EDITORIAL

Ethical Considerations in Clinical Research

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In the May 8, 2011 issue of *Annals of Surgical Oncology*, Guest et al. published two papers summarizing their results of a single-institution survey reporting the prevalence of burnout, psychiatric morbidity, and quality of life of 97 surgeons at Memorial Sloan Kettering Cancer Center (MSKCC).^{1,2} Of the 72 respondents, 42% reported burnout, 27% reported psychiatric distress, 30% screened positive for “potentially problematic alcohol use,” and 13% reported the use of sleep medications. Very importantly, as Drs. Balch and Shanafelt point out in their accompanying editorial, these factors can adversely affect “patient safety, quality of patient care, and even contribute to medical errors.”³ In addition to reporting the prevalence of burnout, the authors attempt to identify modifiable aspects of the work environment. One of these modifiable factors related to the taboo associated with burnout; 32% of participants reported a great need to change the “taboo to discuss personal distress and the culture of bravado.” One could argue that the open publication of these results from a prestigious and internationally recognized cancer institution, which demonstrate consistency with national data on surgeon burnout, will help in deconstructing the taboo and stigmatization associated with addressing personal distress in the workplace.

Unfortunately, acknowledgment of the prevalence and associated stigma of physician burnout and the desire to lessen that stigma are not sufficient measures to remove the stigma—at least not immediately. The current reality is that burnout, psychiatric distress, and “potentially problematic alcohol use” are emotionally charged subjects that can have significant social implications including the stigmatization

and marginalization of a community. In this case, the community in question is alarmingly specific—an identified institution’s surgery department with fewer than 100 members.

In all population-based research and especially with community-based research addressing behavioral issues, the question has been asked: Can a community’s right to privacy be violated even if individuals within the community have consented to the disclosure of information?⁴ We believe that the referenced studies indicate the answer is “yes”; that by identifying the department of surgery by institution, this community’s privacy has been compromised. Furthermore, the published results focus on psychosocial issues that could potentially lead to the stigmatization of this select group of surgeons, placing at risk the welfare of both the individuals who participated in the survey and, importantly, the 25 surgeons who did not.

Therefore, we believe that these publications highlight important topics relating to the ethical conduct of clinical research. The guiding principles of clinical research in this country: respect for persons, beneficence, and justice, are based on the fundamental tenets historically promoted by the Nuremburg Code, the Helsinki Declaration, and the U.S. National Commission that issued the Belmont Report in 1979 and are now set forth in the Code of Federal Regulations. These principles are designed to protect human subjects with institutional assurances through formal institutional review board (IRB) review and informed consent obtained by the principal investigator or his or her designee.

It certainly appears that the investigators took precautions to protect the rights of individual participants and thus uphold the Belmont principles. IRB approval and the voluntary nature of the survey study are documented in the methods section of the publications, suggesting that subjects were informed that their voluntary participation implied consent and that the results of the survey could be used for future publications. Because of sensitivity to the small sample size of a specific department and in order to

ensure individual anonymity, demographic and practice characteristics data were not collected. The aim of the survey was to develop “targeted, preventive measures that would be acceptable to participants and reduce stress in their lives.” The goal of publishing the results is presumably to share these data in hopes that other institutions will also develop useful interventions to address the important problem of physician burnout and physician mental health. It is safe to assume that the benefits of this research will be distributed fairly, as the subjects of the survey will also be the recipients of the planned future interventions.

However, one might ask if all possible measures were taken in these studies to avoid the inherent breach of confidentiality that occurred as a result of the reciprocal link between individual and community and to avoid the potential harm of stigmatization associated with these results. We would submit that the answer to this question might be “no.” By combining the data with other similar institutions or by not identifying MSKCC, the privacy breach and potential harm could have been avoided without compromising the integrity or impact of the results. Secondly, where does the primary responsibility for oversight of the ethical aspects of behavioral clinical research reside? The social implications of population health research is an area that traditionally has

not been a primary concern of IRB reviews; but it is an area that deserves dialogue and certainly everyone, including investigators, institutions, sponsoring organizations, and journals disseminating knowledge to the scientific community, must share accountability for the ethical aspects of clinical research.⁵

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