The committee cited the modest antiretroviral activity of the 120 mg/d dosage, the paucity of data on the antiviral activity and safety of the 60 mg/d dose, and uncertainty about the reversibility and long-term consequences of adefovir-associated nephotoxicity. This was the first time an FDA advisory committee had voted against the approval of a new antiretroviral agent. This sends a strong message that despite the urgent need for effective antiretrovirals in treatment-experienced patients, the activity and safety of new drugs must be well characterized at the approved dose. The fate of adefovir as a drug now lies in the hands of the pharmaceutical sponsor and the FDA, who must determine if additional data supporting the 60 mg/d dosage can be obtained and whether such data could lead to drug approval. Careful assessment of the risk: benefit ratio of adefovir is needed especially for treatment-experienced patients with advanced HIV disease.

This setback for adefovir should not discourage efforts to identify and develop antiretroviral agents that are active against drug-resistant HIV. Indeed, the more than 20 new drugs currently in various stages of clinical development offer considerable hope for the future. Among the most promising drugs are the “second generation” protease inhibitor ABT-378/ritonavir, a second nucleotide analog PMPA (phosphonomethoxypropyladenine), and the HIV fusion inhibitor T-20. Each of these drugs has antiretroviral activity in patients with drug-resistant HIV strains, and their safety profiles are encouraging. These new antiretrovirals should be tested quickly as part of novel, multidrug combinations to improve the outcome for the increasing number of HIV-infected patients who today are without effective treatment options.

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of their options and help them reach an individualized decision about the right course to take.

The article by Braddock and colleagues\(^4\) in this issue of THE JOURNAL suggests physicians have not generally embraced the concept of shared decision making in day-to-day office practice. This article describes a careful analysis of audiotapes of encounters between patients and primary care physicians or surgeons in 2 states. Across a spectrum of definitions on the completeness of informed decision making, these physicians did poorly in terms of involving patients in their medical decisions. Interestingly, although surgeons as a group are sometimes characterized as paternalistic (at least by primary care physicians), the surgeons did somewhat better than the primary care physicians in terms of the proportion of their visits that met the various threshold criteria for adequate informed decision making.

Are the results of this study valid and generalizable? The robustness of the study’s results as the definition of adequate shared decision making was varied, as well as the acceptable interrater agreement on these categorizations, support the study’s validity. Given that the recruitment strategy appears to have oversampled physicians with 2 or more previous malpractice claims,\(^5\) which may in turn result from faulty communication styles, the generalizability of the results might well be questioned. However, the results were so extreme that it seems unlikely that a different recruitment strategy would have yielded data that would indicate widespread adoption of the shared decision-making paradigm.

Why do physicians appear to be so paternalistic in day-to-day office practice? Physicians most likely would argue that there is simply insufficient time to adopt the shared decision-making approach, particularly in the current managed care era, in which most office-based physicians feel pressured to see an increasing number of patients in the same amount of time. In fact, the encounters with primary care physicians in this study averaged about 16 minutes in duration, and a median of 3 patient concerns were tackled. In such a visit, basic history taking and a focused physical examination will usually precede a discussion about diagnostic and therapeutic options; physicians may simply tell patients what to do without much elaboration to move on to the next examination room quickly. Perhaps the surgeons studied, who dealt with fewer patient concerns in visits only slightly shorter in mean duration than those of primary care physicians, did better simply because they had more time. Alternatively, inculcation in the routine of eliciting written, informed consent before performing operations may have sensitized surgeons to the need for informed decision making.

Time is certainly a major issue in trying to incorporate shared decision making into office practice. Trying to explain, in a balanced way, the complex issues behind controversies such as whether to perform a PSA test or prescribe estrogen replacement therapy cannot be done quickly. For decisions that must be faced routinely in office practice, educational materials such as pamphlets, videotapes, or even interactive videodiscs may be helpful for communicating basic information about a decision and the possible outcomes of different management options, so that clinicians’ limited time can be spent not on basic education, but on tailoring the management strategy to the patient’s preferences. Several randomized trials of some decision aids have shown that they can make patients better informed about their conditions and the risks and benefits of their management options.\(^6\) For example, a 20-minute videotape on the PSA decision has not only improved patient knowledge about the PSA test, but also significantly reduced rates of PSA testing in 2 separate randomized trials.\(^7\,\,8\) Incorporating education interventions into routine practice can be cumbersome because most offices are not set up for such an effort, particularly for anything more complicated than brochures.

Some physicians may even question whether patients want to be involved in making their personal medical decisions. Research on this question has been contradictory. Deber and colleagues\(^9\) have brought some clarity to this area by distinguishing problem-solving tasks from decision-making tasks. A problem-solving task involves getting to the one right decision in a particular situation, a solution unaffected by patient preferences, while decision making involves choosing from a number of reasonable alternatives, where the optimal choice will be preference-driven. Their research strongly suggests patients do want to participate in the latter, but not the former, tasks.\(^9\)

The results of the study by Braddock and colleagues present a challenge to the medical profession. Most physicians would accept the importance of informed consent to patient management as something more than just a medical-legal necessity. If that is the case, we, as physicians, must do a better job of practicing what we preach. Physician time will be a major impediment, and new strategies, including more effective and efficient use of educational materials and decision aids in office practice, will need to be developed and tested as part of the solution.

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