

# Virtual Mentor

American Medical Association Journal of Ethics  
February 2010, Volume 12, Number 2: 87-90.

## CLINICAL CASE

### Technical Skill and Informed Consent

Commentary by Robert M. Sade, MD

Dr. Crick is participating in a randomized clinical comparison of percutaneous aortic valve replacement therapy with standard medical therapy in a group of patients with aortic valve disease and comorbidities so severe that they cannot undergo open aortic valve replacement. Dr. Crick's surgical team, part of a multi-institutional investigation, has sought and obtained IRB approval of the study. Each surgeon received didactic training and performed the first two procedures under the supervision of a surgeon experienced in the technique. Mr. Alton, 65, is the 15th patient on whom Dr. Crick will perform the procedure.

Without surgery, the patient has a 50 percent probability of dying in the next 18 months. Two of Dr. Crick's previous trial patients died following their surgeries, although their deaths may have been due to significant comorbidities. Four other operations resulted in paravalvular leaks that required further surgery. The other surgeons on Dr. Crick's team have had a lower rate of complications and the study's Data Safety Monitoring Board has cleared the group to continue the trial. Dr. Crick is confident that Mr. Alton will benefit from this procedure and that the study results will lead to greater benefits for future patients than the current medical standard. In providing information to Mr. Alton during the informed consent process, is Dr. Crick ethically obligated to divulge data about his experience with the procedure beyond what is outlined in the approved IRB consent form?

### Commentary

The clinical investigation of a surgical device described in this vignette is unusual because reports of randomized clinical trials (RCTs) are much less common in the surgical than the medical literature: only 5 to 10 percent of the research papers published in cardiothoracic surgery journals are RCTs [1], compared with about 24-35 percent in the medical literature [2]. There are good reasons for the relative paucity of surgical RCTs. A 10 mg tablet is a 10 mg tablet, no matter who prescribes it, but a particular surgical procedure varies considerably according to the surgeon's technical skill and techniques. Also, surgical proficiency changes with time, leading to improved outcomes as the surgeon ascends the learning curve. Finally, double-blind studies are nearly impossible in surgery for the obvious reason that the surgeon always knows which techniques and devices he or she is using. Target populations in surgical investigations are often quite small, making accurate statistical analysis difficult [3]. This problem can be overcome by using multi-institutional design to increase numbers of subjects, as was done in this case.

Surgeons are motivated to pursue good outcomes for their patient-subjects, as those are good outcomes for the surgeons themselves. Other motivations, however, may cloud the surgeon's judgment. For example, the patient-subjects in the vignette study are not candidates for standard open-heart aortic valve replacement, so recruitment into the study will increase the number of operations surgeons perform and, consequently, will augment their incomes [4]. Intangible motivations such as enhancing the reputation of the surgical group and of individual surgeons through participation in a large research project can also lead to a biased presentation of the benefits and risks during the informed consent process, in order to recruit a large number of patient-subjects [3]. A surgeon must constantly guard against such biases during the informed consent process, in both research and clinical surgery.

None of these potential conflicts of interest is likely to occur in this RCT, however, because none of the potential subjects is initially under the primary care of the surgeon—they are under the care of a cardiologist, and the informed consent process for inclusion in the study will be undertaken by the cardiologist or the cardiologist's designee, not by the surgeon, who is likely to see the patient for the first time after informed consent and randomization. The surgeon will, of course, provide a separate informed consent process before the surgery is undertaken, but at that point, the potential for bias is minimal.

As the study progresses and information regarding outcomes becomes available, conveying new information to the patient-subject could be biased by the possibility that the patient-subject might choose to withdraw from the study, thus potentially harming the reputation of the surgeon or group of surgeons or weakening the trial. The question raised at the end of this vignette is whether Dr. Crick has an ethical obligation to provide the patient-subject new data in addition to the information contained in the IRB consent form. Dr. Crick does have such an obligation, because providing relevant new information is required by Food and Drug Administration and Department of Health and Human Services regulations that control informed consent in studies involving human subjects: "A statement that significant findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject" [5, 6]. In Mr. Alton's case, the question is whether there are any significant new findings, and, if so, precisely what they are. While overall trial results may track the expectations asserted in the IRB consent form, Dr. Crick has experienced a higher complication rate than the other surgeons in the group; perhaps Mr. Alton should be apprised of this new information.

I suggest that these data need not—and perhaps should not—be reported to Mr. Alton because the fact that Dr. Crick's complication rate is higher than that of the other surgeons in the group should not be considered a "significant finding," for several reasons. First, the Data Safety Monitoring Board (DSMB) is responsible for ensuring the safety of all patient-subjects in a clinical trial, including determining whether a particular surgeon is not competent, and it made no such determination regarding Dr. Crick. The standard for acceptable performance of a surgeon in clinical

surgery and in surgical research is neither excellence nor superiority: it is competence [7]. Dr. Crick meets that standard, so information about complication rates is not a significant finding. Moreover, each surgeon-investigator received didactic training and expert supervision of the first two procedures; this is less experience than is often required in surgical research protocols, suggesting that the surgeons in the study are broadly experienced in open-heart surgery and have had demonstrably good results.

Second, we know that Dr. Crick's complication rate is higher than that of the other surgeons in the group, but we do not know whether the group's complication rate is much higher, much lower, or about the same as those of surgeons in the study's other participating institutions, so Dr. Crick's rate may be well within acceptable range or may even be better than the average rate of all surgeons. The DSMB has recommended that Dr. Crick's group continue the trial, suggesting that the group's overall complication rate is not egregiously high compared with that of surgeons in other institutions.

Third, this higher rate of complications could be explained by Dr. Crick's learning curve—along which progressive improvement in outcomes is expected—having a lower slope than those of the others in the group, given that learning curves differ among even the most accomplished surgeons. Alternatively, this higher rate might entirely disappear after those data are risk-adjusted for comorbidities and other risk factors. The higher complication rate could be due merely to chance variation in outcomes; Dr. Crick has done 14 percutaneous valve replacements, but this is far too small a number to permit statistical analysis that could reliably differentiate these outcomes from those of other surgeons in the group or from those of all the surgeons in participating institutions.

This complication rate alone says nothing about Dr. Crick's competence as a surgeon or the benefits of percutaneous aortic valve replacement, so to provide Mr. Alton with the results of Dr. Crick's specific procedures would be misleading at best, and could lead to a poorly informed—and therefore unwarranted—decision not to participate in the study, which would do a disservice to Mr. Alton.

## References

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