty in clinical departments who have already demonstrated success in obtaining peer reviewed funding.
- This program is targeted towards faculty who commit to at least 40% of their time to the conduct of investigator-initiated, hypothesis driven, biomedical research.

Addressing the Problem

MD Research Facilitation Awards Penn State Hershey Medical Center

- The candidate must be the Principal Investigator on a peer reviewed NIH grant or of peer-reviewed support from foundations. Candidates with K and R series NIH awards will be eligible to apply for this program. The level of commitment as PI would need to represent 20% or more.
- This award will support **only investigator time**. No support is being provided for equipment or other personnel.

Addressing the Problem

MD Research Facilitation Awards Penn State Hershey Medical Center

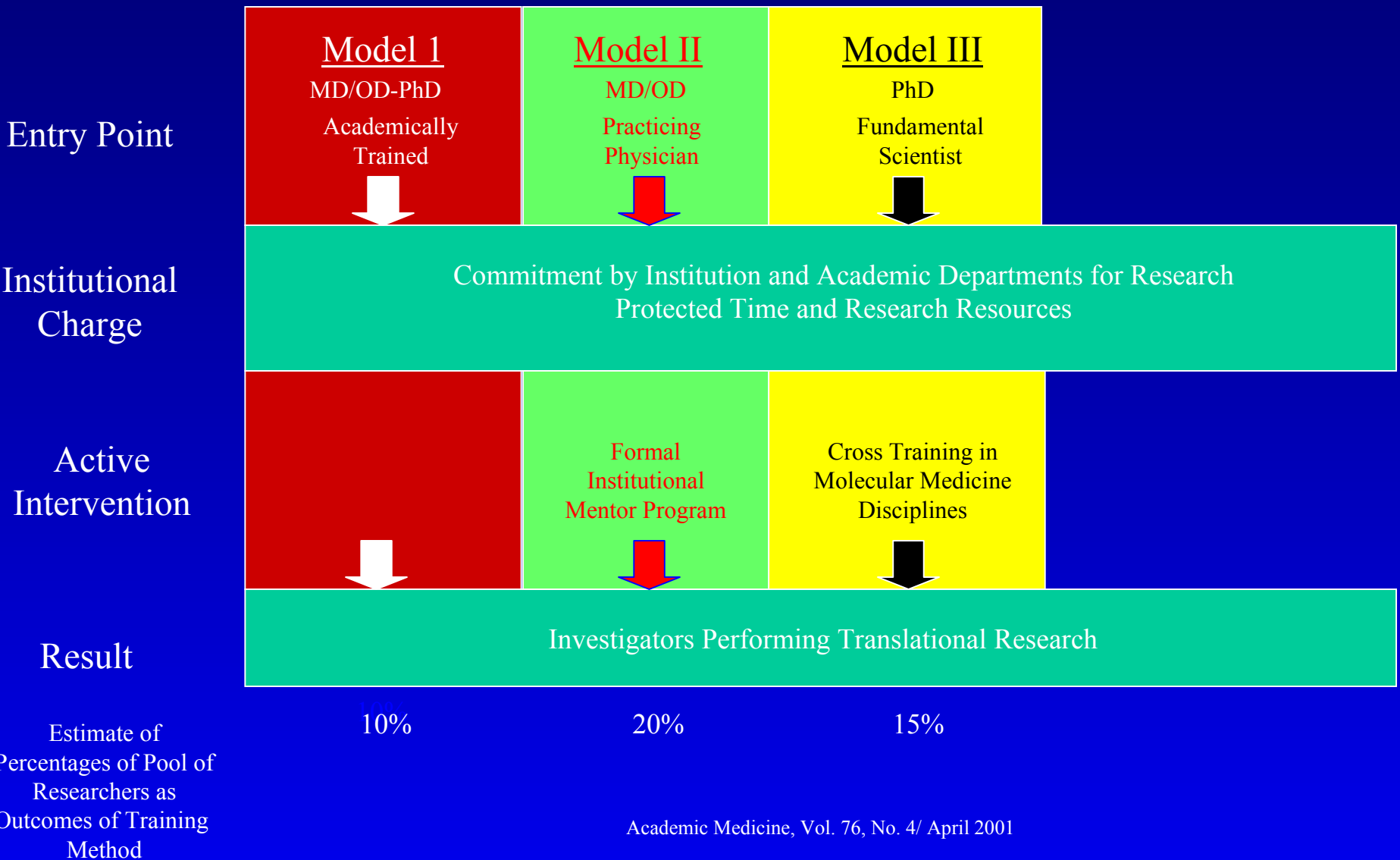
- The Department Chair's portion of the application will include a detailed plan specifying how the dollars from this award will be used to reduce the applicant's clinical workload.
- This plan should include some specific information on the candidate's present level of clinical activity and the plans to reduce this activity by 25%.
- It is expected that this section will be written by the chair or section head and not by the applicant.

Address the Problem

PSU – Physician Scientist Stimulus Package (draft)

- College Salary support for 100% of research effort for 3 years.
- Cost sharing by Department for start-up package.
- Salary savings for academic pursuits.

Addressing the Problem



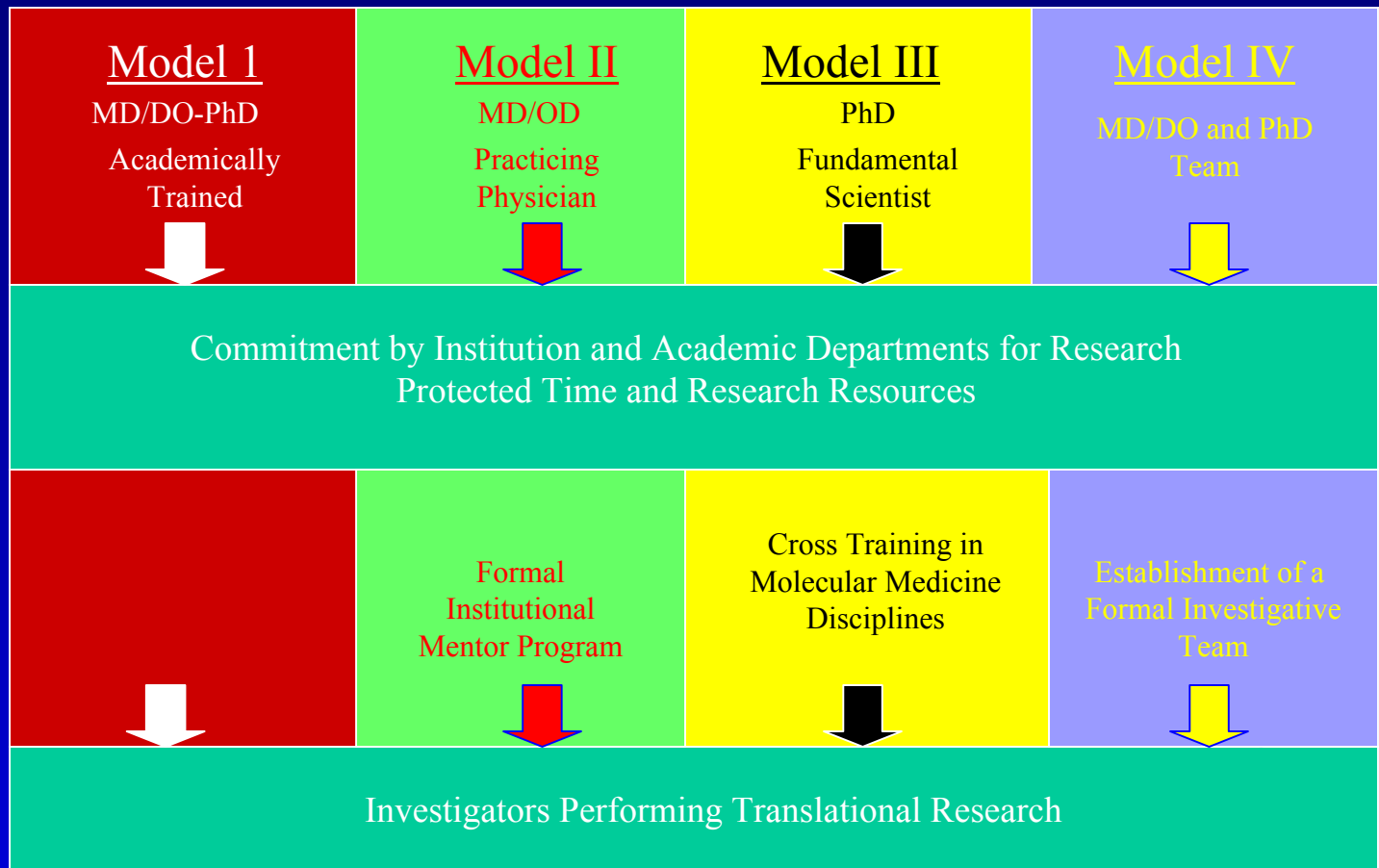
Academic Medicine, Vol. 76, No. 4/ April 2001

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Addressing the Problem



10%

20%

15%

55%

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Address the Problem

Feasibility Grants

- Require MD and PhD working on joint project
- Pilot funding

Addressing the Problem

National Institutes of Health Center for Scientific Review

Action Steps

CSR has recently undertaken a number of steps to address both potential application concerns and review concerns related to clinical applications. These include the following:

- CSR has hired an experienced clinical investigator as an “advisor for review of clinical research” (Dr. Kotchen) to recommend approaches for assuring appropriate peer review of clinical applications and to serve as a liaison with the external clinical research community.

Addressing the Problem

National Institutes of Health Center for Scientific Review

Action Steps

- CSR has developed supplementary guidelines for the preparation of clinical research applications. These guidelines are intended to remind both reviewers and applicants of points to consider that may be unique to clinical applications. These guidelines are available on the CSR Web page http://www.csr.nih.gov/REVIEW/clin_research_appls.htm, with links to NIH Institutes for further Institute-specific information.

Addressing the Problem

National Institutes of Health Center for Scientific Review

Action Steps

- On an ongoing basis, for each of its Integrated Review Groups (IRGs) and study sections, CSR is now tracking and comparing priority scores of clinical with laboratory oriented research applications.
- CSR has initiated a study to determine if study section members who are clinical investigators score clinical grant applications differently from reviewers who are laboratory investigators. This study is being conducted to evaluate the concern that clinical applications are disadvantaged in review groups that include relatively small numbers of clinical investigators.

Addressing the Problem

National Institutes of Health Center for Scientific Review

Action Steps

- Currently, there are six CSR study sections that deal almost exclusively with patient oriented research, including two recently established committees - clinical oncology and clinical cardiovascular sciences. These two study sections have been well received by the clinical research community. CSR continues to evaluate the desirability of creating additional clinical study sections.

Addressing the Problem

National Institutes of Health Center for Scientific Review

Action Steps

- With considerable input from external consultants and advisory groups, the design phase of the CSR study section reorganization has been completed. One goal of the reorganization is to assure a “density” of approximately 25 to 30 percent of clinical applications in all study sections reviewing clinical applications.
- * To increase the pool of clinical investigators who might serve as grant reviewers, at recent presentations, CSR has invited clinical professional societies to submit names of qualified clinical investigators to be considered as potential reviewers.

Challenge to Academic Health Centers

Markey Trust: Strong Translational Program Attributes

- **Leadership.** Programs that require collaboration among departments and that bridge the basic and clinical sciences must have strong institutional leadership by department chairs and deans to enable organizational change to occur.
- **Mentoring.** Successful training is dependent on the presence of excellent mentors. Dual mentors (one a basic scientist, the other a clinician scientist) may be crucial for both physicians and Ph.D. scientists who train in translational research.

*Bridging the bed-bench gap
Markey Trust: 2004*

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Challenge to Academic Health Centers

Markey Trust: Strong Translational Program Attributes

- **Identification of Candidates.** A competitive process and early identification of excellent candidates are essential to recruiting the best trainees.
- **Defined Program.** A carefully structured program with attention to elements of training, defined course work, mentoring, networking opportunities, and research experience was found in programs that the Committee considered to be excellent.

*Bridging the bed-bench gap
Markey Trust: 2004*

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Challenge to Academic Health Centers

Markey Trust: Strong Translational Program Attributes

- **Protected Time for the Physician Trainees.** Time must be protected from the additional responsibility of patient care if the physician-scientist is to obtain sufficient training to enable him or her to compete with their Ph.D. colleagues in research productivity.
- **Sustainability.** As expected, training programs that have endured were able to obtain funding to continue from other sources or from their institutions.

*Bridging the bed-bench gap
Markey Trust: 2004*

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Report Card

Conclusion

- Careful attention to the support of clinical research by academic health centers, private foundations, the pharmaceutical industry, and the NIH remains crucial.
- Investigators as well as academic health centers must pay particular heed to research ethics and to potential conflicts of interest, so that the reputation of clinical research is not sullied.

Nathan & Wilson, NEJM, 2003

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