

Comment

William D. Dupont

Royall is to be congratulated for his lucid and provocative paper on a very difficult but extremely important topic. There appears to be near universal agreement that the quality and strength of medical inferences can be optimized by well-run randomized clinical trials (RCTs). These experiments provide the fastest and surest way to improve medical therapy. For this reason, the use of RCTs in medical research is in the best interest of society as a whole. The ethical dilemma that is posed by these studies is that what is in the best interest of society is not necessarily in the best interest of the individual research subject. In weighing the competing interests of the individual and society, Royall comes down hard on the side of the patient. His *personal care principle* dictates that the physician must only consider the best interests of the patient and must totally discount the interests of society if they conflict with those of the patient in any way. If we accept the absolute priority of this principle, then Royall's contention that RCTs are rarely ethical is unavoidable. The key question then in evaluating this paper is whether the personal care principle deserves the weight that Royall gives it.

Perhaps the least convincing part of Royall's paper is Section 2.4. Although throughout the rest of the paper he adheres to an exceedingly strict application of his personal care principle, in this section he appears to accept that physicians may violate this principle when required to do so by law. I would argue that in an ideal society law should be the codification of morality rather than the other way around. For example, the military draft laws required American men to kill Vietnamese in the Vietnamese War. However, few people would argue that those laws in and of themselves provided a moral justification for these acts. Conversely, the morality of the physician reporting a patient with gunshot wounds rests not with the legal requirement to do this, but rather with the premise that the rights of society to apprehend fugitives has a higher moral claim than those of the fugitive to confidential care. Thus, to my mind, you either

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have to extend the *personal care principle* to apply to all patients regardless of the forensic aspects of their health, or admit that this principle does not have absolute priority in adjudicating the competing interests of different members of society. If, however, you take the latter course, it is unclear to me why the best interests of future patients should not have at least some bearing on the action of physicians in their treatment of you or me today. I will accept that a physician's primary obligation should be to his current patients. But I believe that it is possible to take a reasonable moral stance that stops short of Royall's *personal care principle*. For example, we might adopt the following as an alternative.

Acceptable Evidence Principle: A randomized clinical trial must be stopped prematurely as soon as enough evidence has accumulated in favor of one treatment over another to change the medical practice of a large majority of medical experts. That is, at each interim review of the data, we ask ourselves, "suppose we were to stop the trial and publish now, would our publication in addition with all other information known about this treatment and disease be sufficient to change the standards of medical practice?" If the answer to this question is "yes," then we are morally obliged to terminate the trial and publish. If it is "no," we have a moral justification to continue the trial even though the statistical evidence from our study favors one treatment over the other.

The *acceptable evidence principle* has the following consequence that I find appealing. If I believe that treatment A is better than treatment B and yet know that if I share by evidence with the world many reasonable people will not agree with me, then one of two things must be true. First, I may be wrong and the total evidence may be far less convincing than it appears to me. This would argue in favor of continuing my study to obtain further evidence. Alternatively, I may indeed be right. However, even if this is the case, since all lives have equal worth, it is not clear that I am justified in putting the few lives who are at risk in my current study ahead of the many lives that would be lost in the future if I publish unconvincing results today.