

CORRESPONDENCE

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In Reply:—We appreciate the interest of Drs. Lam and Artru with respect to our article.¹ We agree that there may be several interpretations to their findings that intracranial pressure did not increase when nitrous oxide was replaced by sevoflurane.² However, we are not aware of studies showing that intraparenchymal fiberoptic catheters provide a more accurate measurement of intracranial pressure than lumbar cerebrospinal fluid pressure (LCSFP) in patients with unobstructed fluid pathway between the intracranial and spinal CSF fluid spaces. Furthermore, any obstruction of the fluid pathway in our study should have caused us to underestimate the increase in intracranial pressure caused by sevoflurane. We disagree with Drs. Lam and Artru's reinterpretation of our results that LCSFP is higher during sevoflurane anesthesia compared with propofol-nitrous oxide anesthesia. Because we added sevoflurane to propofol-nitrous oxide anesthesia, a more accurate interpretation of our results is that addition of sevoflurane to propofol-nitrous oxide anesthesia increased LCSFP. We also agree that the choice of the control group is critically important in interpretation of the observations. In our study, the only variable part of anesthesia was sevoflurane, whereas Drs. Lam and Artru varied two anesthetics with known effects on intracranial pressure (sevoflurane and nitrous oxide) compared with the respective control groups.

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Pekka Talke, M.D.
Associate Professor
James E. Caldwell, M.B.Ch.B.
Associate Professor
Charles A. Richardson, Ph.D.
Assistant Professor
Department of Anesthesiology
University of California-San Francisco
San Francisco, California 94143
talkep@anesthesiology.ucsf.edu

References

1. Talke P, Caldwell JE, Richardson CA: Sevoflurane increases lumbar cerebrospinal fluid pressure in normocapnic patients undergoing transphenoidal hypophysectomy. *ANESTHESIOLOGY* 1999; 91:127-30
2. Artru AA, Lam AM, Johnson JO, Sperry RJ: Intracranial pressure, middle cerebral artery flow velocity, and plasma inorganic fluoride concentrations in neurosurgical patients receiving sevoflurane and isoflurane. *Anesth Analg* 1997; 85:587-92

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Informed Consent Issues

To the Editor:—The editorial by Drs. Truog and Robinson was both interesting and thought-provoking.¹ Among the many salient issues discussed, obstacles to effective informed consent was a particularly poignant topic. Truog and Robinson clearly outlined how mandates for informed consent in emergency medical situations nearly stifled important clinical research in this crucial medical venue. Most physicians would agree that some modifications are necessary to ensure patient protection while still allowing investigation in situations in which obtaining consent is difficult or impossible.

However, we must take issue with the example used whereby Truog and Robinson propose bypassing informed consent, ostensibly because "it won't matter to the patient." To review, the authors site an example of comparing two long-used disinfecting surgical preparation soaps to see which has the lowest infection rate. Because they believe that it would be difficult to understand how a patient would have an objection to participating in such a trial, they find it "... difficult to see the value of obtaining specific informed consent..." Furthermore, they think that obtaining informed consent would "... significantly increase the logistical difficulties of performing the trial..." However, it is exactly this situation that should require informed consent. The

scope of the investigation is clear. The outcome of the study is clearly defined. This does not significantly increase logical difficulties, rather, informed consent is even easier to obtain than in many other trials because of the straightforward nature of the study.

The work of Dr. Beecher would be for naught if we subjectively decide which information the patient does or does not need to know. When the ability to obtain informed consent is not compromised because of a life-threatening emergency, patient autonomy should always be respected and consent obtained.

Drs. Truog and Robinson spark an interesting debate on the future of informed consent. They point out specific areas in which dialogue and investigation are needed. However, we should not forsake our ethical or professional obligation to our patients to simplify our research protocols. As Dr. Beecher has shown us, informed consent is an important and inalienable patient right.

Robert W. Kyle, D.O.
Resident in Anesthesiology
Baystate Medical Center
Springfield, Massachusetts 01199

Neil Roy Connelly, M.D.
 Director of Anesthesia Research
 Baystate Medical Center
 Associate Professor of Anesthesiology
 Tufts University School of Medicine
 Springfield, Massachusetts 01199

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In Reply:—We emphatically agree with Drs. Kyle and Connelly that Beecher's legacy¹ will be for naught if we allow our commitment to informed consent for research to wane. Indeed, we see our proposal as reinvigorating this commitment by emphasizing its spirit and refocusing our efforts toward where they are most needed.

Our proposal questions the orthodoxy that automatically assumes and requires specific informed consent for all types of research. In our editorial, we mention a hypothetical randomized controlled trial comparing two brands of disinfectant soap for preparing patients before surgical skin incision, in which half of the operating rooms would use one brand and the other half the other brand. We assume that both brands have been in standard use and that the purpose of the trial is simply to assess which brand is associated with the lowest rate of postoperative wound infection. In this hypothetical example, consider the following:

1. The patients have given a general consent for treatment (although not specific consent to be part of this project).
2. There is no *a priori* reason for believing one of the soaps to be superior to the other.
3. The patients could, and probably would, receive either one soap or the other (in an unpredictable and unsystematic random fashion), but without systematic observation of the results.
4. We have no reason to believe that the nature or the severity of the side effects of the two treatments differ in any significant way.
5. A "reasonable person" would have no reason to choose one soap over the other.²

Now it is true, of course, that a patient could have a known allergy to an ingredient in one of the soaps but not the other, and that this would be an excellent reason for not randomizing that patient. It would be important to ask patients about this possibility. But note that this is true whether or not the patient is enrolled in the trial and has nothing to do with whether it is ethically mandatory to obtain specific informed consent for the research *per se*.

Based on this analysis, we conclude that the value of specific informed consent in this case is nothing more than symbolic. By requiring physicians to engage in a process of informed consent when it is only symbolic and without substantive value, we undermine our commitment to the process when it really does matter (which is most of the time).

Furthermore, in this case, not only does the process of obtaining informed consent lack value, it unnecessarily impedes the acquisition of useful knowledge. If, for example, the project calls for stocking half the operating rooms with one soap and the other half with the other soap, then there are real logistical hurdles if, for purely capricious

Reference

1. Truog, RD, Robinson, W: Informed consent: The achievements of the past and the challenges of the future. *ANESTHESIOLOGY* 1999; 90: 1499-1500

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reasons, a patient does not want to be included in the trial. Furthermore, it raises questions as to the treatment that the patient should receive if not enrolled in the study. Should the alternative soap be obtained specially just to demonstrate that the patient is not in the trial? Or would it be acceptable to use the "assigned soap" on this patient but just not collect data on the outcome? The point is that when we blindly follow the rules without regard for the underlying value and spirit of the concept, we end up having to address questions that are devoid of meaning.

This example may seem trivial. Indeed, that is a part of the point we are trying to make. In most circumstances the value of obtaining specific informed consent for research is not trivial and should be given serious attention. When we insist on rules and procedures solely for their own sake, however, we risk eroding our commitment to the very important principles on which they are based. This is the risk to Beecher's legacy that we must seek to avoid.

Robert D. Truog, M.D.
 Department of Anesthesiology
 Children's Hospital
 Director, Multidisciplinary Intensive Care Unit
 Boston, Massachusetts 02115
 truog@a1.tch.harvard.edu
Walter Robinson, M.D., M.P.H.
 Assistant Director
 Division of Medical Ethics
 Harvard Medical School
 Staff Physician
 Division of Respiratory Medicine
 Children's Hospital
 Instructor in Pediatrics
 Harvard Medical School
 Boston, Massachusetts

References

1. Kopp VJ: Henry Knowles Beecher and the development of informed consent in anesthesia research. *ANESTHESIOLOGY* 1999; 90:1756-65
2. Truog RD, Robinson W, Randolph A, Morris A: Is informed consent always necessary for randomized, controlled trials? *N Engl J Med* 1999; 340:804-7

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