It is not fair to ask of others what you are unwilling to do yourself.
—Eleanor Roosevelt

TWO ETHICAL EXEMPLARS

Michigan ICU Study

In the United States, 80,000 bloodstream infections related to catheters occur each year in intensive care units (ICUs) leading to increased lengths of stay and costs (Miller & O'Grady, 2012). Researchers continue to investigate interventions to reduce morbidity and costs (Kim, Holtom, & Vigen, 2011). In 2004, clinicians from Johns Hopkins University coordinated a prospective cohort study to examine the impact of introducing evidence-based strategies to reduce infection rates in all ICUs in Michigan (to be referred to in this chapter as the Michigan ICU study). Just over 100 ICUs participated in the 18-month study (Pronovost et al., 2006). A large and sustained reduction in rates of catheter-related infections occurred (up to 66% reduction). The median number of infections per 1,000 catheter-days decreased from 2.7 at baseline to 0 during the final study period ($P < 0.002$).

The study involved a number of educational interventions targeted at ICU personnel to improve patient safety. This included designating one physician and one nurse as team leaders in each ICU. The researchers developed a checklist to promote clinicians' use of five evidence-based procedures recommended by the Centers for Disease Control and Prevention. These were (a) hand washing; (b) using full-barrier precautions during insertion of central venous catheters; (c) cleansing the skin with chlorhexidine prior to catheter insertion; (d) avoiding, where possible, the femoral site for catheter insertion; and (e) removing unnecessary catheters. Neither expensive technology nor additional ICU staff was required, though each hospital provided adequate staff to implement the educational intervention.

The study had limitations and, as with any study, required critical appraisal (Daley, 2007; Jenny-Avital, 2007). Nonetheless, the results were praised in *The New York Times* as "stunning" because of how the study saved more than 1,500 lives during its 18 months (Gawande, 2007). However, a few weeks after the study results were published, the Office for Human Research Protections (OHRP), the federal agency charged with protecting people involved in research in the United States, ordered an investigation into possible ethical violations in the study (Miller & Emanuel, 2008). In November 2007, the OHRP ruled that the project had violated ethics regulations and should be shut down, including planned expansions in other states (Gawande, 2007).

The OHRP held that the Michigan ICU study had violated two ethics regulations. The study was submitted to the Johns Hopkins University IRB, which deemed it exempt from review. The IRB viewed the project as an EBP implementation and QI initiative, not clinical research. The OHRP disagreed and held that it was research. Informed consent was not obtained in the project because it was considered exempt from IRB review (Pronovost et al., 2006). OHRP held that informed consent should not have been waived for this reason because it viewed the project as clinical research.

Wide application of OHRP's approach could mean that "whole swaths of critical work to ensure safe and effective care would either halt or shrink" (Gawande, 2007). In the resolution to the situation, both the parties agreed that the study was clinical research because an educational intervention of unknown efficacy was being tested on clinicians (OHRP, 2008). At the same time, it is most likely that the study would have satisfied the regulations for expedited IRB review since it involved no more than minimal risks (Miller & Emanuel, 2008). The IRB review could also have determined that informed consent was not ethically required since the five infection-control guidelines were evidence-based (i.e., their

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expected outcomes previously had been demonstrated through research) and patients were not being put at additional risks (OHRP). The protocol could have been introduced as part of standard clinical practice and covered by patients' general consent to treatment. Thus, their autonomy would still be respected even though explicit informed consent was not obtained. The OHRP also concluded that since the Michigan ICU study demonstrated the effectiveness of its interventions, future implementation and monitoring of the checklists would not be research but improving clinical care.

Spanish ICU Study

The importance of establishing whether a project is research or evidence implementation is revealed by another exemplar, this time in Spain. An educational program on compliance with evidence-based guidelines in patients with severe sepsis was prospectively evaluated for its impact on mortality (Ferrer, Artigas, Levy, et al., 2008). About 20% of Spain's ICUs participated. Based on the results, the authors concluded that if the educational program was implemented in all Spanish hospitals, 490 lives might be saved each year. As with any project or study, this one had limitations and should be critically appraised, especially as its design falls at a lower level of evidence in the study hierarchy for interventions (Kahn & Bates, 2008). This makes causation difficult to establish, but the project remains a good example of an educational program introduced to promote evidence-based guidelines on a national level while also including an objective evaluation of its impact. It would appear to be ethically sound based on its promotion of beneficence and nonmaleficence.

The project was subsequently criticized for ethical reasons similar to those of the Michigan ICU study. Based on viewing the Spanish project as clinical research, the project coordinators were criticized for not obtaining informed consent from the patients involved and thus not respecting their autonomy (Lemaire, 2008). The authors defended their decision on the basis that the project was EBQI and thus part of good clinical care (Ferrer, Artigas, & Levy, 2008). They gave several reasons for not viewing their project as clinical research. Foremost among these was that the educational program taught previously established evidence-based guidelines and did not expose patients to test interventions. In particular, they noted that the project was reviewed by the research ethics committee at every participating hospital and in that way ensured that appropriate ethical standards were maintained.

If the people who make the decisions are the people who will also bear the consequences of those decisions, perhaps better decisions will result.
—John Abrams

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