

tioning whether the outcome the team desired was truly an authentic decision on the part of the patient or a choice that the team reframed to obtain the patient's agreement. From the description of the patient, her rehabilitation potential was limited and it seems very unlikely that she would have returned home after more therapy.

When older, frail patients with decision-making capacity say they want to go home, clinicians should listen to them.

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**Financial Disclosures:** None reported.

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**In Reply:** I completely agree with Dr Bernheim and colleagues that the ethical dilemma described in the article only exists because of the patient's socioeconomic status. Although not included in the article, the original Grand Rounds presentation addressed the larger context of the systems of health financing and delivery as they relate to patients with financial and social resources similar to this patient.

I read with concern the account by Dr Quigley and colleagues about laws in England and Wales that allow for patients to be forcibly removed from their dwellings. I agree with their suggestion that in cases like Mrs A's, having a meeting of all stakeholders sooner rather than later is advisable. As described in the article, a meeting like this occurred 8 months before Mrs A was hospitalized.

I agree with Dr Spiess and Ms Tomm that home hospice could have been considered in this case. Hospice is a wonderful resource that is underutilized.<sup>1,2</sup> However, it is not clear that this patient would have been enrolled into home hospice at the point she was hospitalized. She was completely dependent and alone, with no financial resources to pay for caregivers. Citing safety concerns, only 1 of the 3 hospice agencies in the Baltimore, Md, metropolitan area that I subsequently contacted would unequivocally enroll a patient like this into home hospice.

I am sympathetic to several of the points raised by Drs Brummel-Smith and Spike: the risks of institutional settings, interpreting outcomes for clinicians' own benefit, being careful about how information is framed when communicating with patients, and the importance of listening to patients. I disagree, however, with their intimations that the health care professionals caring for Mrs A fumbled with respect to each of these issues. And I object to their sugges-

tion that with respect to her death, the people taking care of her were culpable.

Brummel-Smith and Spike conclude by stating that when patients "... say they want to go home, clinicians should listen to them." The implication is that her health care providers erred by not simply listening to this patient and unthinkingly acquiescing, at the outset, to her demand to go home. I disagree. A major teaching point of the article is that a better response to complex cases like this is to engage in a process that includes open and ongoing dialogue, information gathering, and careful deliberation. This approach usually leads to improved mutual understanding and, perhaps (but certainly not always), a change in perspective—by either the patient or the involved health care professionals. As a result, the involved parties may make different choices than was initially the case. Certainly, listening to patients is a major part of this process, but it is not all that is required.

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**Funding/Support:** Dr Carrese is supported by the Morton K. and Jane Blaustein Foundation Inc.

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## Medicare Requirement for Research Participation

**To the Editor:** In their Commentary, Dr Pearson and colleagues<sup>1</sup> discuss the ethics of the relatively new policy by the Centers for Medicare & Medicaid Services (CMS) for coverage with evidence development (CED). This has been required for expanded coverage of such technologies as implantable cardioverter-defibrillators<sup>2</sup> and carotid stent systems.<sup>3</sup> I am concerned about the authors' assertion that differential access to CED technologies by various segments of the Medicare population is "a regrettable practical reality but does not constitute an injustice."

If CED technologies were truly experimental—analogue to a drug undergoing a phase 3 clinical trial—there would be no particular injustice. However, many CED technologies have already demonstrated benefits in large randomized controlled trials (RCTs).<sup>4,5</sup> There may be lingering unanswered questions about the generalizability of trial results among elderly persons or whether "real world" effectiveness will mirror experimental efficacy, yet it is likely that CED technologies that have been proven effective in experimental settings are, in fact, beneficial among Medicare beneficiaries. Thus, the driving factor behind CED is not clinical evidence, but cost. To prevent the unlikely but costly policy error of providing perpetual coverage for an expensive treat-

ment that does not ultimately prove beneficial among Medicare beneficiaries, CMS has instituted CED as a method of potentially amending future coverage decisions based on the observational evidence gathered among beneficiaries in non-experimental settings.

Yet by restricting coverage to patients at selected clinical sites with a CED registry or qualifying institutional characteristics, CED policies inevitably create unequal probability of receiving technologies that have a high probability of being beneficial. By virtue of their access to certain facilities within the US health care system, selected Medicare beneficiaries are systematically covered for treatments that are probably beneficial, based (in Bayesian terms) on their prior probability of benefit as estimated by the clinical trials. Conversely, other beneficiaries are systematically excluded from coverage for these same highly promising treatments. Such a system is inherently unjust.

Contrary to the authors' assertion, all clinically appropriate Medicare beneficiaries are entitled to equal access to CED technologies, because the probability that these technologies are "reasonable and necessary"<sup>6</sup> (in the words of the Medicare statute) greatly exceeds the probability that they are not. It is regrettable that the CMS CED policy is therefore likely to contribute to the imbalance of access to quality care in the US health care system, and thus likely to exacerbate health care disparities.

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**Financial Disclosures:** None reported.

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**To the Editor:** In their Commentary, Dr Pearson and colleagues<sup>1</sup> presented a timely discussion of the ethics of research participation as a condition of coverage. We agree that this arrangement may be morally justified, as considerable uncertainty often exists for many years about the effectiveness and the safety of new therapies.<sup>2</sup> Coverage with evidence development could become an important tool to reduce the abuse of emerging technologies while increasing knowledge about their true efficacy.<sup>3</sup>

The best way to evaluate efficacy, however, is a double-blind RCT. There is a significant ethical difference between mandating that patients agree to have their clinical

data entered into a registry and mandating enrollment into an RCT in order to get coverage. In the latter option, the patient would have only a 50% chance of getting the active therapy (and a 50% chance of getting a placebo). This is not technically "coercive" and perhaps the 50% chance of getting the treatment with coverage is better than no coverage at all. However, from the patient's perspective, the 50% chance of getting a placebo (and knowing these odds) might be viewed as harm, even if the treatment is found later to be more detrimental than a placebo. Furthermore, we can think of no precedent in which insurance coverage is dependent on entry into an RCT.

The purpose of health insurance is to reduce a patient's uncertainty about coverage in the event of illness. Tying coverage for uncertain emerging therapies to enrollment into an RCT may be a powerful way to curtail the spiraling increase in health care costs. Such a novel arrangement, however, would probably require more elaboration; better definition of the funding sources and responsibilities for the research (involving support from industry while assigning data analysis to an independent body to avoid bias); public explanations of the goals of this arrangement, as well as its formal legalization; and careful evaluation of the gains, failures, and unintended consequences of such a profound innovation.

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**Financial Disclosures:** None reported.

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**In Reply:** Dr Groeneveld's comments highlight the difficulty, and importance, of distinguishing the evidentiary thresholds that are linked to the research requirements of Medicare's CED policy. He posits that new technologies covered through CED have a high probability of being beneficial and that unfettered coverage for them is required to ensure access to quality care. If Medicare does its job right, this will not be true.

Coverage with evidence development should only be considered for technologies for which the benefits and risks for many patients are truly uncertain. At the time new technologies come under consideration for coverage, there are often many serious questions about the evidence supporting their use. Little information is usually available on the risks and benefits within particular patient populations. There is rarely good evidence on the comparative effectiveness of

new technologies compared with established alternatives. Data on the long-term risks and benefits beyond a year or 2 are routinely absent. As an example of these concerns, the cautionary tale of autologous bone marrow transplant for metastatic breast cancer is a reminder that what appears promising may not ultimately prove beneficial.<sup>1</sup>

For a technology being considered for CED, Medicare will have determined that the evidentiary questions are too significant to warrant unlimited coverage as “reasonable and necessary.” Groeneveld cites implantable cardioverter defibrillators and carotid stents as technologies with RCT data strong enough to warrant unlimited coverage. However, careful inspection of the data on defibrillators has raised questions for many in the field about which patients are most likely to benefit.<sup>2</sup> Questions about the safety of carotid stents have been validated with recent publication of trial data showing stenting to be far less safe and effective than traditional surgical approaches.<sup>3</sup> These technologies did not make the grade, there is no entitlement to them, and thus CED is not coercive. The high cost of some new technologies will be a relevant factor in prioritizing CED efforts, but it is the absence of sound evidence that should drive and justify the process.

We agree with Drs Brezis and Lehmann that patients and clinicians will view quite differently CED requirements for participation in a registry as opposed to an RCT. But the ethical legitimacy of CED rests in part on whether the research required will be able to provide useful information on the true risks and benefits of a new technology. When this information can be gleaned from a well-conducted registry, we agree that it would be the best choice. Often, however, an RCT is the only way to provide rigorous data that can help physicians and patients make educated clinical decisions, as was shown in the case of the national trial of Lung Volume Reduction Surgery.<sup>4</sup> Linking CED to participation in an RCT may therefore be highly ethical and just, given the evidentiary uncertainties involved. We do agree, however, that as a “new technology” itself, CED deserves careful evaluation early in its policy life, and the ethical lessons learned will be valuable to all as policy makers continue to forge new approaches to creating a learning health care system.

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**Financial Disclosures:** Dr Pearson reports that he serves as a part-time consultant for American’s Health Insurance Plans, and from September 2005 through June 2006, he served as Special Advisor, Technology and Coverage Policy, at the Centers for Medicare & Medicaid Services. Drs Miller and Emanuel reported no financial disclosures.

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## Financial Disclosure Policies of Scientific Publications

**To the Editor:** In her editorial, Dr DeAngelis<sup>1</sup> described her experience developing and enforcing JAMA’s financial disclosure policy and discussed how, despite extensive efforts at education, some authors still lack clear understanding of JAMA’s current disclosure requirements.

The issue of disclosure in publications is very important. Recently, the Federation of American Societies for Experimental Biology (FASEB), representing more than 80 000 biomedical researchers, developed overarching principles and voluntary standards for the conduct and management of academia-industry interactions from the scientists’ perspective.<sup>2</sup> Several of these recommendations speak to the dissemination of research results. FASEB urges investigators to be aware of and adhere to individual journal policies on disclosure of industry relationships. If the researchers are unclear about these policies, contact with the editor is encouraged.

Journal policies vary widely with respect to disclosure policies. We appreciate that biomedical journals are diverse in scope, audience, and the types of research reported (both clinical and basic science), and thus may approach financial conflicts of interest differently. However, there is a clear need for some consistency in journal disclosure requirements. Variable policies may result in confusion and non-compliance by investigators, allowing authors to “shop” or seek out journals that might have less stringent disclosure or related requirements. We believe that journals should avoid requiring investigators to judge whether there may or may not be a relationship that could create bias. Instead, they should require disclosure of relevant industry relationships and let editors and readers have access to this background information.

Investigators are individually responsible for their activities. At the same time, the broader scientific community has a shared responsibility to provide clear and rigorous standards, fair and efficient review and oversight of relationships, and adequate guidance to investigators before and throughout relationships with industry, including the publication of research results. We agree with DeAngelis that institutions have a critical role in the education of faculty members about these issues. FASEB is moving forward with a collaborative effort to increase awareness of conflict of interest issues and progress toward more consistent practices.<sup>3</sup>

When in doubt, investigators should err on the side of transparency when communicating to their institutions, journals, scientific meetings, other investigators, and the