The requirement of informed consent is vital to the ethics of human subjects research. Patient-subjects enrolled in clinical trials should be informed of the risks, costs, and benefits associated with participation in the trial. It is far from obvious, however, just how much, and what kind of, information should be disclosed in the process of securing informed consent. In "You Get What Someone Else Will Pay For," Deborah Barnbaum points out that patient-subjects are not typically informed about the projected costs to future patients of the interventions being tested in the trials in which they participate, and she advances a thought provoking case in favor of doing so. She concludes that "if today's research participants volunteer to test medical interventions that someone else will pay for in the future, they should be told how much those interventions are going to cost future patients."

Barnbaum might be right. Still, there are complications that need to be considered. Start with the worry about exploitation. Suppose that some patient-subjects participate in a trial that down the road results in a new and better treatment becoming available on the market. Suppose further that the new treatment will be too costly for them to afford. Have they been exploited? Barnbaum suggests that the answer may be yes. She also suggests that if they had been informed of the future costs of the new treatment, and if they had given their consent to participate in the trial in light of that information, the exploitation concern could be put to rest. Thus, if we take exploitation seriously, then we may need to disclose this information in the informed consent process.

But this is not quite right for a couple of reasons. First, exploitation can occur when all parties have given their free and informed consent. For example, an unconscionable contract remains exploitative, even when it is freely entered into with full knowledge of its terms. So disclosing information to patient-subjects about the projected future costs of interventions tested in trials would not rule out the possibility of exploitation in these trials. Second, and a bit more controversially, if patient-subjects are given adequate compensation for their participation in a trial, they may not have a claim to have future access to the intervention that is being tested in the trial in which they participate. The point here is an extension of the one pressed by Emanuel et al. with respect to the ethics of clinical research in developing countries.[1] To rebut the charge of exploitation, it may only be necessary to provide fair compensation and to inform patient-subjects of the nature of the compensation that they can expect to receive. It may not be necessary to ensure that the compensation take the particular form of having access to the intervention tested in the trial. True, this point is not now widely accepted in the domestic context of research in the United States, but it is hard to see why the logic would not apply here, if it is sound in the developing countries context.

Putting exploitation concerns aside, the real case for disclosing the information about the future costs of the intervention being tested in the trials may be one that invokes the value of autonomy. Should not patient-subjects have access to all relevant information so that they can judge whether participation in the trial makes sense for them? But this brings us back to the issue of what constitutes relevant information. Barnbaum assumes a fairly tight link between understanding the future costs of an intervention and understanding direct future access to it. However, since most people do not pay for medical care directly out of pocket, access to an intervention will be a function not only of cost, but also of the extent to which third party insurance providers agree to cover the new intervention. Information about the extent to which any given third party provider will cover the intervention in the future will often be unavailable and/or unknowable. In the absence of that information, it is much less clear that having information about the projected future costs of the intervention will be helpful to patient-subjects in their assessments of the trial.

Barnbaum also advances a different line of argument, one that focuses on the overall risk/benefit ratio associated with an intervention. IRBs need to determine that a trial presents patient-subjects with a favorable risk/benefit profile. To do this, she suggests, they will need to have information about the projected future costs of the intervention. But do patient-subjects also need to have this information so that they too can make a judgment on the overall risk/benefit profile of the trial? It is not clear that they do. Consider an analogy. IRBs need to determine whether a trial is scientifically well-designed to determine whether it is ethically appropriate to go forward with it. It does not follow that each patient-subject also must make this
In general, the assessment of a clinical trial requires a division of labor; and some persons are better situated than others to evaluate different aspects of the trial and its design. Those who serve on IRBs should have competence and experience in assessing both the scientific and the ethical merits of proposed trials. Patient-subjects may not have either the competence or the experience to do so, and it may be more appropriate to ask them to focus on the direct risks, costs, and potential benefits that the trial presents to them. This does not settle the matter, of course.

One might object, as Barnbaum does at one point, that it is not the job of IRBs "to leave things out of a consent form on the assumption that the participant won't find it relevant." They should, she claims, always err on the side of disclosing information. However, as a general rule, there are reasons to think that this is not correct. Sometimes too much information can be disclosed. To determine what is adequate or relevant information, one must be on guard against two mistakes. One mistake is failing to disclose enough information. The other mistake is to disclose too much information, thereby making it too difficult or costly for participants to appreciate the information they need to understand. The provision of less relevant or irrelevant information can make it hard for people to process the more relevant information, such as the direct risks and benefits associated with their participation in the trial. Both mistakes can compromise informed consent. And a rule that counsels us to always err on the side of disclosing more information, while safeguarding against the first mistake, overlooks the second.

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