



NIH Roadmap Workshop: Clinical Research Training in Medical and Dental Schools

May 11–12, 2004

**Crystal Gateway Marriott
Arlington, Virginia**

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Introduction—The NIH Roadmap

Under the leadership of Director Elias A. Zerhouni, M.D., the National Institutes of Health (NIH) has embarked on a multiyear process to identify major opportunities and gaps in biomedical research that the NIH as a whole must address to optimize its entire research portfolio and make the biggest impact on the progress of medical research. This process, called the NIH Roadmap, outlines a vision for a more efficient and productive system of medical research and identifies the most compelling opportunities in three main areas: New Pathways to Discovery, Research Teams of the Future, and Re-engineering the Clinical Research Enterprise. These areas will provide the science, management, and personnel, respectively, to help the NIH catalyze the changes needed to transform new scientific knowledge into tangible benefits for people.

The third area of the NIH Roadmap will re-engineer the clinical research enterprise by adopting a systematic infrastructure that will better serve the evolving field of scientific discovery. Components of this roadmap area include expanding clinical research networks using an informatics system called the National Electronic Clinical Trials and Research Network (NECTAR), translational research core services, and enhanced clinical research workforce training. This last component is the focus of the NIH Roadmap Workshop: Clinical Research Training in Medical and Dental Schools.

Clinical Research Workforce Training

The NIH Roadmap Trans-NIH Clinical Research Workforce Training Committee is exploring ways to cultivate and train a cadre of clinical researchers who will have skills commensurate with the increasing complexity and needs of the research enterprise. Duane Alexander, M.D., Director of the National Institute of Child Health and Human Development (NICHD) and chair of the working group, described the following areas of working group activity:

- Because research will be conducted increasingly in multidisciplinary settings, the NIH will award five or six K12¹ institutional grants this summer to support post-doctoral career development in multidisciplinary clinical research. These grants help introduce trainees in different medical specialties to disciplines such as epidemiology, bioinformatics, clinical study design, and data management during the first year of their training program. The NIH will reissue the Request for Applications (RFA) for K12 grants for competition in fiscal year 2005.

¹The K12 Mentored Clinical Scientist Development Program Award provides support to an institution for the development of independent clinical scientists.

- The NIH has proposed a National Clinical Research Associates Program to increase the involvement of community-based practitioners in NIH clinical research. Physicians, dentists, and nurse practitioners who enlist in the program will enroll and follow their patients in NIH-supported clinical research, especially large-scale clinical trials. This approach has the potential to enroll a patient population that would be more representative of the overall U.S. population and to diffuse the innovations from the trials into clinical practice more rapidly. A feasibility study will examine issues such as the interest and availability of community-based practitioners; the incentives, training, and informatics linkages that would be needed; and the relative cost-effectiveness of the approach compared to the current way of conducting clinical trials.
- The NIH has expanded the Clinical Research Training Program (CRTP) at the NIH Clinical Research Center. The CRTP enables medical and dental students to spend a year at the center participating in clinical research and to receive training in a number of clinical research issues. This program was doubled in size, from 15 to 30 students per year. The expansion of the CRTP without sacrificing the quality of participating students or mentors is the first concrete accomplishment of the NIH Roadmap.
- The NIH plans to address the issue of academic recognition for clinical investigators by convening a meeting of leaders in academic medicine.
- The NIH is addressing the need to reach potential clinical researchers earlier in the pipeline through medical and dental schools. Graduates of the existing Medical Scientist Training Program (MSTP), an integrated program of graduate training in the biomedical sciences and clinical training offered through medical and dental schools, receives the combined M.D.-Ph.D. degree. The majority of MSTP students pursue careers in basic biomedical or clinical research. One focus of the current workshop is to explore the types of incentives or modifications that should be added to the MSTP or whether an alternative, parallel program should be developed to provide medical students with clinical research training as a primary, rather than secondary or incidental, focus.

NIH Roadmap Workshop: Clinical Research Training in Medical and Dental Schools

For the current workshop, the working group convened NIH staff members and outside experts from the research community to obtain their advice as individuals on how best to design a system that can support and encourage the development of a clinical research workforce among medical and dental students. The goals of the workshop are to address the following issues:

- How to increase the number of students in the pipeline who are entering clinical research
- How to attract and train future leaders in clinical research during medical and dental school
- How best to design clinical research training programs during the years in medical or dental school
- How to evaluate whether the clinical research training programs are meeting students' needs and making a difference

- How to initiate a viable career path and improve retention in the clinical research field
- How to set up a coordinated and consolidated continuum of programs that build on each other and can be integrated into medical and dental school curricula
- What barriers can be expected and how they can be surmounted.

The workshop was organized around four different models of clinical research workforce training that could be conducted in medical and dental schools. Plenary and breakout sessions addressed the following components:

- Clinical research training in the MSTP
- Clinical research training in Master's degree programs
- Clinical and translational research training in yearlong pullout programs
- Short courses (e.g., summer or part-time courses) in clinical research.

The diverse group of experts from academia and NIH were provocateurs, who presented an overview and initial ideas for each type of training activity, and respondents, who provided initial comments. All workshop participants had the opportunity to comment at the end of plenary sessions and during three periods of concurrent, small-group breakout sessions. The final day of the workshop included plenary summaries of breakout session discussions.

Clinical Research Training in the Medical Scientist Training Program

Provocateurs: Eugene Orringer, M.D., University of North Carolina at Chapel Hill; and David Robertson, M.D., Vanderbilt University

Respondents: Gary Hunninghake, M.D., University of Iowa; Gary Koretzky, M.D., Ph.D., University of Pennsylvania; and Peter Stacpoole, M.D., Ph.D., University of Florida

Program Description

The National Institute of General Medical Sciences established the MSTP in 1964. Each year, some 170 incoming medical and dental students (in about 40 different programs attending 45 degree-granting institutions) receive support to pursue the combined M.D./Ph.D. degree. Most of these students go on to successful careers in basic biomedical or clinical research.

By integrating the spectrum of medical, dental, and graduate training required for the aggressive investigation of human disease, the MSTP is ideal for highly qualified candidates who can benefit from a broad as well as selectively deep training experience during medical and dental training. Graduates typically pursue a structured curriculum that can be tailored to their strengths and interests. Although the goal of the program is to produce graduates who can function independently in both basic research and clinical investigation, most programs are flexible enough to permit students to steer a course toward their chosen academic or clinical specialty.

Participants in the breakout groups considered what issues must be addressed to increase the likelihood that MSTP grantees will choose a career in clinical investigation and patient-oriented research (POR) if an RFA were developed to enhance the combined-degree pathway.

Major Questions or Issues

Breakout groups identified the following basic questions that need to be answered before final decisions are made about revising the MSTP:

- How can M.D./Ph.D. programs be framed and conducted to become a more coherent process for producing physician-scientists? An important consideration is that many graduates obtain their most significant laboratory experience from the basic science curriculum. Care must be taken not to endanger a manifestly successful program.
- What is the best conceptual model? The model must take into account that although a majority of MSTP candidates are “stem cells” (young college graduates who are eager to aggressively pursue a career in medicine), more than half of practicing clinical investigators are “late bloomers” (medical and dental school graduates who may have finished their residency and fellowships before migrating to clinical training).
- Does the interest in clinical research already exist? If not, how can it best be stimulated? Considerations include whether post-training incentives can be built into the MSTP to make careers in clinical research more attractive and what unique incentives appeal to postgraduates.
- How can the Ph.D. component best be integrated into other existing professional degree programs for dental and nursing programs as well as medical schools?
- What balance should be struck between the didactic and the research components of the program? No standard, agreed-upon curriculum currently exists for training clinical investigators.
- How well are the existing programs working? Students in the more prominent clinical research Ph.D. programs usually have completed medical school and often residencies and post-residency training programs. How can these existing programs be improved?
- Must advanced degree training in clinical research have a laboratory component?

The breakout groups identified one evident and important threshold question: Should the NIH create a parallel but new program or incorporate reforms into the current MSTP infrastructure? Consideration of this question raised the following points:

- Breakout group members were evenly split on this question before discussion began. By the end of the workshop, most members favored tweaking the existing program, although a few maintained that institutions wanting to strike a new path should not be discouraged.
- The primary reasons for retaining the MSTP were its success in producing quality physician-scientists and the effective infrastructure established to implement the program at many participating institutions. Rather than have the MSTP compete with a new

program for students or resources, participants thought it would be better to make the MSTP structure more flexible and provide more options so that institutions could tailor the program to their own strengths and resources. The approach also would avoid the expensive startup costs involved in creating a new infrastructure.

- The best strategy might be to find ways to take into account the idea that clinical research involves a continuum and entails collaboration among professionals along a spectrum, from scholarly work to hypothesis-driven research to POR.
- One way to attract and train more clinical investigators might be to offer a new program that would confer a dual degree by training medical and dental school students for a Master's degree in clinical research. Such a program might qualify for current MSTP support.

Program Design

The breakout groups developed numerous ideas about how to structure an RFA to enhance the combined-degree pathway. After looking at physician-scientists who have emerged as clinical investigators, participants identified three different pathways to a career in clinical research:

- Obtain both degrees at the same time (includes both the MSTP and other programs)
- Complete medical or dental school first, then obtain the Ph.D. degree
- Complete the NIH K12 program (1 year of didactic courses, with mentoring and a laboratory component).

Why—Goals

The following goals emerged from the breakout groups:

- The central goal of the combined-degree programs is to attract students with good potential and then guide them along the clinical research career path. Program designers need to foster passion for clinical investigation and keep students on the combined-degree pathway.
- Mentors can be more pivotal than exposure to specific courses in guiding students onto and along the clinical research career path. Some participants expressed concern about the continued availability of enough quality mentors to meet the needs of students. To foster this important feature of the Ph.D. component of combined-degree programs, the following factors should be considered:
 - Mentors match better with students when both are in the same department and are interested in similar research questions.
 - The scope of the mentoring relationship should be broad, including subject matter, methodology, and career issues.
 - Effective mentoring programs should permit a student to work with more than one mentor; conversely, a single mentor may work with a group of students.

- Good mentoring is an art, but skills can be learned, and institutions should structure their programs accordingly. At first, mentors probably should serve as co-mentors and work with teacher-trainers as well as their students.
 - Mentoring is crucial throughout the student’s career and should not be undermined by a student’s move to a new institution. Institutions need to provide structural incentives to preserve mentoring liaisons even when students or their mentors move to different institutions. It would be helpful for mentors in clinical research to follow the practice of mentors in the basic sciences, who stay actively involved with their protégés after the students begin to get funding and move into independent research.
- The Ph.D. degree retains significance in the field, and its value should be clarified as compared to a Master’s degree. Currently, M.D./Ph.D. students are being trained to become leaders in the clinical research community. Whereas Ph.D. degrees inherently take a student deeper into a field and a particular research question, Master’s degrees generally provide a broader overview of the field. The extended mentorship available to Ph.D. students encourages them to develop both a focus and a mature interest for their own research, enabling them to become true scientists (with a mastery of statistics, epidemiology, and the skills of clinical training) and leaders, not mere methodologists.
 - Institutions and programs should bring allied health disciplines into the fold and minimize structural distinctions among medical, dental, and nursing disciplines.

Who—Selection of Students

The crux of a successful training system entails selecting the right students for the clinical investigator pathway. The breakout group discussions focused on the characteristics of potential program candidates and how to attract them.

- **Current Students.** Participants identified the following characteristics of students currently enrolled in the MSTP:
 - The MSTP has been very successful at keeping people in the field.
 - About 90 percent of MSTP graduates receive clinical training (i.e., a residency and probably a fellowship) when they return to the laboratory for postdoctoral training. More than 70 percent of graduates who have completed such training are conducting some kind of clinical investigation, although not necessarily POR.
 - Many students arrive as “stem cells,” matriculating through an MSTP right after college. Many of these students aspire to become the proverbial “triple threat”—clinicians with patients, laboratory research innovators, and teachers.
 - Experience in a demanding program usually forces a compromise. Analysis of MSTP students who have chosen basic science careers over clinical investigation reveals they have had less exposure to clinical science training than have students who persist on the clinical investigator pathway.

- **Target Students.** Participants made the following suggestions about ways to select future students for the MSTP:
 - The MSTP admission process should be designed to identify candidates who are most likely to succeed in whatever career they choose.
 - Admission committees should not exclude students from the MSTP strictly on the basis of Medical College Admission Test (MCAT) scores. Some institutions select MSTP candidates primarily on the basis of essays.
 - The current MSTP could be restructured and incentives could be provided to double the number of M.D./Ph.D. applicants.
 - Although few in number, the 6-year college/medical or dental school programs offer fertile ground for orienting young “stem cell” students toward the clinical investigator career path.
 - Another way to recruit researchers is to encourage contact between students already enrolled in the MSTP and first-year medical or dental school students, who might be uninformed about or disinterested in clinical research. This approach can create a powerful cross-pollination effect that might spark new interest in clinical research.
 - Program designers should continue to look for “converts” throughout the sequence of the MSTP. One way would be to keep opportunities and RFAs openly competitive and not restricted to MSTP graduates. Potential researchers may be well into medical school or even their residency when a yearlong pullout program experience or clinical rotations push them toward clinical investigation.

- **Incentives.** Questions include whether built-in incentives during the post-training period can make an academic career in clinical research more attractive and what unique incentives would apply to postgraduates. Participants made the following points:
 - Incentives should be identified and developed to appeal to the range of students who might be attracted to clinical investigation as well as the “best and brightest” candidates who would be most likely to succeed, including premedical and 6-year B.S./M.D. students. Prematriculation programs can provide such potential researchers an opportunity to learn about, and even experience, clinical research.
 - The MSTP should be structured to appeal to *both* “stem cells” and “late bloomers.”
 - Mentoring programs could become a strong incentive, depending on how mentorship is structured and how well its successful examples and potential are communicated and publicized.

- **Challenges.** The breakout groups agreed that the clinical investigator arena might be facing a crisis, although better data are needed to confirm this. Historically, 70 percent of faculty members at MSTP institutions consist of “late bloomers” who come to clinical research after completing a fellowship. However, a dramatic drop in the number of “late bloomers” is predicted to reduce by half the number of clinical investigator applicants over the next 10 years. Although the breakout groups recommended doubling the number of applicants, an increase of only 10 to 20 percent is reasonable given the moderate changes that are likely to be adopted within the current MSTP structure. Proactive efforts will be required to attract enough clinical investigator applicants.

When—Timing/Duration

For program designers, the issue of when Ph.D. students are exposed to clinical training and topics related to clinical research raises questions about whether the various options and choices found in different programs might correlate with migration to and success in clinical research careers. At least four classes of candidates deserve distinct consideration: (1) students in college or even younger; (2) students entering medical or dental school; (3) students already in medical or dental school (usually but not necessarily where an MSTP is active); and (4) M.D. graduates who have begun or even finished postdoctoral training, residencies, or fellowships.

Participants identified the following considerations about the timing of exposure to clinical research training:

- The later in their education that students commit to the clinical research path, the less likely they are to change their mind, and the more likely they are to succeed with fellowships and securing jobs and R01² awards. Most Ph.D. programs in clinical research involve training at the postgraduate level through programs such as K12 grants. At the postgraduate stage in students' academic training, the payoff is more readily apparent and is achieved sooner. Having had experience with patients, these students are in a better position to frame worthwhile research questions. Such experience often positions fledgling clinical investigators to compete for K awards³ and R01s within a few years.
- Conversely, in the MSTP model, potential candidates would need to receive substantial early experience with clinical research. This approach is more likely to convert students into clinical researchers because many are still looking for their subject interests and career path. The MSTP structure should be flexible enough to allow students to make their choice after a full year or two in the program and to accommodate students at various ages, with differing levels of training and laboratory and clinical experience. Students' interests change, and programs should establish accessible "on and off ramps," whereby students are not penalized for either joining or leaving the clinical investigator track as they progress through the MSTP. This flexibility should accommodate yearlong pullouts—programs that provide intensive classroom and practicum experience in clinical investigation to students.
- Because training as a clinical investigator can be demanding, students often develop the necessary commitment only after considerable exposure to actual laboratory and POR experience. More opportunities to generate excitement about research should be established in college and medical or dental school to attract "stem cell" students onto this path.
- Dr. Peter Stacpoole proposed a model M.D./Ph.D. program for clinical investigators that would leverage current programs and resources (e.g., GCRCs, the K30⁴ curriculum), put

² R01 Research Project Grants provide support to an institution on behalf of a principal investigator for a discrete project related to the investigator's interests and competence. Most of the research that the NIH supports is maintained through this funding mechanism.

³ K awards are NIH Career Development Awards.

⁴ The K30 Clinical Research Curriculum Award is given to institutions to stimulate the inclusion of high-quality, multidisciplinary didactic training as part of the career development of clinical investigators.

postgraduate training on a short track, and lead to a K23⁵ award as much as 4 years earlier than the normal course. Because the K23 award belongs to the funded investigator and may be pursued in whatever laboratory/institution is feasible, this award could encourage people to migrate to other institutions where they could embody an enthusiasm for clinical research that might attract others to the field. However, this model makes some assumptions and may require some modifications to the K awards.

What—Content/Skills

Discussion about curriculum content and skills was framed by the fact that no well-defined and agreed-upon set of competencies for POR training exists. Moreover, the continuum nature of modern medical research and the collaboration involved in many projects blur even the core definition of clinical research. Thus, program designers have had considerable latitude in striking their own balance between a program's didactic coursework and its laboratory/research components. At many MSTP sites, didactic courses might include biostatistics, clinical epidemiology, pharmacology/experimental therapeutics, and even clinical trials. The Ph.D. component is more variable, especially regarding students' laboratory and clinical experiences. It might include human biology, pathophysiology, POR, and health services research.

Discussions among the breakout groups identified the following lessons learned about content:

- Programs should strongly consider a survey course that describes the research enterprise and career path.
- Exposure to various kinds of meta-analysis (e.g., cost-effectiveness analysis) would prepare students more effectively for clinical research.
- The Ph.D. candidate must gain sufficient actual clinical research experience to be able to compete for a research grant upon graduation.
- Coursework should be sufficiently flexible to address different needs in various settings. Content should be developed on a continuum, not in discrete blocks.
- Mastering the complexity of clinical regulations and working with institutional review boards (IRBs) can be a daunting challenge and could disenchant some potential investigators. The breakout groups were mixed as to how and when the “reality” of this vital aspect of clinical research should be conveyed.
- The NIH could offer students a cost-effective grant of \$3,000 to \$5,000 to help them design and work on a clinical research project, with the aim of whetting their appetite for research.

How—Methodology/Organization

The breakout groups discussed pragmatic ways to reorganize the national MSTP framework and/or the MSTP at individual sites to increase the emphasis on clinical research training. These changes could enrich all participants, including students in the basic sciences, by increasing

⁵ The K23 Mentored Patient-Oriented Research Career Development Award supports 3 to 5 years of supervised study that allows the grantee to develop independent clinical research skills.

awareness of the clinical investigator option and ways that multidisciplinary scholars collaborate across the biomedical spectrum. Participants suggested the following approaches to reorganizing the MSTP:

- **Structural Issues.** Breakout discussions raised the following points about possible structural changes:
 - The goal at MSTP institutions should be to increase awareness of the continuum nature of research and to break down the entrenched barriers between clinical and basic research and applied and laboratory research. The cross-fertilization between basic research students and clinical research students in most medical and dental school classes might encourage some students to change their research focus.
 - The pivotal role of clinical research needs to be reinforced across the medical and dental school curricula. This emphasis can be straightforward (e.g., tweak and enhance the curriculum with courses such as biostatistics, epidemiology, pharmacology, and therapeutics) or more complicated (e.g., add training, practicum, and laboratory components that actually explore POR). Programs that do not lead to a Ph.D. can be designed to produce well-prepared clinical investigators.
 - The structure of the program and the faculty could be reorganized to give clinical research a more integral role. Medical, dental, and nursing departments in non-MSTP institutions could be encouraged to envelop clinical investigation Ph.D. degrees into their existing structures. Such changes will need to be institute-specific and—given the current structure, tradition, and institutional outlook—could be challenging at some institutions. Dr. Stacpoole’s model (see above under ***When—Timing/Duration***) weaves GCRC experience, K30 work, and clinical rotations into the first 3 years to prepare students to actively pursue their Ph.D. component in a clinical field.
- **Director of Clinical Research.** To redress the structural bias that exists at many institutions, medical and dental schools could reorganize their governing structure and establish a position (e.g., director of clinical research, director of clinical studies) that would have parity in terms of perception and decisionmaking power with the director of medical studies. The clinical studies director would not assume a heavy administrative burden but would serve as an advocate and shepherd for the clinical research aspects of the school, including increasing awareness, seeking resources, and integrating clinical research into as many aspects of training and the curricula as appropriate. This recommendation would apply to all medical and dental M.D./Ph.D. programs, not only to institutions with an active MSTP.
- **Leverage and Linkage.** Even if a designated director of clinical research is not established, advocates for clinical research can do better under the current structure. Participants provided the following suggestions:
 - Many POR programs are not taking full advantage of currently available resources, such as the federal support programs (e.g., MSTP, Dental Scientist Training Program, GCRC, K12 programs).
 - If the MSTP is producing a high proportion of basic scientists and the culture cannot be easily changed, an alternate track to attract students into clinical investigation could be established.

- After students have committed to the clinical research path, GCRC opportunities and resources should be explored.
- **Flexibility.** The breakout groups noted the following considerations about the need for program flexibility:
 - The program is a long track, which tends to increase student debt and extends the time until students are able to start earning money. Administrators need to help students find solutions that keep their options open to pursue clinical research.
 - If students have more freedom to forestall their ultimate decision about which path they will pursue, more may end up in clinical research. Their progression through the MSTP should be hindered as little as possible while they are still in a position to commit (or return) to clinical research. Competition for federal support should be opened to allow a more favorable reception of grant requests for POR.

Barriers and Solutions

Breakout groups identified the following barriers and potential solutions related to the MSTP:

- **Availability of Mentors.** Ways to increase the pool of willing and qualified mentors to meet an expanded demand include enhancing the mentoring process, providing incentives, and allowing qualified mentors to work with aspiring Ph.D. students from different departments.
- **Debt and the Time Frame Required for a Ph.D.** Clinical investigators often abandon strictly clinical research after obtaining a Ph.D. because laboratory research jobs offer them an immediate way to start repaying their academic debt. The debt issue needs to be addressed by loan forgiveness, subsidies, and forestallments. The 11-year timeframe to complete the MSTP, subsequent training, and residency needs to be reduced, possibly to lessen the debt incurred but certainly to enable students to begin repaying their loans sooner. Students should be provided financial counseling through a loan *prevention* program.
- **Support.** Clinical investigators need access to funding for their work. Independent research is not always given due consideration by the current academic review process. The value of the clinical research enterprise needs to be more directly reflected and rewarded by promotion and tenure committees at investigators' institutions and rewarded in the mainstream medical training system. The process for credentialing and accrediting Ph.D. and fellowship programs should better reflect this enhanced status of clinical research. If the GCRCs were located in more states, students might be able to take advantage of in-state tuition for residents, which is significantly lower than out-of-state tuition.
- **Preparedness.** Some M.D./Ph.D. students have only minimal research experience when they apply for K30 research grants. Other students may not be versed in the regulatory environment. Even those who do have such knowledge face a difficult transition between the end of Ph.D. training and the beginning of R01 research. The NIH needs to create tools to enable new clinical researchers to initiate and secure grants.

- **Program Flexibility and Multidisciplinary Emphasis.** Participants made the following comments about the central issue of fostering multidisciplinary research:
 - A straightforward way to foster a multidisciplinary emphasis is to stimulate more multidisciplinary teams, which are essential for clinical research. The NIH could help overcome obstacles within divisions and departments by fostering integrated research teams at the medical or dental school level.
 - Multidisciplinary R01 and P01⁶ research teams could include K23 projects of related research and could apprentice medical students who are completing Ph.D. programs. This approach would give students more comfort and familiarity with the multidisciplinary approach to clinical investigation by folding them into a functioning research system.

Evaluation

The central issue for the breakout groups was how well the existing M.D./Ph.D. programs are working. Participants suggested the following ideas for developing reliable evaluation data and conclusions:

- Evaluators could develop comparisons to the postresidency and existing Ph.D. programs that serve medical school graduates (e.g., University of Colorado, Johns Hopkins University).
- It is important to establish the workforce needs. It was suggested that 4,000 combined-degree candidates would be needed, based on the number of current candidates and the number that could be accommodated in a revamped MSTP scenario.
- To determine the success of a program at a given point in time, the following candidate measures should be considered:
 - The ability to compete for and obtain peer-reviewed funding at the R level⁷ and perhaps at the K level
 - Status as principal investigator or co-principal investigator on research grants
 - Ability to initiate POR/clinical research
 - Ability to conduct POR/clinical research (proxies not identified)
 - Publication record
 - Age, with the idea of evaluating programs and strategies to reduce the age at which candidates obtain funding or begin an academic career
 - Career path immediately after completing the training
 - Mentor experience, as a way of feeding back into the system.

Participants suggested that other measures should be solicited from a specific set of scholars in the field. Evaluators also should consider comparisons to analogous situations in academia.

⁶ The P01 Research Program Project award provides an institution, on behalf of a principal investigator, with support of a broadly based multidisciplinary or multifaceted research program that has a well-defined major objective or theme.

⁷ R series grants are investigator-initiated research grants.

Clinical Research Training in Master's Programs

Provocateurs: Carlton A. Hornung, Ph.D., M.P.H., University of Louisville; and Larry Moreland, M.D., University of Alabama at Birmingham

Respondents: Jeffrey Martin, M.D., M.P.H., University of California at San Francisco; Jeffrey Probsfield, M.D., University of Washington; and A. Laurie Shroyer, Ph.D., M.S.H.A., University of Colorado Health Sciences Center

Program Description

The NIH supports clinical research training in Master's programs via the K30 Clinical Research Curriculum Award (CRCA). The NIH developed this program to attract talented individuals to the challenges of clinical research and to provide them with the critical skills needed to develop hypotheses and conduct sound research. The CRCA is awarded to institutions to support the development of new didactic programs in clinical research where they are not currently offered, or to support the improvement or expansion of existing programs. The CRCA fosters core knowledge and skills common to all areas of clinical research and includes formal coursework in clinical research design, hypothesis development, biostatistics, and epidemiology. Currently, 59 institutions are recipients of K30 awards.

Major Questions or Issues

Breakout groups discussed issues related to Master's-level programs for medical and dental students. A key challenge is how to engage medical or dental students in making clinical research a step in their career pathway. The following questions were raised:

- How can an environment that fosters curiosity and passion be created?
- What are the institutional or accreditation barriers and the competing interests among faculty in the basic sciences versus faculty in the clinical sciences, and how can these barriers and competing interests be addressed?
- What factors operate to lead medical and dental students toward clinical research, and how can these factors be optimized?
- Does medical and dental school present the best opportunity to select and recruit individuals into clinical research, or is this already too late?

Some of the key skills and didactic material required to conduct clinical research may already be part of the medical or dental school curriculum. Thus, additional questions include:

- Can this existing material be augmented to incorporate a Master's degree in the medical or dental school curriculum to produce a joint M.D. or D.M.D. and Master's degree?
- How can new or additional material or learning be added to enhance an already crowded curriculum and provide individuals with sufficient skills to conduct clinical research?

Other issues that need to be considered when designing Master's programs for medical and dental students include the following:

- Clinical science is inherently complex; consequently, no single approach to training can accommodate all students.
- Programs need to build a logical sequence of modular didactic graduate course experiences that provide a continuum of advanced academic training options and coordination with accreditation requirements.
- Programs need to incorporate approaches to tele-education and distance learning.

Program Design

The breakout groups noted that Master's programs need to consider how to provide the best clinical research training for *tomorrow's* students, a focus that the groups thought would require substantial changes to the current medical and dental school curricula. Also suggested was a paradigm shift to thinking of degree programs as part of a *career development* continuum, rather than merely blocks of time when individuals receive a certain amount of academic training. This new paradigm has implications for mentorship and the various pathways to a career in clinical research. Summarized below are key elements of program design at the Master's level.

Why—Goals

Group discussion focused on two distinct goals for the Master's program—training medical and dental students in clinical research and getting students excited about clinical research. In keeping with these goals, it was suggested that Master's programs should try to accomplish the following:

- Offer multiple and flexible programs in clinical research and POR as well as in specific disciplines (e.g., clinical epidemiology, biostatistics, health services).
- Encourage students, beginning at the undergraduate (i.e., premedical) level, to develop an interest in clinical research careers.

Who—Selection of Students

A broad-based and diverse group of students should be selected to participate in Master's programs. It was suggested that clinical research training also should be available to nonclinicians (e.g., students in basic science) as well as to students in disciplines such as biomedical engineering and biomedical physics. These individuals will interface with clinical research in critical areas and could help accelerate the translation of science to improve health. Some K30 programs have expanded to include other members of the academic health science center professions (e.g., coordinators, data managers) who support principal investigators.

When—Timing/Duration

It was agreed that at least one extra year would be necessary to obtain a Master's degree during medical or dental school and that timing is critical for this less standard pathway toward a career in clinical research. Debate centered on when students should take the coursework for their Master's degree—either concurrently with medical or dental school or as part of a K30-type

training program during residency or fellowship. Discussion about these two approaches to timing the award of a Master's degree is summarized below:

Dual-Degree Approach. Getting a Master's degree in a clinical research discipline along with a M.D. most likely will take 5 to 6 years. Students who finish a dual degree in medical school will then need to go into clinical training and probably will not have an opportunity to write an R01 grant application until 3 to 5 years after they have completed the dual degree. The following points were made about this approach:

- Providing research training to first- or second-year students in medical and dental school might be too early for them to benefit fully because they do not have enough clinical training and context to ask the right research questions. In addition, skills learned during the first year or two of medical school might be difficult to retain during the subsequent 5 to 6 years of clinical training and subspecialty training.
- An alternate view was that it is better to start clinical research training earlier in medical and dental school because students' openness to learn may have decreased by the time they reach their residency training and begin the program as fellows.
- The optimal timing for the Master's program depends on the individual student. It is important to provide multiple entry points and "just-in-time" access to clinical research training so that students can start coursework when they have the need and interest to learn.
- An early payoff of Master's programs might be that they produce better residents and fellows. Although it was acknowledged that students might lose some skills, the "jumpstart" provided by the Master's program would enable them to apply what they have learned and focus on independent research.
- Master's programs can help address the shortage of clinical investigators by getting more students interested in clinical research at an early age. These programs have the potential to produce many more trained researchers than do Ph.D. programs.
- The dual-degree approach can work, but only if students receive continuing mentoring and support during the 6 to 7 years between achieving their dual degree and being ready to launch their investigative clinical career.

Postdoctoral Master's Degree Approach. Individuals who get a postdoctoral Master's degree through programs such as K30 awards will have had more extensive and intensive clinical experience in patient care before receiving their clinical research training. Breakout group participants commented that the additional clinical experience would enable postdoctoral students to focus more directly and initially on POR, formulate better research questions, and get more out of the training process than they would have as undergraduates. Moreover, students who are awarded a postdoctoral Master's degree are more likely to be ready to write a K23 or other grant application.

General comments about the timing of a Master's program included the following:

- The Master's and other clinical research training programs should be considered as part of a lifelong learning continuum. They do not provide all of the training necessary to become an independent researcher.
- It might be helpful to give medical and dental students an early opportunity to experience clinical research, perhaps in a less intensive fashion than if they were working toward a degree. After students are clinically trained and can formulate their own research questions, they could get more extensive and intensive training for clinical investigation.
- A small-scale program should be funded to determine the right time to train medical and dental students. It might be possible to learn how to select the right students who will benefit most from clinical research training.
- An important timing issue is *when* mentoring should occur. Early mentoring of students who are committed to medicine but not yet to clinical research might encourage students to be more supportive of clinical research, even if they do not become clinical investigators.

It was agreed that although the timing of clinical research training appears to make a difference, this observation is based only on theory, not on data. Questions about the optimal timing should be examined, and students should be offered flexibility as to when they take their Master's level training.

What—Content/Skills

Depending on the institutions, clinical research training programs may offer master of science degrees with an emphasis on clinical science, clinical investigation, health services research, and health information technology. Some programs also offer a master of public health degree and a master of science in public health degrees. Master's degrees also are offered in disciplines such as epidemiology and biostatistics. Fellows may be able to get Master's degrees in POR as part of graduate school in some institutions.

Although participants agreed that the content of clinical research training at the Master's level should be didactic and experiential, the question of how much time to allot to each type of content has not yet been answered.

Dr. Hornung reported that K30 program directors have wrestled for several years with the issue of what core competencies to include in K30 or clinical research training programs. He suggested that the following skill domains should be a minimum requirement for a Master's degree awarded in clinical research training programs:

- Responsible conduct of research, for example, demonstrating awareness of conflicts of interest, regulatory affairs, human and animal subject protection
- Clinical epidemiology and research methodology (e.g., observational and experimental designs, diagnostic test performance/treatment assessment)
- Biostatistics (e.g., quantitative and qualitative analysis)

- Evidence-based medicine or dentistry
- Cultural competence and communication skills (e.g., written and oral communications for professional and public audiences)
- Clinical investigation laboratory-based skills (e.g., genetics and molecular epidemiology)
- Health services and outcomes research (e.g., health-related quality of life, cost-effectiveness)
- Health information technology (e.g., bioinformatics, e-health, database and Web design and management)
- Project management (e.g., team building and leadership)

It was argued that the core competencies of many Master's programs do not prepare people sufficiently to become independent investigators capable of successfully competing for clinical research grants. Whereas Master's programs tend to produce investigators who support clinical trials, Ph.D. programs are more likely to produce leaders in clinical research.

How—Methodology/Organization

Breakout groups made the following suggestions about how Master's programs should be designed:

- Integrate clinical research didactic courses into the medical and dental school curricula.
- Balance didactic coursework with actual experience in clinical research.
- Provide flexible pathways that can be customized according to students' individual needs.
- Provide pathways that are continuous, from identifying potential investigators and recruiting them into training programs to finding ways to support them until they are mature investigators with self-sustained funding.
- Incorporate a Master's degree into a sequential, modular approach to clinical research training. One approach would be to allow students who are awarded their Master's degree in medical or dental school to apply the same credit hours in a meaningful way toward a Ph.D. in their postgraduate training.
- Consider whether institutions with K30 awards and an existing clinical research curriculum could use this infrastructure easily and cost-effectively to train medical students. Although the K30 program currently is designed to prepare people for the doctorate level, the NIH should expand the grant criteria to include medical students. In addition, K30 trainees could be recruited to excite medical students about clinical research careers.

- Blend a Master’s degree program into the MSTP to provide an alternate pathway for students who want additional training in research but are not willing to commit to an extra 4 years of study.
- Provide a culture that is more supportive of clinical research. Possible approaches include:
 - Offering programs in which undergraduates can have an early experience of clinical research
 - Making undergraduate courses more relevant to clinical research (e.g., offering statistics instead of calculus) and presenting students with cases (e.g., research problems) to promote problem-based learning
 - Identifying feeder schools that can provide input to the medical or dental school
 - Offering elective courses for which undergraduates could receive academic credit toward their Master’s degree in clinical research when they reach medical or dental school.
- Design a re-entry vehicle for dual-degree students who have earned a Master’s degree. The re-entry program should bring students up to speed in areas such as methodology and statistics after they have finished their residencies and fellowships.
- Build bridges among health professions schools by sharing courses, expertise, and students. For example, a program could swap faculty or students between institutions for a year).
- Consider partnering with professional societies and perhaps industry to extend resources and access expertise. Industry already recruits many physicians to help conduct clinical trials; however, partnering with industry could raise conflict-of-interest and IRB issues.
- Consider the future role of physician investigator certification examinations that currently are administered by bodies such as the Association of Clinical Research Professionals. This certification might be an important consideration for the training of the proposed National Clinical Research Associates.

Barriers and Solutions

Breakout groups identified the following barriers and potential solutions for Master’s programs:

- **Financial Support for Students.** Although many established funding mechanisms support postdoctoral fellows for 2 or 3 years, most institutions do not have a mechanism to support medical or dental students while they take the time needed to get a Master’s degree. Participants suggested the following solutions:
 - The NIH should establish innovative approaches (e.g., mechanisms similar to the K12) to support medical students during these periods dedicated to clinical research training.
 - Institutions could develop a program to retain Master’s students as teaching assistants for coursework with trainees who are a year or two behind in the program.

- Loan forgiveness programs are needed for individuals pursuing a career in clinical research.
 - Institutions need to address the issue of whether medical and dental students should pay in-state tuition rates, rather than much higher out-of-state rates, while they are taking graduate courses in clinical research.
 - The NIH should expand opportunities for T35⁸ funding, with multidisciplinary opportunities for individuals entering medical school.
 - The NIH should examine how much it is spending on clinical research training, including the actual number of medical students supported each year by the NIH and its individual Institutes. The NIH should address the apparent drop in this funding.
- **Lack of Mentors.** A career development approach to clinical research training will increase the need for and demands on mentors. Ways to address the anticipated shortage include providing incentives such as changing the promotion process to reward mentoring activities and paying mentors for each predoctoral student (as K12 awards do for postdoctoral students). Some schools require departments to recognize faculty time devoted to mentoring. Institutions also should carefully screen student applicants to match them with the most appropriate mentors.
 - **Existing Curriculum and the United States Medical Licensing Examination, Step 1.** The basic science emphasis on the United States Medical Licensing Examination (USMLE) examination dictates not only the curriculum for the first 2 years of medical school but also the admissions requirements for medical school. This emphasis on basic science and math skills might lose undergraduates who would be interested in clinical research training. Suggested solutions include revising medical school entrance and board examinations to include more emphasis on clinical research disciplines and encouraging curriculum committees to make similar changes to medical and dental school curricula. Plenary comments noted that the USMLE has attempted to integrate basic science with the clinical arena.
 - **Degree Requirements in Clinical Research at the Master's Level.** K30 program directors have questioned whether M.D./M.P.H. and M.D./M.S.P.H. degrees are appropriate preparation tracks for clinical research investigators and associates. Shifts in requirements for these two Master's degrees have increasingly emphasized coursework in topics such as environmental health and health administration and education, rather than in core material for the clinical research curriculum. The NIH definition of clinical research includes behavioral science, health services research, and other topics that are mainstays of the M.P.H. and M.S.P.H. curricula. However, it was suggested that these programs are more appropriate for training people to perform research in areas such as epidemiology and health policy, rather than people who do the type of work conducted at clinical research centers. Master's programs that are considering whether to offer M.P.H. and M.S.P.H. degrees should consult with the Association of Schools of Public Health and the Council of Education for Public Health about specific coursework required for these degrees.

⁸ T35 National Research Service Awards are Short-Term Institutional Research Training Grants to provide individuals with research training opportunities during off-quarters or summer periods to encourage careers in biomedical and behavioral research.

Evaluation

Postdoctoral training programs, especially the K30 programs, need to be evaluated independently for their productivity. Evaluators must take a careful look at the long-term productivity of individuals who complete a Master's degree as part of a dual degree, compared to people who achieve the degree during their residency or fellowship years. However, different evaluation models and sets of outcome measures should be used to assess the productivity of these two groups of graduates. Because data or formulas to establish the success of Master's programs currently are lacking, a continuous quality improvement perspective is needed.

Clinical and Translational Research Training in Yearlong Pullout Programs

Provocateurs: Donald Landry, M.D., Ph.D., Columbia University; and Frederick Ognibene, M.D., National Institutes of Health

Respondent: William Galey, Ph.D., Howard Hughes Medical Institute; and Bernard Maria, M.D., M.B.A., Medical University of South Carolina

Program Description

The following programs offer yearlong programs in clinical and translational research training:

- **Howard Hughes Medical Institute Scholars and Fellows.** The Howard Hughes Medical Institute (HHMI) is the only yearlong program that offers tuition support toward completion of a medical or dental degree or loan repayment of debt. The Research Scholars Program (The Cloisters), run in partnership with the NIH, brings 42 awardees to the HHMI campus each year, where they take classes and engage in research for 1 year. The Research Training Fellowships for Medical Students program annually provides awards to 60 students, who conduct research at their home campus in a year-out program. Indicators of the HHMI's success include that fact that about 10 percent of HHMI students eventually complete an M.D./Ph.D. and 70 percent publish a scientific paper after their year of research. Of the 300 students who completed HHMI programs in the 1980s, more than 60 percent are still engaged in research; of this 60 percent, more than 90 percent are engaged in patient-related research.
- **Doris Duke Clinical Research Fellowships at Columbia University.** The Doris Duke Charitable Foundation sponsors a minimum of 50 fellows per year for a 1-year fellowship conducting clinical research and obtaining didactic clinical research training at one of 10 outstanding medical schools. Fellows receive stipends plus health insurance. Students matriculated at any medical school in the United States are eligible to apply to any or all of the 10 designated medical schools.
- **Clinical Research Training Program.** The NIH's CRTP awards clinical research grants to 30 applicants for a year of training at the NIH. The award includes a stipend, book allowance, paid health insurance, money for meeting travel, dinners, and lectures.

- **National Center for Research Resources, Division for Clinical Research Resources Program.** The NIH's National Center for Research Resources offers one clinical research fellowship per GCRC each year, or approximately 35 awardees annually. The award includes an annual stipend and money for meeting travel.
- **Sarnoff Endowment for Cardiovascular Sciences.** The Sarnoff Endowment for Cardiovascular Sciences offers up to 15 clinical research awards per year. These awards comprise an annual stipend, travel and moving expenses, and health insurance.

Major Questions or Issues

Breakout group members discussed critical pathways to becoming a clinical researcher. Participants agreed that 1-year programs are valuable tools for promoting clinical research, but changes might be needed in the design and evaluation of these programs. The yearlong research opportunity must be flexible, well protected, and financially well supported. The major issues discussed included the decreasing number of students who are interested in clinical research; the declining interest observed in students over the course of their 4 years of medical or dental school; and the need to recruit, support, train, and compensate good mentors.

Program Design

In addressing the possible need for changes in yearlong programs, the breakout groups discussed the elements of the program design described below.

Why—Goals

The overarching goals of the yearlong programs are to:

- Increase the number of clinical researchers
- Give students a real feel for the nuances and excitement of clinical research
- Provide medical science leadership.

Noting that none of the yearlong programs aims to provide complete training for medical scientists, participants suggested the following additional goals for yearlong programs:

- Attract a more diverse population of participants than do lengthier training programs
- Help students decide whether they should take further training in clinical research
- Produce 100 percent of the “advocates” for the research enterprise.

Who—Selection of Students

All research programs, including yearlong programs, are competing for the same shrinking pool of applicants. The percentage of medical students interested in research careers is declining and will continue to drop because the growing number of female medical students are less

interested than male students in the current programs that offer research opportunities. Specifically targeting women for selection might help increase the shrinking pool of applicants.

Only about one-half of applicants to yearlong programs come from medical schools because medical students face cultural pressures to stay “on the treadmill” and graduate as soon as possible. The following other factors influence students’ choices about enrolling in a yearlong program:

- **Culture.** In the past, the medical education establishment emphasized the value and need for more primary care physicians; as a result, fewer students went into clinical research.
- **Awareness of the Programs.** Most medical school students know about the HHMI-NIH Research Scholars Program (The Cloisters); few know about the CRTP.
- **Citizenship.** One-third of U.S. medical residents did not graduate from medical schools in the United States and consequently have not had access to these yearlong research training opportunities.

When—Timing/Duration

The discussion about timing focused on when students should take a year out for research during medical or dental school. One suggested approach would offer training early, despite the heavy course load of first- and second-year medical and dental students. A second approach would provide training whenever the student was ready for it. A third approach would delay training until the student had the clinical medicine framework and was seeing patients.

A concentrated full-year program that links the student to a mentor would be valuable and offer the most continuity. However, other options should be available, such as a 4- or 5-year program in which research is interspersed with the medical or dental school curriculum. Each program could be individually designed. The research could continue throughout clinical training.

Participants discussed the following options:

- A 1-year concentrated course within a 4- or 5-year medical or dental school curriculum
- Short courses that are taken before medical or dental school with a booster session between the first and second year of medical or dental school
- A yearlong block of research at the end of third year, with an optional year extension (with negotiations toward having a degree granted at that time). Participants discussed the following advantages of this approach:
 - Peers are brought together and mentor each other.
 - The course is the student’s “job” for a year.
 - Students are better able to decide whether clinical research is right for them.
- A continuous year of research training versus an integrated (segmented) year. Participants discussed the following benefits of the integrated approach:

- Students can plan ahead for their research segments.
- Students have continuity in working with a mentor throughout all 5 years.
- This approach is more flexible and can be customized.

Most participants favored a flexible approach in which students could participate whenever they felt ready.

The discussion also covered the following points:

- Some students are interested in clinical research, but do not want to take the time to get a Ph.D. degree. A yearlong program might fulfill their needs.
- Students who have completed a yearlong program do not appear to have spent any less time in their medical school training.
- A large drop-off of interest in research occurs between the time students start medical or dental school and when they graduate. Consequently, there is a need to nurture their interest in clinical research throughout that period.
- Some participants felt that the optimal timing for the yearlong research experience is after medical and dental students have finished their clerkships. However, other participants supported making yearlong programs available without many prerequisites whenever students were interested.
- There is a bias among students and institutions toward yearlong programs that take place after the third year of medical or dental school. However, many students prefer taking a year off after their second year.
- A 5-year plan for medical school could incorporate a year of clinical research training into the curriculum to allow maximum flexibility. Whether the research year is segmented or not depends on the content the program.

What—Content/Skills

Discussion about the content of yearlong programs focused on the relative importance of didactic curriculum versus mentoring. The discussion about content produced the following points:

- It would be helpful if the yearlong coursework could be structured to lead to a Master's program.
- Case studies could be used to help present didactic content.
- Some core competencies need to be taught.

Participants discussed the possibility of tying clinical research training to the core competencies of medical school. However, some expressed concern that such an approach would create a kind of Master's program in clinical trials and outcomes research that would not provide students with the experience of doing clinical research. A suggestion to include an actual protocol/IRB component in the yearlong program content generated some opposition because the

complexity of dealing with IRB regulations might discourage predoctoral students. Other participants favored the inclusion of this element because it would give students an appreciation of the IRB's importance in the protection of human subjects and other ethical issues.

Participants considered the model of the Doris Duke Clinical Research Fellowships at Columbia University, which devotes 15 percent of students' time to a core curriculum that includes biostatistics and ethics; it does not include any science courses. The Doris Duke curriculum also includes an IRB practicum. The mentorship component includes a requirement for students to be involved in one or more research projects involving conception, IRB prosecution, formulation of consent forms, data acquisition and interpretation, and publication—all under the guidance of a mentor. Most participants agreed that mentorship is more important than didactic courses in the yearlong programs.

Another good model for providing students with guidance on finding a mentor is the CRTP process. CRTP students are paired with tutors who help them determine the qualities they want in a mentor. The tutors then give the students several possible choices of mentors, whom the students interview before choosing one.

HHMI scholars are encouraged to contact previous protégés of potential mentors to obtain feedback on whether the mentors have a track record of successfully graduating students, securing funding, publishing articles, and treating people well. The Accreditation Council for Graduate Medical Education has made it mandatory for programs to provide a contact list of previous protégés so that students can learn about potential mentors.

The discussion of mentorship covered the following additional points:

- Mentors should not be burdened with overseeing the details of their protégés' didactic coursework.
- Mentorship includes all the people with whom students interact in the laboratory and in the program.
- Offering seminars is another form of mentoring.
- Peer mentors are important in students' clinical research experience.
- Ways to improve mentorship skills might include mentors from the yearlong programs partnering with schools of education to learn how to become better mentors. The NIH Intramural Program is launching a mentorship training program.
- Good mentors are assigned too many students. It is important to find ways to recruit good new mentors.
- There should be a college of mentors and financial rewards for mentors.
- A segmented or integrated year is more difficult than a continuous program for mentors.

How—Methodology/Organization

Discussions on methodology among the breakout groups centered on a grassroots approach versus a center-of-excellence approach. Yearlong programs should be structured so that students receive from their institutions some sort of academic recognition for their work. Academic health centers are at the center of current research but are failing economically. Few centers are capable of sustaining the infrastructure needed for a clinical research training program.

Many students who are interested in doing clinical research are at institutions that cannot support them; therefore, centers of research (e.g., the Doris Duke centers) might offer a way to provide more training opportunities. Students could go to these centers for a year of clinical research training and then return to their home institutions after their year off. Another possible solution might be for the NIH to revive the intramural Clinical Associates Program, which provided a 2-year opportunity, with a reasonable salary and other benefits, between the second and third years of residency. The program also would provide a good networking and peer support atmosphere. Most academic institutions could offer this kind of program on an interdepartmental basis, but residencies may need to be structured to accommodate the 2 years off, especially if the training program is multidisciplinary.

Participants favored the creation of a periodic electronic community meeting or Webcast for all yearlong scholars. This forum could supplement the physical meeting that now takes place at the end of the yearlong programs. A model for this activity might be the Doris Duke Clinical Investigator Student Trainee (CIST) Forum, which brings students together to talk about career paths, loan repayment, and ways to balance career and family. The CIST Forum also is constructing a database of information on yearlong scholars.

Barriers and Solutions

Participants discussed the following barriers to yearlong programs and suggested some potential solutions:

- **Retention of Interest and Skills.** A critical challenge for students who take yearlong training programs is how to keep their interest and skills in research current while they are completing the remaining years of medical or dental school and their residencies. The NIH could address this barrier by encouraging 6-year combined-degree programs, especially at institutions that have a medical or dental school on campus and thriving clinical research programs.
- **Financial Debt.** Debt from medical and dental school expenses poses a significant barrier to participation in yearlong programs. However, the NIH loan repayment program provides some help. A 1980–1993 study showed no correlation between the level of medical students' debt and whether they went into research. However, participants agreed that more current data are needed to fully assess the effects of students' debt burden on career decisions.
- **Funding.** Both students and mentors should receive balanced financial support. In addition, students should receive some small financial recognition from their medical or dental school for achievements, such as being published. Another potential source of support is the use of the Institutional Training Grant as a mechanism by which to request a certain number of individual training grants. These grants could be held for students who want to request funding for a year off to participate in clinical research training. The

grants already would be in place, and institutions could award grants to students without a lengthy review process.

- **Culture.** The medical and dental school cultures pose a barrier to yearlong training programs. One solution in medical schools would be to create more opportunities for medical students and program participants to observe the links between clinical investigation and patient care. Another solution would be to expand the scope of more programs to include dental as well as medical students.

Participants also discussed the following points about barriers and solutions:

- The NIH is running out of mentors. Good mentors need to be recruited.
- No central organization of data exists on the number and location of yearlong program slots that are available.
- Awareness of the yearlong programs needs to be raised at all medical and dental schools.

Participants thought that the existing infrastructure should be used to solve the need for more yearlong research opportunities. The breakout groups recommended that training grants, e.g., the T32⁹, include the opportunity to add a year off for medical students or residents to perform clinical research. The review process should be shortened to a 6-week turnaround, possibly using the local GCRC as the review mechanism. Ancillary studies to the NIH's large clinical trials might offer opportunities for a yearlong program for medical students.

Evaluation

Reliable, long-term data are needed to frame issues and make resource decisions regarding yearlong programs. Measurements should focus on how many yearlong pullout program participants continue on the clinical researcher career path. Evaluation should include qualitative measures such as focus groups and interviews with people who have recently completed their training.

Short Courses in Clinical Research

Provocateurs: Patricia Hibberd, M.D., Ph.D., Tufts University; and Stephen Hulley, M.D., Ph.D., University of California, San Francisco

Respondents: Wishwa Kapoor, M.D., University of Pittsburgh; Michael McPhaul, M.D., University of Texas Southwestern Medical Center at Dallas; and Jay Piccirillo, M.D., Washington University School of Medicine

⁹ T32 National Research Service Awards Institutional Training Grants enable institutions to provide opportunities for predoctoral and postdoctoral research training to individuals selected by the institutions.

Program Description

Short courses present a fourth option for generating interest and training medical and dental students in clinical research. These courses provide a less intensive way to introduce larger numbers of students to clinical research and thereby impact the clinical research pipeline. Short courses provide the perfect opportunity for students to find out whether they are suited for clinical research. Examples of activities that are offered in short courses include summer programs that teach about clinical research and research methods, short rotations at GCRCs, and 2-day courses that are offered as part of continuing medical education seminars. More generally, instruction on the design and interpretation of clinical research should be included in the epidemiology and biostatistics that is a required component of every medical and dental school curriculum.

Major Questions or Issues

The distribution and content of short courses is not well understood because each institution has its own program and courses are not standardized. Moreover, evaluation systems for short courses are lacking. Although there is a need to think globally about all short courses, no national clearinghouse, database, or other accessible compilation of available short courses in clinical research currently exists. However, the NIH and the Association of American Medical Colleges is considering inventorying clinical research training programs ranging in length from 1 day to 5 years.

Issues related to program design include the need to determine what the goals and intended outcome of short courses should be, who should take short courses, when short courses should be offered, how to incorporate short courses into the curriculum, and how to evaluate short courses. Other issues discussed at the workshop included whether to focus on short courses for medical and dental students rather than a broader array of health professional and college students, where short courses fit in medical and dental school curricula, the lack of standardization for short courses, and the difficulty of providing practical experiences in clinical research with high quality mentoring.

Program Design

Breakout groups discussed the key elements of program design for short courses on clinical research in medical or dental schools.

Why—Goals

Participants suggested the following goals:

- Provide skills and a belief system to ensure that graduating medical and dental students can read and critically evaluate clinical research in the medical and dental literature and understand the basis for evidence-based medicine and dentistry and practice guidelines.
- Generate excitement about clinical research as a career by providing students with role models and opportunities to participate in clinical research. Progress toward this goal will help create a pipeline of students entering training and maintaining skills in a variety of didactic and mentored clinical research programs.

- Provide basic knowledge and skills to enable future physicians and dentists to participate ethically and effectively as clinical research collaborators.
- Provide the first step in acquiring the knowledge and skills needed by future principal investigators and leaders in clinical research. Short courses can prepare and motivate students for Master's and Ph.D. programs.

Short courses also support clinical research training in the following ways:

- Introducing clinical research as an academic career by providing supportive faculty as mentors and role models from the start of medical or dental school
- Introducing the importance of clinical research in improving patient care and health outcomes
- Providing opportunities for medical and dental students to interact with students from other disciplines (e.g., business, law, psychology, engineering) and to broaden their horizons in multidisciplinary research
- Using multidisciplinary research environments and groups to evaluate and redesign courses.

Who—Selection of Students

Participants made the following suggestions:

- All medical and dental students should have basic knowledge and skills in clinical research.
- Additional training should be made available to selected medical and dental students.
- Including other types of students in short courses will provide opportunities to leverage with other disciplines (e.g., nursing, pharmacology, engineering, veterinary science, nutrition) that are likely to be included on multidisciplinary clinical research teams.
- The clinical researcher pipeline begins with high school and college students. “Starter” courses that address clinical research and statistical methods would be valuable for introducing concepts and generating excitement about clinical research among these students.

When—Timing/Duration

Participants made the following comments:

- Core skills in research design and critical evaluation of the literature should be taught in required courses early in the first year of medical or dental school.

- Additional components could be offered each year during medical and dental school, both integrated with other courses and offered between sessions.
- Starter courses in epidemiology and statistics should be offered in high school and college.

What—Content/Skills

Breakout groups suggested two types of short courses:

- Didactic with an emphasis on problem-based learning
- Practical clinical research experiences.

How—Methodology/Organization

Participants made the following suggestions about how short courses should be designed:

- Initial core skills taught at the outset of medical or dental school should involve the understanding of study design, critical thinking, and skills to access the medical literature.
- The basic knowledge and skills that all students should master during medical or dental school would be integrated throughout the curriculum. Required courses would include epidemiology and study design; biostatistics; clinical epidemiology/critical evaluation/evidence-based medicine and clinical decision making; preventive medicine and public health; ethics, behavior, and health policy; and health disparities and community-based participatory research. Students also would learn skills for becoming effective participants on multidisciplinary teams and embracing new topics and expertise relevant to clinical medicine.
- Advanced training electives for selected students would include the following options:
 - Courses in designing clinical research, clinical trials, genetic epidemiology, biostatistics, and meta-analysis (coursework would vary depending on the institution)
 - Selected Web-based courses whose approaches are designed to engage students
 - Hands-on experience in a 1- to 6-month practicum doing research. This experience might include working with a mentor (e.g., in a K24¹⁰ program), working at a GCRC, or gaining exposure to IRB meetings and processes. Practicums are often feasible during the break between the first and second year or during the fourth year as an elective. Students can participate most effectively in practicum experiences that take place longitudinally across substantial periods of time.
- Short courses can be designed to illustrate the impact of clinical research. For example, case studies and small group problem-based learning can be used to engage student interest. Short courses also can address the relationship of clinical research to private industry and foundations.

¹⁰ The K24 Midcareer Investigator Award in Patient-Oriented Research supports clinicians for protected time to devote to patient-oriented research and to act as mentors for beginning clinical investigators.

- In addition to the graduate medical and dental education arena, other audiences for short courses might be found in the continuing medical education and industry arenas.
- An important consideration is whether it is better to dedicate short courses for medical and dental students or integrate short courses into post-MD and post-DDS clinical research training programs.

Barriers and Solutions

- **Mentor Limitations.** The breakout groups identified limits on the number of skilled mentors with adequate time as a leading barrier facing short courses. The following suggestions were made about ways to enhance mentoring:
 - The NIH should provide mechanisms, in addition to the K12 and K30 programs, to train, reward, and set aside protected time for mentors.
 - Institutions should provide basic science mentors with substantive training in clinical research.
 - Institutions should encourage the use of co-mentoring, which would offer a student two mentors, with distinct but complementary expertise and skills (e.g., clinical research and basic science, epidemiology and a clinical specialty, content and methods).
 - Institutions could establish new criteria for the promotion of mentors. This approach would require changing the reward system, expectations, and perceptions for faculty members.
 - To leverage mentors' R01s and other grants for mentoring funds, the NIH could provide a large number of small supplements for mentoring students. These should have a brief, rapid-turnaround application process similar to the minority supplements that provide administrative supplements to existing grants for the support and recruitment of underrepresented minority investigator.
 - The NIH and institutions should provide adequate funding through a variety of mechanisms to compensate mentors for their involvement in mentorship activities.
 - Institutions with strong research programs should partner with less research-intensive institutions to provide mentors and other guidance and support.
- **Fiscal Limitations.** Medical and dental education is one of the areas most in need of fiscal support. Suggested approaches to overcoming fiscal limitations include the following potential solutions:
 - The NIH should revise priorities to put more emphasis on clinical research training.
 - Institutions should consolidate programs and resources, improve efficiency, partner with other institutions, and use the K30 and K12 programs and the GCRC to teach students about clinical research.
 - The NIH should provide support for student research activities by broadening the T35 and T32 programs.
 - The NIH should develop a mechanism to allow institutions to apply for modest supplements to existing grants to support mentoring and student research.
 - Innovative thinking is needed to find external funding sources, such as industry and continuing medical education programs.
- **Difficulties in Designing Research Questions for Practicum Experience.** The limited duration of short courses poses challenges for designing feasible research

- questions that can be investigated and answered by relatively unskilled medical or dental students in a short period of time. Participants suggested the following solutions:
- Have students work with experienced mentors on an existing project to gain experience in carrying out a literature review and meta-analysis in designing and conducting a pilot study, in developing and pretesting an instrument, or in collecting and managing data. .
 - Have students design a clinical research protocol, and participate in an interdisciplinary mock review of each other’s protocols.
- **Lack of Support for Students.** Stipends and other support are lacking for students’ research and travel to conferences. One potential solution is to institute a new funding mechanism, resembling the minority supplement program, to provide large numbers of small supplements to existing NIH grants (e.g., R01s) to support student clinical research activities. These supplements should have brief, rapid-turnaround application processes.
 - **Insufficient Institutional Commitment and Curriculum Committee Barriers.** Institutions are not sufficiently committed to providing short courses in clinical research for their students, and curriculum committees are more likely to promote basic science courses than clinical research courses. Participants suggested that institutions can take the following actions to overcome these barriers:
 - Increase the level at which indirect costs are generated for training grants from 8% to a much higher level to adequately address the overhead costs to institutions of these training activities.
 - Revise the allocation of grant funds so that direct costs can include more education expenses.
 - Educate curriculum committees and deans about the importance of clinical research education.
 - **IRB and Regulatory Challenges.** IRB and Federal regulations are an essential but complex, time-consuming, and often problematic aspect of clinical research that can seem daunting to students (as well as researchers). Instruction in these topics is important, but should focus more on case-based ethics discussions than on regulatory mechanisms to avoid discouraging potential clinical investigators at the beginning.
 - **Disparity Among Schools.** Considerable disparity exists among institutions that have clinical research programs and those that do not. Participants suggested the following approaches to address this disparity:
 - The NIH should expand the number of initiatives similar to the K30 grants. The K30 program has been especially efficient and cost-effective and could serve as an excellent model for catalyzing clinical research training for medical and dental students at all U.S. schools. The NIH should consider expanding these programs to target the education of medical and dental students, which is not a goal of the K30 programs (which target students who already have an MD or other advanced health degree).
 - Institutions should develop mechanisms to share resources across all medical and dental schools, providing interaction at faculty, scholar, and mentor levels.
 - Medical and dental schools should use the NIH Roadmap to guide clinical research curricula.
 - Regional centers of excellence for clinical research education could be created to focus resources and train students who would return to their institutions. However,

the creation of such centers might work against attempts to reduce disparity among institutions

Evaluation

Short courses need to undergo rigorous evaluation, and research is needed to improve evaluation systems for short courses. Supplements to grants could be provided to evaluate programs. Suggested approaches to assessing short courses include the following:

- Short-term or surrogate measures include student performance on exams, course and mentor evaluations, and program evaluations. However, these surrogate outcomes do not have intrinsic value unless they lead to improved career outcomes, which are difficult to evaluate.
- Long-term follow-up mechanisms to examine career outcomes should be designed to collect pertinent information that is as complete as possible. Determining appropriate ways to categorize career directions and make comparisons poses a challenge. Long-term measures could include indicators of students' career development several years after taking the course, such as important the students' career milestones, number of grants received, and publications. Breakout groups made the following comments about long-term follow-up mechanisms:
 - The NIH should consider requiring grantees to monitor and track the impact of short courses on the production of clinical researchers. No data on this outcome are currently available.
 - The impact of short courses on the general ability to participate in clinical research, and to critically evaluate the medical literature, should be evaluated in all medical and dental students

Closing Remarks

Allocation Exercise

During the opening plenary session, participants received a voting sheet on which to indicate how they would allocate \$100 (in \$5 increments) in hypothetical NIH funds among six options related to existing or potential research training programs. Tabulations of the forms collected at the beginning of the workshop indicated that participants would have allocated funds to the six training programs as follows:

| Training Program | Allocation |
|--|-------------------|
| Adding clinical research to existing MSTP programs | 13.9% |
| Setting up a new M.D./Ph.D. program in clinical research | 20.1% |
| Master's programs in clinical research | 24.3% |
| Yearlong pullout programs in clinical research | 18.3% |
| Short courses in clinical research | 10.7% |
| Adding clinical research to medical school curriculum | 12.8% |

An analysis of the hypothetical allocations indicated some clustering by training programs. For example, Master's programs and yearlong pullout programs were clustered most closely together.

Voting sheets were redistributed on the final day of the workshop to determine any change in how participants would distribute the hypothetical funds. Results from forms collected on the final day of the meeting were to be tabulated and e-mailed to participants.

Summary Remarks

Robert Star, M.D., of the National Institute of Diabetes and Digestive and Kidney Diseases, described the following crosscutting themes that were raised during the workshop:

- **Fortuitous Timing.** The NIH Roadmap's effort to train the clinical research workforce comes at a propitious time, when patients are again becoming the focus of study. The clinical research community is challenged with determining how to train leaders in research, other members of research teams, and all students going through medical or dental school. This work is focusing institutions on the importance of clinical research and prompting interactions between the clinical research community and the broader scientific community that otherwise might not have occurred.
- **Career Development versus Academic Training.** This effort goes beyond academic training to an entire career development pathway. Moreover, the focus is on the career development of not merely an individual but of the entire clinical research team, including principal investigators, pharmacologists, nurse clinicians, and study coordinators. A goal should be to support, train, and maintain this cadre of individuals on their career pathways and to ensure that each path is viable.
- **Range of Programs.** A full range of programs is needed because each program has a distinct purpose in training various members of the research team and filling the pipeline of future clinical researchers. For example, whereas the M.D./Ph.D. program is a way to train team leaders, the Master's program may be best situated to training other team members. The Master's and 1-year pullout programs may be important first steps for engaging some individuals in clinical research. The short courses are the first step in filling the pipeline, and the medical and dental school curriculum is needed to train future clinical research associates.
- **Career Development Structure.** The NIH would like to see a career development structure that focuses on teaching clinical research skills, which are more critical than the specific degree earned. This structure would have some of the following characteristics:
 - Fluid, continuous programs with blocks of training that build on each other
 - Flexibility (e.g., in terms of timing and depth) that is centered on the students' interests and needs
 - An integrated community in which students and mentors all learn from each other by working together
 - Availability of ombudsmen to represent students and help them in matters such as choosing a mentor or solving problems that may arise
 - A way to ensure that students get credit for all the work they do

- Development of a national shared core curricula so that institutions do not have to continually reinvent the same wheels
 - Loan prevention as well as loan repayment
 - National meetings that bring together mentors and trainees to share ideas and network
 - An evaluation and tracking component that is built in from the beginning with defined outcomes or surrogate outcomes.
- **Mentors.** Although the K12 award includes support for mentors, more needs to be done to help institutions devise a formal status for mentors, designate time for training mentors and doing the mentoring, and provide payment so that documentation is available when tenure committees are considering promotion.
 - **Pipeline.** The pipeline issue needs more consideration, including how to stimulate interest in clinical research careers early by reaching colleges and high schools.
 - **Broad Involvement.** The NIH clearly cannot undertake the clinical research workforce training effort alone. The involvement of the entire clinical research enterprise, including industry and professional associations, is needed.
 - **Need for Innovation.** The K30 award was intended to catalyze innovation by letting institutions use the funds as they saw fit. This flexibility encouraged the development of many good ideas.
 - **Economic and Ecologic Issues.** One important question is whether the career development tracks or pathways are economically viable now and will be viable 5 years from now. Also important is an ecologic analysis of how one change to the health care system (e.g., adding a training program) affects the rest of the system.
 - **Other Ideas.** The workshop generated other ideas for clinical research training, including the development or reinvigoration of a medical or dental school research track and a sabbatical program for retraining or cross-training basic scientists in clinical research.

These themes and the other ideas that emerged from the workshop demonstrate the importance of the NIH obtaining external feedback from institutions, where many innovations are being developed. These ideas will be incorporated into an RFA during the coming months.



NIH Roadmap Workshop: Clinical Research Training in Medical and Dental Schools

May 11–12, 2004



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