Incorporating Clinical and Translational Science into the Undergraduate Medical Education Curriculum

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The accreditation standards established by the Association of American Medical Colleges (AAMC) are divided into 12 different standards with each standard having sub-categories or "elements." Standard "7" includes elements related to the content of a medical school's curriculum. Unrecognized by most translational scientists and by leaders of clinical and translational science institutes is the fact that one of the 9 elements of standard 7 specifically requires that a medical school include an educational program in translational research in its curriculum. Standard 7, Element 3 (7.3 SCIENTIFIC METHOD/CLINICAL/TRANSLATIONAL RESEARCH) states that: "The faculty of a medical school ensure that the medical curriculum includes instruction in the scientific method (including hands-on or simulated exercises in which medical students collect or use data to test and/or verify hypotheses or address questions about biomedical phenomena) and in the basic scientific and ethical principles of clinical and translational research (including the ways in which such research is conducted, evaluated, explained to patients, and applied to patient care). However, the AAMC provides little or no guidance about how to teach students about CTS. Thus, translational scientists, the Association for Clinical and Translational Science (ACTS) and the Clinical Research Forum (CRF) have the opportunity to help craft CTS educational and research programs for undergraduate education.

The AAMC and the Liaison Committee on Medical Education (LCME) provide generic rather than formulaic information as to how a medical school should educate undergraduate medical students about CTS. For example, medical schools are required to provide a narrative response that: 1) List[s] the course(s) that include instruction in and assessment of content related to the scientific method; 2) Include hands-on or simulated exercises in which medical students collect or use data to test and/or verify hypotheses or to experimentally study biomedical phenomena; 3) List all required courses and clerkships that include formal learning objectives that address the basic scientific and ethical principles of clinical and translational research and the methods for conducting such research; and 4) Note the location(s) in the curriculum in which medical students learn how such research is conducted, evaluated, explained to patients, and applied to patient care and how students' acquisition of this knowledge is assessed. Therefore, there is great latitude as to how an individual medical school teaches CTS allowing individual CTS leaders to craft an educational experience for their own students.

The absence of specific guidelines regarding CTS education enables the Association of Clinical and Translational Science (ACTS) and the Clinical Research Forum (CRF) to develop a national education program in CTS. A national program would facilitate the creation of a physician workforce that has the requisite knowledge to; effectively critique clinical studies before incorporating new treatment strategies into their clinical practice; serve as investigative sites for clinical and translational research; and recognize novel adverse effects of newly approved drugs and devices. In the boldest sense, a successful undergraduate program in CTS could build a level of interest in medical students early in their careers that may result in a greater number of students pursuing careers as physician scientists and or clinician investigators.

We believe that a successful educational program in CTS must be based on several fundamental premises. First, students should have a didactic experience that introduces them to the common themes that underlie all successful research: research ethics, biostatistics, data security, medical and research informatics, clinical trial design, the omics (genomics, proteomics and metabolomics) and epidemiology. Second, CTS, like medicine itself, cannot be taught exclusively in a classroom or in a small group session. Students must have hands-on experience in either a laboratory, a clinical research center or a data center in order to have a full understanding of the strengths and weaknesses of the different investigative modalities. Third, in order to attract students to CTS as a career choice, we must introduce CTS early in the curriculum. Waiting until the 4th year to introduce CTS will insure that students will pay little attention. In fact, CTS projects should be introduced as early as possible to enable students to pursue a research project throughout the four-year curriculum if they are so inclined. In addition, by getting students excited about CTS research early in their medical education there will hopefully be an increase in the number of students who elect to pursue research for an entire year under the sponsorship of the National Institutes of Health, the Sarnoff Foundation or the Howard Hughes Medical Institute.

At the Temple University School of Medicine we have taken a series of steps to effectively introduce our students to the clinical and translational sciences. Starting with this year's entering class, we are requiring each student to complete a scholarly activity in the clinical and translational sciences during their four years in medical school. The concept is being introduced during the first half of year one. Students will receive didactic information during a two week block at the end of the first year which will include information about the ethics of clinical investigation, clinical trial design, epidemiology, biostatistics, investigational review board procedures, health disparities and

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DOI: 10.1111/cts.12333

other topics related to translational research. Faculty members will be drawn from the Center for Translational Medicine, the Department of Clinical Sciences, the Temple Clinical Research Institute, the Center for Bioethics, Urban Health, and Policy, the Center for Health Disparities, and the Center for Transformative Medicine. Each student will be expected to present a poster and/or oral presentation at the annual Translational Science Research Symposium that is held each spring. A panel of faculty from each relevant center and department that undertake translational research serve as advisors for the students to help them select a project and a mentor. Students are encouraged to begin their projects during the summer between their first and second years in order that they can continue projects across the four years of the curriculum. However, some students may opt to begin their projects during elective time in their third or fourth year.

Our students are also exposed to CTS during their clinical rotations through journal clubs that dissect clinical research studies. For example, during the medicine clerkship students are provided with a recent clinical trial that has been published in a high impact journal. The group is then divided into two groups with one group serving the role of an FDA advisory board and the second group representing the study sponsors and the principal investigators. The sponsors present the data to the advisory board that then makes a recommendation regarding the approvability of the new drug or device. Similar journal clubs are held in each of the remaining core clinical clerkships.

Meeting the presumed intent of Standard 7.3 has several important challenges. For example, many of the medical schools that have been created in the past two decades, including the first for-profit allopathic medical school, support only modest amounts of translational research.[1] Developing hands-on opportunities for their students in CTS may be difficult if not problematic for these schools. This could result in an increasing number of practicing physicians who are unprepared to participate in clinical research and further diminish the pipeline of physician scientists and clinician investigators. The ACTS should create on-line curricula that will provide students who do not have access to CTS research with the fundamental concepts that underlie CTS. The ACTS and/or the CRF should also provide opportunities for students to pursue translational research using internet-based resources and databases and on-line mentoring. The requirement for experience in translational science is one of many reasons why shortening the undergraduate medical education curriculum to three years is shortsighted.

A second challenge for medical schools is how to evaluate and assess CTS curricula. Both formative and summative evaluations of individual students is possible based on written or oral examinations that test their knowledge of CTS and on the success of their research projects. It will be far more difficult to assess the important long-term benchmarks relevant to CTS: the number of students that pursue a career in clinical or translational research; the number of students who participate in clinical research projects once they are in practice; and the comfort level that physicians have in critiquing studies that have appeared in high priority journals. Carefully constructed surveys may provide important information although some type of incentive will be required to insure that an adequate number of physicians participate in the survey.

The AAMC should be congratulated for recognizing the importance of knowledge about and experience in the clinical and translational sciences for the practicing physician as well as for the physician scientist and the clinician investigator. However, the AAMC has left it up to individual schools of medicine to create the programs that will provide students with the requisite experience in CTS. Therefore, there is an important need for the ACTS and the CRF to create CTS curricula, to identify the competencies for students participating in CTS educational programs, to design the tools that institutions can use to assess and evaluate their programs, and to develop on-line CTS curricula and research opportunities that students can access when support is limited at their own institution. The inclusion of CTS in the undergraduate curriculum should result in a physician workforce that is better prepared to care for patients in an era when practicing physicians will be asked to participate in real-world clinical research and to critically evaluate the increasing number of clinical studies evaluating a plethora of new drugs and devices. Ideally, inclusion of CTS early in the undergraduate education will also open the pipeline and increase the number of physician scientists in the United States. **CTS**

Reference

1. Feldman AM, Runge MS, Garcia JG, Rubenstein AH. American medical education at a crossroads. *Sci. Transl. Med.* 2015; 7: 285fs17.