Pharma Exposure Occurs Early in Training and More Often in Rural Clinical Sites

To the Editor: “Is the public likely to benefit if practicing physicians and medical educators must perform their duties amidst the clamor and striving of merchants seeking to increase the sales of drugs by conscripting ‘education’ in the service of promotion?” Charles May, MD,1 penned this in 1961, but it could just as easily have appeared today. The recent findings of Sierles and colleagues2 are both a cause for cautious optimism and a call for more aggressive action in the ongoing discussion of interactions between physicians and the pharmaceutical industry.

Sierles and colleagues make an important distinction about where pharmaceutical marketing exposure is taking place: teaching sites outside the academic medical center (AMC). At the University of Washington, we surveyed first-year students placed in medically underserved settings for a summer clinical immersion. We learned that by the end of their first year, over one-third had already eaten an industry-sponsored meal. Further supporting the findings of Sierles and colleagues about off-campus exposure, we discovered that student exposure to pharmaceutical sales representatives was greater in rural than in urban settings.

Timing of exposure is also an important consideration. Although Sierles and colleagues focus on third-year medical students, medical students can be exposed to off-campus pharmaceutical industry marketing much earlier—even before they matriculate. For example, the increased emphasis admissions committees have placed on prematriculation physician shadowing means that premedical students may be exposed to pharmaceutical marketing before they are equipped to evaluate the ethical implications of this entanglement between doctors and industry. After enrollment, office-based preceptorships and early clinical immersions are additional areas worthy of attention. Off-campus experiences in community settings may limit the impact of conflict-of-interest (COI) policies and place students in ethically uncomfortable situations.

We echo Sierles and colleagues’ call for early and frequent training on the role of the pharmaceutical industry in health care, and we agree that AMCs should consider revising their relevant COI policies to extend to off-campus learning environments.

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References

In Reply to Evans et al: I appreciate Dr. Evans and colleagues’ expansion of our understanding of which teaching sites experience the greatest amounts of student exposure to drug company marketing. I concur that addressing conflicts of interest must happen in premedical and early medical curricula as well as in the third and fourth years. The quotation from Dr. May, in 1961, about “conscripting education in the service of promotion,” vividly illustrates the ongoing struggle to maintain an appropriate relationship between academic medicine and the pharmaceutical industry.

In 2008 the Association of American Medical Colleges (AAMC) recommended that “Academic medical centers should make clear to their faculty, students, and staff that to the extent certain interactions with industry are prohibited within academic medical centers, they are also prohibited off-site.” They did not discuss strategies for obtaining compliance with this prohibition. Several of my coauthors, who are primary care physicians, perceived that there would be considerable difficulty in obtaining compliance from volunteer preceptors outside the academic medical center, upon whom medical schools rely heavily for outpatient assignments. We would welcome suggestions from Dr. Evans and colleagues, from the AAMC, or from others about how best to approach or engage these preceptors to address conflicts of interest.

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Reference

The Research RVU (rRVU): In Search of a Methodology to Incentivize and Compensate Clinicians for Participation in Clinical Research Activities

To the Editor: In their Commentary, Embi and Tsevat1 present a valuable discussion concerning one of the chief “roadblocks” to recruitment of clinical trial research subjects. That roadblock is lack of incentivization for busy, overstretched clinicians to participate in clinical trial research. Not discussed are factors present in current clinician compensation systems that can further discourage providers from clinical research participation.

The majority of clinician providers in this country are currently compensated through relative value unit (RVU) or similar performance-based systems, and the majority of U.S. medical facilities do not have dedicated research-only teams. This is especially true at community-based, nonacademic facilities where increasing numbers of clinical trials are now being performed. Therefore, clinical research trials at these facilities are predominantly performed by clinicians and teams who are simultaneously performing standard-of-care (SOC) duties. Clinical performance tracking systems are increasingly electronic medical record based and may track clinicians utilizing various contact time and level-of-effort performance formulas, such as the RVU. Such systems may not identify time and effort performed with clinical trial patients as research activities, and funding streams are purposely kept separate from SOC documentation and compensation tracking as mandated by funding bodies. Thus clinician performance directed toward clinical research activities

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may not be recognized and tracked by these clinical performance tracking systems. This leads to the peculiar situation of a clinician generating increased incomes for the facility (research payments are frequently in excess of SOC payments for the same effort) while being seen by their clinical performance tracking systems as underperforming for that period. In turn, the clinician may actually be financially penalized (significantly disincentivized) for generating increased facility revenues, due to a lack of research performance tracking.

Trial sponsors and managers, if made aware of this dichotomy, can offer to compensate clinicians by making performance payments directly to researchers. However, such direct compensation payments, if not accompanied with time and performance documentation, can be misinterpreted by various watchdogs as “kickback” situations and thus seen as a violation of regulations such as the federal antikickback statues, or Stark Law, as well as reportable under the Sunshine Act.3

A research RVU (rRVU) or other performance-based system needs to be developed that can accurately document research performance and ensure that clinicians are appropriately compensated and incentivized for all time and work directed towards clinical research, especially in situations where clinicians are also simultaneously performing SOC duties.

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References

In Reply to Severance: We appreciate Dr. Severance’s interest in our relative research unit (RRU) model for incentivizing clinicians to contribute to the research enterprise. We agree with Dr. Severance’s major points, but wish to clarify and expand on some of them.

The point of our article was in fact the very one that Dr. Severance articulates in his letter—namely, that a need exists to measure and incentivize nonresearcher clinicians’ involvement in research-related efforts, including but not limited to clinical trial recruitment. Our suggested RRU approach explicitly does not pertain to clinician–researchers, who are already compensated for their research activities in other ways (e.g., salary support on grants). In that vein, Dr. Severance utilizes the term “research RVU (rRVU)” in the same way that we use the term “RRU”; we prefer “RRU” because others have defined the rRVU as a mechanism to compensate researchers, as opposed to nonresearcher clinicians, for whom the term RRU would apply.

We believe that the need for an RRU incentive model has only intensified in the time since our Commentary was published. The advent of value-based payment models will create a need for additional practice-based research. Efforts to operationalize the learning health system, realize the benefits of major investments in electronic health records (EHRS) and related health information technology infrastructure, and engage in evidence-generating medicine activities at the point of care increasingly rely upon nonresearcher clinicians. The Centers for Medicare and Medicaid Services (CMS) plan to roll out two clinician payment mechanisms. Under one of them, the Merit-Based Incentive Payment System, payments will be based on performance quality, resource use, clinical practice improvement activities, and meaningful use of EHRs. Given the importance of research in discovering and assessing the effectiveness of new and existing evidence, we believe that a need exists to measure and incentivize clinician contribution to research should be an added payment criterion for CMS and other health care payers, as well as study sponsors, and that RRU could be the mechanism to capture those contributions.

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Leadership Training and Stress Relief

To the Editor: In a recent letter to the editor, Peter N. Mittwede1 considers ways of coping with the stress and burnout affecting trainees and early-career physicians.2 I concur with his suggestion that service to patients and community, combined with the development of leadership skills, will help alleviate some of those pressures.

The March/April issue of the Physician Leadership Journal explored the renewal experienced by physicians participating in medical missions to treat patients in impoverished countries. More than 500 groups organize at least 6,000 medical missions a year and universities are scrambling to keep up with demand. “You go and just do something because it’s simply the right thing to do,” stated St. Louis neurosurgeon Paul Young. “Missions satisfy something inside you that originally drove you to medicine.”

Though they are often personally fulfilling, medical missions are first and foremost about caring for patients in need. Young now spends his mission trips teaching neuroscience to local physicians so that when he leaves, there are more skilled neurosurgeons left behind. “Everyone who goes on medical missions will say it was one of the best experiences of their lives,” Young said. “You come...”