

Medical Research and Media Circuses

By ANNE LEDERMAN FLAMM

In this issue of the *Hastings Center Report*, E. Haavi Morreim analyzes the appropriateness of a restrictive information dissemination policy that was implemented during the clinical trial of the AbioCor artificial heart by AbioMed, the device's manufacturer and trial sponsor. During the trial, some prominent critics compared it to a "gag order restricting public debate about a device that had been financed with millions of public dollars" and alleged that the company's predominant motive was to protect its business interests.

Morreim urges consideration of the controversial events as a case study to illuminate the larger issues surrounding the relationship between scientific research and the media. She maintains that disclosure of moment-by-moment, patient-centered details should be discouraged because patient privacy cannot adequately be protected. Moreover, because the information is anecdotal and often competitively distorted, it does not support valid judgments about the intervention's value, and its release risks the integrity of the research trial. Morreim identifies a complicated web of stakeholders in addition to "the public," and she recommends that sponsoring corporations and their collaborators formulate a disclosure policy at the outset of a trial that includes, at a minimum, periodic reports of material, cumulative data. Sharing the plan encourages collegiality among collaborators, manages the expectations of the press and the public, and enables patients and their families to be counseled about what information will be released (with and without their consent) and what factors patients and families themselves should consider before releasing information independently.

Morreim cautions against drawing universal conclusions from the "intensely human-interest" AbioCor case study because it is not typical of "mainstream clinical research." Her warning inspires the question, why not? Does the sensational nature of a high-profile trial justify special disclosure rules?

Certainly the heightened level of human interest calls for a media policy, some plan for handling inquiries about patients. None is needed in the typical, "non-intensely human-interest" research setting, in which no one asks for information. But imagine if someone did. What should be the response of an investigator of, say, a Phase 3 chemotherapeutic

agent, to a reporter who asserts, "Tell me how your patients are doing today. . . Of course I won't run their names, but I'd like to know their creatinine and albumin levels. I'll be checking in daily. Call me if somebody crashes."

The fact that investigators in routine clinical research are not obligated to provide even periodic updates directly to the public ought to make us question the assertion that the obligation exists in high-profile settings. As Morreim gently posits, the public's broad interest in high-profile trials stems not from our right as citizens to debate important public issues, but from our curiosity. Media reports of the AbioCor trial probably inspired some viewers to consider its benefits and burdens to society, but many more probably tuned in to the coverage to see whether the recipient of an artificial heart looks like the Tin Man, or still loves his wife.

The public's right to information about emerging scientific developments is not based on a trial's "human interest" quotient. According to Morreim, the right derives either directly from the public funding given a project or from society's more general role in determining the worthy allocation of research-related resources. Thus if the public has a right to information about developing high-profile trials, a comparable right applies to all trials. In light of the harms posed by both the lay and the medical communities' premature judgments, the high-profile context may warrant even greater discretion than what Morreim recommends.

Morreim rightly observes that intense human interest reflects our "urgent desire to understand and respond to what is going on around us." The drama and uniqueness of the artificial heart intensifies our existential struggle to establish its, and our, significance. If real-time witnessing of the impact of the implant on recipients' quality of life contributes to such analysis, then periodic, cumulative reporting is appropriate. But no one is entitled to form judgments about the ultimate value to society of a clinical trial in the absence of scientifically valid results. Whatever one thinks about the public's ability to discern fact from fiction in the context of scientific research, they cannot do it with an incomplete data set any better than can the investigators and oversight agencies. A high-profile clinical trial, when the public is tuned in and clamoring for information, provides the best opportunity to explain why early value judgments and moment-by-moment reports are inappropriate in any trial setting.

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