science because most treatment advances are of a modest evolutionary nature that would be very difficult to detect with even well-run observational studies (Dupont, 1985).

It should also be noted that the contemporary survival rates of patients who did not receive ECMO were not nearly as grim as Bratlett et al. (1985) suggest. For example, O'Rourke et al. (1989) observed a survival rate of 60% for patients on conventional therapy in the early 1980s while Dworetz, Moya, Sabo, Gladstone and Gross (1989) reported a survival rate of 90% in patients who received conventional therapy in 1986. Indeed it is far from clear that Bartlett's group could not have conducted an ethical RCT of conventional design if they had been able to provide the best available non-ECMO therapy as the alternate treatment. (See Lantos and Frader, 1990, for a concise review of this literature.)

In spite of the preceding reservations, the issues raised by Royall cannot be easily dismissed. Patients with serious illness are highly vulnerable, and the task of obtaining truly informed consent from them can be exceedingly difficult. This is particularly true when the patient has the option of receiving either of the treatments under study outside of the trial. Currently we are using an egregious double standard in which new pharmacologic treatments must be rigorously evaluated before they become generally available, while new surgical procedures are immediately offered to anyone with the ability to pay. I believe that society has a right to expect that generally available treatments have known and acceptable levels of efficacy, and that new treatments will be evaluated in a way that will lead to continued progress in medicine. The ethical problems of randomizing a patient to an experimental or standard therapy are greatly simplified if the patient's only chance of obtaining the experimental therapy is by entering the experiment. A truly informed consensus as to the ways in which human experimentation should be performed can only be obtained through public debate and the political process. Perhaps the most reasonable position to take is that the *personal care principle* should be followed except in those situations where a political consensus, codified in law, has been reached to the contrary. Our current laws on experimental medical treatments arose, in part, as a backlash to the snake oil salesmen of the 19th century who victimized countless sick and vulnerable patients with worthless or harmful elixirs. These laws mandate the conduct of RCTs prior to making new drugs available to the general public. I believe that most of the ethical issues raised by Royall could be resolved by applying similar regulations to all medical and surgical treatments. With suitable safeguards to protect human subjects, randomized clinical trials can provide an ethical and the optimal means of advancing medical science in societies that wish to protect patients from the adverse effects of unproven therapies while searching for improved treatments for patients in the future.

ACKNOWLEDGMENTS

This work was supported in part by NIH Grants and Contracts NHLBI HL-14192, NIAID NOI-AI-52593, NHLBI RO1-HL-43167, NCI RO1-CA-46492, and NCI RO1-CA-50468.

Comment

Robert J. Levine

I agree completely with Richard Royall's conclusion that in some situations in which clinical investigations are "badly needed... nonrandomized controls are the only ones that can be obtained ethically" (Levine, 1986, pages 185–212). Here I shall comment on two components of the analysis which led him to this conclusion: (1) The values of science are portrayed as distinct from and generally, at least potentially, in opposition to those of ethics. (2) The physician's competent judgment is viewed as the dominant factor in determining his or her responsibility with regard to recommending therapies to the patient.

1. I am aware of no substantive challenge to the widely held conviction that the randomized clinical trial is the most scientifically sound approach to

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