

The Elephant in the Closet

Clandestine Population Based Experimentation Under the Guise of Cost Containment

By W. Andrew Kofke, M.D., and Michael A. Rie, M.D.

The Americans will always do the right thing ... after they've exhausted all the alternatives.

–Winston Churchill

Who among us would volunteer to participate in a research project with the sole dependent variables being money saved and death rate?

The cost of health care is a major societal issue. We now are consuming some 15 percent of our gross national product on health care, with perhaps no commensurate increment in health quality. Given that our society has to do other things like feed people and otherwise provide for the general welfare and defense, it is incumbent upon us to find ways to control costs. This unfortunately has led to a culture of cost containment in health care modeled after successful efforts to increase efficiency in the non healthcare industries. Industrial cost containment proceeds on principles of Pareto Economics which follows cost benefit theory as depicted in Figure 1. (Figure 1 is in a separate file on the web site.) If a form of medical care has value, then small additional increments at point A will have large increases in outcome benefit. As care is maximized, the benefit curve flattens. Conversely, the cost containment manager assumes that cost cutting at point B will result in minimal or no change in measurable benefit and a net acceptable decrease in costs per unit of production (“widgets” in management science). Unfortunately, widgets are not patients possessed of biologic variability and contractual health care rights to existent human and legal standards of care.

We suggest here that the current clinical environment in American hospitals has led to widespread violations of patient care protection (safety) manifest as human experimentation at the system level. In this environment all physicians, including anesthesiologists, are ethically pledged to uphold professional and societal ethical standards of care.

Thirty-eight years ago Henry Beecher characterized widespread abuses in clinical research in which patient welfare became subservient to experimental goals.¹ Dr. Beecher, a senior anesthesiologist, pain management observer and consultant to the Office of Strategic Services (predecessor to today’s Central Intelligence Agency), understood the horrors of human medical experimentation practiced in

The Elephant in the Closet–Cont’d

Nazi concentration camps of World War II. His impact on the ethics of human subjects employed in experiments or research was far reaching.² The U.S. government subsequently created human subject protections as a requirement for receiving Federal research funds.

Dr. Beecher’s ethics could not have anticipated the contemporary reality of quality improvement methods applied from industry to patient care cost containment. The systems management culture has clouded the meaning of physician moral responsibility in the patient-doctor trust relationship. If resources are finite, then our duty to educate society about implicit managerial rationing of care without public accountability becomes essential to preserving our professional ethical integrity.

Most clinicians have personal experience dealing with cost containment mandated decrements in the quality of care they render. We have also found many examples in the peer-reviewed literature of such cost containment activities being done without patient knowledge:

- Posner et al.³ described the use of their Quality Improvement (QI) system to document near misses without morbidity following systemic efforts to improve efficiency in an anesthesia department.
- Goldner et al.⁴ described replacement of anesthesiologists by electrophysiology technicians in administration of sedation for cardioversion.
- Marx et al.⁵ described a systematic process of decreasing diagnostic tests and faster triage to the floor in an intensive care unit, indicating in the verbal discussion afterward a possible increase in mortality related to their efforts.
- Wallace et al.⁶ reported no increased morbidity from their efforts to replace physician sigmoidoscopists with nonphysicians.
- Aiken et al.⁷ described the negative impact on morbidity and mortality of efforts to decrease nursing availability to hospitalized patients.
- And, most recently, Suarez et al.⁸ documented increased morbidity and possibly mortality in a group of subarachnoid hemorrhage patients in whom albumin administration was prohibited by the P&T committee at University Hospitals of Cleveland. This prompted a letter to the editor by Rie et al.⁹ outlining the serious ethical violations that were unwittingly reported. This was also reported to the federal Office of Human Research Protections (OHRP) as a potential violation of interest to them. Their response:

The Elephant in the Closet—Cont’d

... it appears that the restriction on the administration of human albumin by the University Hospitals of Cleveland was not research as defined by HHS regulations at 45 CFR 46.102, ... From the information submitted to OHRP, it appears that the hospitals' restriction on the administration of human albumin was not a systematic investigation, and was designed to reduce hospital costs and perhaps reduce morbidity.

This leads to a need to examine and analyze the basis for this government decision which indicates that cost containment activities require no ethical oversight.

Quality improvement (QI) is a JCAHO mandated activity in every hospital. There are different categories of QI. The oldest type of QI is one wherein a mishap or near miss undergoes scrutiny, and if a system problem is identified, then it leads to systemic changes in process of care. Another type of QI is one wherein a prospective change in a process of care is implemented, followed by the QI folks collecting data and documenting the effects of such change. Generally, such projects deal with ways to improve quality, such as evaluating a new brand of Foley catheter or assessing nursing practices and their contribution to infection rates. However, more recently this mode of QI has also been used to develop new ways to control the cost of care. Typically, in contradistinction to the project trying to improve quality, a cost containment project is implemented by one part of the organization, say the Pharmacy and Therapeutics committee, while another part of the organization, the QIers (or perhaps angry physicians), record the negative dependent variables, possibly with neither group communicating with each other until a negative outcome has developed and investigation leads to the cause.

This leads to the current controversy of what constitutes research.¹⁰ The United States federal definition is as follows: “A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” This definition indicates that labeling a project as research requires both that it must be systematic and that there is intent to contribute to generalizable knowledge.

As demonstrated by the OHRP decision, the generalizable criterion becomes the usual standard in deciding whether QI is research and thereby necessitates ethical oversight. We question the appropriateness of this criterion as it may exempt risk-laden QI projects from review. Theoretically, virtually any experiment could be performed if done under the guise of cost containment QI. Moreover, it should be apparent that the results of virtually all QI interventions, with small modifications, could be generalized. We conclude that the generalizable knowledge

The Elephant in the Closet—Cont'd

basis of determining whether QI constitutes research is morally suspect and insufficient for the protection of patients.

It may be simpler to call such activities “experiments” and thus semantically escape this debate. Further supporting this notion is the observation that the Nuremberg Code did not embrace the term “research,” rather using the more generic phrase “experiment,” indicating that a hypothesis is being tested and that the outcome is not certain. Notably, the Nuremberg Code may be a legally accepted basis for litigation. Perhaps we will see our trial lawyer friends or the U. S. Attorney General using the Nuremberg Code to successfully litigate around the federal definition of research that is being used to protect clandestine cost containment experiments as we describe.

We recently have summarized the ethical and legal issues of cost containment when “process of care changes” are driven by the primary motivation of institutional and corporate cost containment (by people other than the patients’ physicians) without patient awareness or consent, and then followed (usually by different individuals) for the impact on morbidity/mortality and cost benefits.¹¹ We suggest that such procedures constitute human experimentation subject to the general moral standards widely acknowledged in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Commission report. As we have stated,¹¹ the Nuremberg Code now has legal standing in American common law regarding a legal standard of informed consent when patients are subjected to potentially risky process of care changes.

What should be done to address this ethical conundrum between the societal need to contain costs while respecting the rights of individual patients? One approach would be to have institutional overseers approve all potentially risky cost containment interventions. The Institutional Review Board (IRB) is one possible overseer which is already composed of individuals that represent patient interests. But as recently pointed out in the Chronicle of Higher Education, the cost of this could be prohibitive to already overburdened IRB committees.¹² Moreover, mandating consent forms and acquisition of patient consent for every cost containment activity would introduce an untenable bureaucratic nightmare.

Another alternative would be to create a separate institutional entity within the QI infrastructure charged with screening such interventions, and with referral to IRB for particularly problematic cases. This is similar to the system employed at Dartmouth Hitchcock Medical Center.

The Elephant in the Closet–Cont’d

A third possibility would be to simply provide public disclosure of all significant cost containment activities and let patients decide if they wish to undergo care at a given hospital making such disclosure. This would be compatible with Medicare’s decision to fund expensive new therapies with the provision that Medicare recipients accepting such therapy be required to enter federally mandated post-marketing comparative outcomes studies of existent therapies. Patients would at least be forewarned so as to monitor their hospitals for any potential adverse impact.

In any event, whatever solutions are adopted, the overriding principle should be one of transparency. Anyone should be able to find out, perhaps on a web page, any cost containment activity going on in any healthcare facility. This will not eliminate cost containment but it should free the pachyderm for all to see.

W. Andrew Kofke, M.D., M.B.A., is Professor of Anesthesia and Neurosurgery, University of Pennsylvania (UoP) School of Medicine, Philadelphia, Pennsylvania. A graduate of the University of Pittsburgh Medical School, he completed his anesthesiology residency and critical care fellowship at Massachusetts General Hospital and his MBA (Health Science) at the University of West Virginia. Dr. Kofke was on the faculty at Milton Hershey Medical School, University of Pittsburgh and University of West Virginia before moving to UoPenn in 2001. He is involved in basic and clinical neuroscience, with a specific emphasis on the interactions of anesthetic drugs with neural disorders. These interests are intertwined with his clinical practice of neuroanesthesia and neurointensive care. He also has delved into ethical dilemmas in cost containment, assessing potential Nuremberg Code violations in the name of cost containment and quality improvement. In 2003, he published an extensive review of research ethics and the law of health care system quality improvement with Dr. Rie.

Michael Rie, M.D., is Professor of Anesthesiology and Surgery and Critical Care, University of Kentucky (UoK) College of Medicine, Lexington, Kentucky. He graduated from Dartmouth College and Harvard Medical School (HMS). He completed his medical residency at Albert Einstein and his anesthesiology residency and critical care fellowship at Massachusetts General Hospital (MGH). He spent two decades as faculty at MGH and HMS before moving to the UoK in 1991. He had formal training in ethics at the Kennedy Institute of Ethics at Georgetown University. He has published articles on the market morality and rationing of ICU services, and descriptions of continuous quality decrement measurement induced by cost containment without quality accountability. He analyzes risk stratified readmissions to ICUs of respiratory causation to determine medical diagnoses as well as process of care deficiencies and strengths to better calibrate the value purchase of critical care services to patients. He developed a market mechanism in health care policy for distributing scarce resources in ICUs. Most recently, he has participated in the reflections of the Roman Catholic view of allocating scarce resources in ICUs, and he has questioned what respect for human life means in a world of finite

The Elephant in the Closet–Cont’d

resources. In 2003, he published an extensive review of research ethics and the law of health care system quality improvement with Dr. Kofke.

References

- ¹ Beecher HK. Ethics and clinical research. *N Engl J Med* 1966; 274:1354-1360.
- ² Annas GJ, Grodin MA. *The Nazi Doctors and the Nuremberg Code*. New York: Oxford University Press, 1992.
- ³ Posner KL, Freund PR. Trends in quality of anesthesia care associated with changing staffing patterns, productivity, and concurrency of case supervision in a teaching hospital. *Anesthesiology* 1999; 91:839-847.
- ⁴ Goldner BG, Baker J, Accorino A, et al. Electrical cardioversion of atrial fibrillation or flutter with conscious sedation in the age of cost containment. *Am Heart J* 1998; 136(6):961-964.
- ⁵ Marx WH, DeMaintenon NL, Mooney KF, et al. Cost reduction and outcome improvement in the intensive care unit. *Journal of Trauma-Injury Infection & Critical Care* 1999; 46(4):625-629; discussion 629-630.
- ⁶ Wallace MB, Kemp JA, Meyer F, Horton K, Reffel A, Christiansen CL, Farraye FA. Screening for colorectal cancer with flexible sigmoidoscopy by nonphysician endoscopists. *American Journal of Medicine* 1999; 107(3):214-8.
- ⁷ Aiken LH, Clarke SP, Sloane DM, et al. Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. *JAMA* 2002; 288:1987-1993.
- ⁸ Suarez JI, Shannon L, Zaidat OO, Suri MF, Singh G, Lynch G, Selman WR. Effect of human albumin administration on clinical outcome and hospital cost in patients with subarachnoid hemorrhage. *Journal of Neurosurgery* 2004; 100(4):585-90.
- ⁹ Rie MA, Fahy BG, Kofke WA. Albumin. Letter to the editor re: Suarez JI, et al. Effect of human albumin administration on clinical outcome and hospital cost in patients with subarachnoid hemorrhage. *J Neurosurgery* 2004; 101:564-566.
- ¹⁰ Casarett D, Karlawish JHT, Sugarman J. Determining when quality improvement initiatives should be considered research: proposed criteria and potential implications. *JAMA* 2000; 283:2275-2280.
- ¹¹ Kofke WA, Rie MA. Research Ethics and Law of Healthcare System Quality Improvement: The Conflict of Cost Containment and Quality. *Crit Care Med* 2003; 31[Suppl.]:S143-S152.
- ¹² Brainard J. When is research really research? *Chronicle of Higher Education* November 26, 2004.