Do Unknown Risks Preclude Informed Consent?

Abstract: Allen Buchanan and Daniel Brock, in a widely influential account, *Deciding for Others* (1990), advocate a *sliding scale approach* to the determination of whether a patient is competent to make a decision regarding his/her health care. An analysis of two critiques of their position (Beauchamp and Childress (1994), Wicclair (1991 a,b)) reveals a tacit presumption by all of these authors that the greater cognitive challenge often posed by high risk therapies constitutes grounds for an elevated standard of competence. This presumption cannot be consistently maintained in cases where the patient's decision involves experimental therapies. It implies either that informed consent can never take place in such situations, or, perhaps even more counter-intuitively, that a *lower* standard of competency should be used than when the patient is asked to choose only among standard therapies.

I. Introduction

The ethics of informed consent have been the object of increasing attention in recent years, both (1) when patients are presumed capable of making such decisions and (2) in the growing number of cases where the patient is unable to decide for him or herself. Determination of whether a patient is competent or capable of making medical decisions is of obvious importance. In cases of the first type the patient is, within reason, given broad autonomy over which sorts of procedures he or she will be subjected to. In cases of the second type, the final arbiter is someone who acts on the patient's behalf, albeit with the patient's purported best interests in mind.

Medical ethicists agree that for informed consent to occur three necessary conditions of competency must be satisfied: (1) the patient must understand the nature of the decision and be able to communicate, (2) the patient must be able to reason and deliberate, and (3) the patient must possess a fairly stable set of values. Even restricting our attention to adults whose judgment is not impaired by accident, age, or disease, and further to only those decisions involving choices between standard therapies, ethicists recognize that is often difficult to determine whether these minimal conditions are met. How do we determine whether the patient understands the nature of the possible risks and benefits posed by the procedure? Does the patient's decision reflect careful deliberation or is it merely a choice that appeals to his or her nonrational beliefs or values? And what should be done with patients who refuse potentially life-saving blood transfusions for religious or other non-medical reasons? These general questions have been a major concern of many recent works on informed consent, and as such will not be pursued further here.

II. Informed Consent in Experimental Contexts

The issue of informed consent is even more complicated when it occurs in an experimental
Ethicists have raised a number of concerns regarding the tension between a physician's role as a researcher and his or her duty as a caregiver. Several have focused on whether the physician's desire to enroll patients as a subject in her study may lead the physician to frame or withhold information about the study in ways that encourage participation. Conversely, a number of medical researchers have questioned whether the elaborate bureaucratic procedures associated with obtaining informed consent serve to deter patients from participating. Some of these physicians have further claimed that providing full disclosure of the nature of benefits and harms associated with a procedure may be needlessly cruel to patients. This occurs, for example, when a terminally ill patient who agrees to participate is assigned to a control arm after being sold on the merits of the experimental treatment.

There are also interesting ethical questions to consider about the possibility of informed consent that focus less on the experimental context of a patient's deliberation and more on the nature of the risks posed by the therapies being considered. Allen Buchanan and Daniel Brock, among others, have advocated a sliding scale approach to the determination of whether a patient is competent to give informed consent. Essentially, they claim that the greater a possible treatment's risk of harm to the patient, the higher the standard of competency that should be used in evaluating whether the patient's choice is respected. As will be shown below, careful examination of Buchanan and Brock's position (and two critiques) suggests that while riskiness per se does not demand an elevated standard of competency, the greater cognitive challenge often associated with such therapies does.

This point of view runs into difficulties when it comes to experimental therapies. In brief, the argument is as follows: for informed consent to occur, the patient must be competent to make such a decision. Yet when we consider that the poorly characterized nature of many experimental therapies often precludes any decision more sophisticated than a reasonable choice based on the person in question's values, it seems altogether gratuitous to refer to the patient's choice of such a therapy as the judgment of someone "competent" to make such decisions. This analysis of informed consent involving choices in favor of poorly characterized experimental therapies leads to the following dilemma. Either (1) genuine informed consent almost never occurs, because most patients are not competent to make such decisions (a violation of Condition 1 above). Or (2) competency per se is nothing more than being reasonable, and as such (in contrast to Buchanan and Brock's position) decisions under extreme uncertainty require a lower, not a higher, standard of competency than decisions involving standard therapies.

III. Brock and Buchanan's (1990) Analysis

As a preliminary to the analysis of Buchanan and Brock's position, it is important to distinguish between standard and experimental therapies with regard to risk assessment. A "standard therapy" for the purposes of this essay will refer to therapies that are approved by official medical panels such as the FDA on the basis of extensive research. An "experimental therapy", in contrast, will refer to a therapy for which there is no such approval or research context, at least with reference to the ailment in question. Clearly these represent endpoints on a continuum, and each may present considerable risks to the patient. Nevertheless, it is important to distinguish between the two, owing to the nature of the decision processes involved in evaluating each. Standard therapies: (1) are by definition the product of considerable scientific study, (2) often represent a consensus view
about what constitutes the most appropriate treatment, and (3) have a track record that provides physicians and patients with specific information regarding possible benefits and side effects. Experimental therapies, in contrast, are generally less well-characterized, lack consensus support among experts, and often have unknown or poorly characterized benefits or side effects.

Note that while a choice among standard therapies can be challenging, choices between experimental therapies (or between experimental therapies and standard therapies) are cognitively much more difficult, owing to uncertainties surrounding what is known about the precise effects of such treatments. A patient choosing between standard therapies has a more reliable basis upon which to make her decision than patients who attempt to make decisions about the risks associated with experimental therapies. And, as will be shown below, it is this difference in epistemological status of claims regarding experimental therapies that directly affects the extent to which a patient may be said to be competent to make such choices. 12

Buchanan and Brock have argued that the criteria for determining whether a patient is competent should be context- and task- dependent and that an elevated standard should be required in cases where medical risks are greater. 13 In particular, they point out that the standards of competency physicians should apply to patients should depend, in part, on the expected harm and or benefits from the choice and how important self-determination with regard to the choice is to the patient. 14 In support of this claim, they call attention to the fact that: (1) it coheres with current legal and medical practices, and (2) it strikes a balance between the patient's autonomy and respect for his or her well-being.

The basic intuition behind Buchanan and Brock's position is as follows. When the risks to the patient are minimal, for instance when a patient decides to choose one therapy for a minor condition over another that does not differ significantly in risks or benefits, a lower threshold of competency should be used. However, when risks to the patient are high, say if a patient who is a Christian Scientist medically requires but refuses to consent to an appendectomy, a different standard should be applied, often on different grounds. Essentially Buchanan and Brock argue that when the risk of harm associated with a patient's choice is substantially greater than other alternatives, a higher standard of competency "assure[s] that no significant mistakes in the patient's reasoning and decision making are present and is required to rebut the presumption that the choice is not in fact reasonably related to the patient's interests." 15 In other words, when patients choose alternatives for which the associated risk of harm is greater than alternatives, they must be held to a higher standard to ensure that they have understood their choices, reasoned carefully, and have chosen in accordance with their own stable set of values. 16

Let us examine what Buchanan and Brock's views would commit them to regarding a patient's choice of an experimental therapy over an existing standard therapy. Clearly much depends on the specifics of the case--the seriousness of the medical problem, the benefits and harms associated with the treatment alternatives, and the patient's values and beliefs. Nevertheless, if we focus on what has been identified as the salient differences between standard and experimental therapies, the amount, type and reliability of information available, it is possible to sketch how consideration of choices involving experimental therapies complicates Buchanan and Brock's position.

As mentioned above, Buchanan and Brock have argued that an increased standard of competency
should be applied in cases where the risks of harm to patients are greater. It is tempting at this point to claim that choices involving experimental therapies, by their nature, are riskier to the patient than standard therapies, owing to how little is known about them. But such an identification of uncertainty with risk is vulnerable to counterexamples. Consider for instance a terminally ill patient asked to choose between a promising but untested drug that could potentially cure her illness and a standard therapy that will at most prolong her life. In this instance, the mere fact that the outcome of using the new drug is less certain than that of the standard therapy does not entail it involves a greater risk of harm.

If, however, following Buchanan and Brock we focus on the decision-making process, it seems clear their views imply that decisions involving experimental therapies should require a higher standard of competency than decisions involving only standard therapies. Opting for an experimental therapy is a different, more conceptually difficult decision than simply choosing among well-characterized standard therapies—the patient must understand the experimental nature of the treatment, that the precise benefits and harms associated with the treatment are poorly characterized, and that the physician cannot provide more than a tentative basis for claims about whether the patient will actually benefit from the procedure. These latter considerations all suggest Buchanan and Brock would advocate a higher standard of competency with regard to experimental therapies.

**IV. Problems with Brock and Buchanan's (1990) Analysis**

Tom Beauchamp and James Childress dispute Buchanan and Brock's analysis. They point out that the mere fact a procedure is riskier does not entail that a greater level of competency is needed to make a decision about the procedure. Imagine a patient faced with a decision between two therapies A and B. If we compare the decision with a choice between two alternative therapies A' and B', for which the associated risks are higher, it is not at all clear that a choice between A' and B' would be cognitively more difficult. Notice that while this criticism of Buchanan and Brock's position rejects risk per se as a criterion, it does not constitute an objection to their more general position that decisions that are conceptually more difficult should require a greater standard of competency.

In two papers published in 1991, Mark Wicclair has also criticized Buchanan and Brock's analysis. While agreeing that patient decision-making capacity is a task-related concept, Wicclair disagrees with Buchanan and Brock's claim that standards of competency should depend on risk to the patient. He describes Buchanan and Brock's stated position as a two step process, with determination of competency prior and independent of a physician's decision to intercede for the patient's own good in the event the patient's choice is riskier than other alternatives. Since the reason Buchanan and Brock offer for setting aside a patient's choice is that the riskiness of the choice (compared to other alternatives) is grounds for questioning the patient's competency, Wicclair concludes their account conflates the question of whether a patient is competent with the latter question of whether there is a reason to disregard the patient's choice. Importantly, Wicclair's own account does not entirely eschew considerations of risks involved from a judgment of whether the patient is competent. He concedes that considerations of risk may be relevant to a determination of patient competency with regard to a particular decision, not because of risk per se, but rather because choosing a riskier choice requires a greater capacity to appreciate significant risks.
Although Wicclair does not address experimental therapies in his articles, this latter concession affirms a point noted above in connection with Buchanan and Brock's position--the import of the risks associated with experimental therapies may not be risk *per se*, but rather the fact that when patients deliberate experimental therapies, they have a more complicated cognitive task than that associated with a decision between standard therapies. The reader should note that this does not imply a choice between standard therapies is less challenging or difficult than a choice between a standard therapy and an experimental treatment. All that is being asserted is that when a patient considers an experimental therapy, he or she is confronted with a cognitively more complex task, one that involves making a choice under a greater degree of uncertainty than is present in decisions involving only routine therapies.

V. The Dilemma Posed by Experimental Contexts

With these criticisms of Buchanan and Brock's position in mind, let us turn to a third criticism that will serve to highlight a more general problem associated with the possibility of informed consent when it comes to choices involving experimental therapies. The preceding analysis has pointed out that for informed consent to occur, the patient must be competent to make the decision before him or her¾hence the widespread interest in the literature on informed consent regarding decisions involving children, the mentally incompetent and the elderly, who for reasons of emotional and mental maturity, disease, age or accident, may be judged incapable of understanding or deliberating among therapeutic options.

Adult patients whose cognitive faculties have not been damaged by accident, age, disease or the like, can meaningfully be said to be at least potentially competent to choose among standard therapies by virtue of the information available to them. Here it is important to distinguish between a judgment that is merely reasonable and one that involves using the information available to the patient in a systematic manner such that it affects the decision process. With the information available to him or her about the therapies, some education in risk assessment, and the aid of his or her physician, the patient can arrive at a competent judgment about what is the best course of action in view of his or her values and beliefs. For our purposes, the thing to notice is that a patient's competence to choose between standard therapies, whether or not he or she elects to use these faculties, depends upon more than choosing that which is the most reasonable. Decisions involving experimental therapies are often quite different. Patients often have difficulty understanding the basic elements of experimental design, such as randomization, or the experimental nature of the therapies they are considering.23

It is of course true that a person can make a reasonable choice under conditions of extreme uncertainty. Consider for example a roulette style game of chance that you have decided to play. You are told only that if the ball lands on zero, the payoff (some obvious benefit to you) will be double that of a win on any other number. If you are told nothing further, such as the total number of numbers represented on the wheel, whether it is fair, what the normal payoff is, *et cetera*, choosing to bet on zero would nevertheless be a reasonable choice to make.24

It is fair to say that many choices involving experimental therapies (and choices between standard therapies for that matter) are made simply with reference to what would be the most reasonable
given the patient's set of values and beliefs. We should, nevertheless, resist presuming that merely because a choice is reasonable, it has been made by a competent judge. Consider the choice of a person having no experience investing who chooses a stock in line with his or her best guess. It may be reasonable, but it hardly qualifies as a competent choice, even if it is successful. Likewise, a hospital intern confronted with an emergency situation may be forced to choose between two standard therapies, yet the fact he or she chooses the most reasonable option given her training does not mean she was competent to make the decision.

It seems clear that experimental therapies often provide at best a partial basis upon which patients can make their decisions in contrast to those decisions involving standard therapies alone. For the vast majority of patients, who lack training in medical research and risk assessment, what little is known about the experimental treatment will enter into their decision making process primarily with reference to a specification of the potential benefits and harms of the therapy. And as such, the decision is made primarily on the basis of what would be reasonable given the patient's values and beliefs. In this light, competency to make the judgment appears to be equated with merely being reasonable. And indeed, how could it otherwise when the physician who counsels the patient can at best provide an educated guess?

The upshot of these considerations is that if competency involves more than a reasonable decision based on a person's values and beliefs, the threshold involved would be impossibly high for the vast majority of patients who lack the skills and experience necessary to make a competent decision. What would it mean to be competent to make a decision about whether to undergo an experimental therapy on the basis of prior animal and in vitro studies alone? On the other hand, if competency with regard to experimental therapies involves simply making a reasonable choice, then, in contrast to Brock and Buchanan's position, this implies a lower, not a higher threshold of competency should be invoked when it comes to decisions involving experimental therapies.

The reader might object at this point that the present argument over-exaggerates the relative uncertainty of information available to patients involving experimental therapies. The reader should recall that the relevant contrast is between a standard therapy for which there is an established body of evidence on humans and an experimental therapy for which little or no information is available. The relative abundance of information on therapies with established track records makes decisions involving them cognitively easier than those for which there is little or no evidence regarding its efficacy in humans. And again, the question arises, what would it mean to say someone is competent to make a decision about an experimental therapy?

A second objection to the position advocated here that one might raise is the possibility that choosing the most reasonable alternative is in point of fact all that is needed to establish a patient is competent in the face of uncertainty. This seems altogether strange. As noted above, competency in almost any other context requires more than just choosing in accordance with a system of values; it involves using what information is available to make an informed choice that reflects a level of understanding not present in the lay person.

A critic of this reply might retort that if no person has this level of understanding, as a practical matter it would be foolish to require it. Clearly the ought implies can principle is relevant here- we cannot obligate a patient to make a decision in accordance with a standard that is in principle impossible for him or her to attain. But then we are confronted by the other horn of the dilemma as
it has been presented here, namely justifying why a choice involving relatively poorly characterized experimental therapies would require a lower, not a higher standard of competency than choices involving standard therapies.

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ENDNOTES


2. Cases of the second type may also be decided in accordance with a substituted judgment standard which may yield results that may conflict with the patient's objectively determined best interests.


see the *British Medical Journal* 307: 1494-7, and also Souhami and Tobias's reply, "Informed

10. See for example Schaffner, K. F. (1991) "Competency: A triaxial concept" in Cutter, M. and

11. This continuum is often defined with reference to how evidence can be advanced in favor of a
particular therapy. Green, S. B. and Byar, D. P. (1984) "Using observational data from registries to
compare treatments: the fallacy of omnimetrics" *Statistics in Medicine* 3: 361-370 identify
milestones along this continuum as follows: 1. Anecdotal case reports, 2. Case series without
controls, 3. Case series with literature controls, 4. Analyses using computer databases, 5. 'Case-
control' observational studies, 6. Series based on historical control groups, 7. Single randomized
controlled clinical trials, 8. Confirmed randomized controlled clinical trials, 9. Meta-analysis of
trials based on world-wide experience.

12. The reader might, at this point, object that the difference in question is one of degree rather than
kind; after all, many standard therapies were once experimental. My reply to this objection is that
differences of degree, if of sufficient magnitude, can constitute differences in kind (for instance,
consider the difference between the color red and the color green, which differ only by the
magnitudes of their associated wave frequencies).


16. Buchanan and Brock explicitly identify the need to have a higher level of competency with the
greater cognitive challenge posed by riskier procedures (rather than risk per se) in the following
passage: "The greater the risk relative to alternatives—where risk is a function of the severity of the
expected harm and the probability of its occurrence—the greater the level of communication,
understanding and reasoning skills required for competence to make that decision. It is not always
true, however, that if a person is competent to make one decision, then he or she is competent to
make another decision so long as it involves equal risk. Even if the risk is the same, one decision
may be more complex, and hence require a higher level of capacity for understanding options and

17. "In the previous section, we rejected a standard of competency that looks to the content or
outcome of the decision in favor of a standard that focuses on the process of the patient's reasoning.
This may appear inconsistent with our insistence here that the appropriate level of decision-making
capacity required for competence should depend in a significant part on the effects for the patient's
well-being of accepting his or her choice. However, there is no inconsistency. The competence
evaluation addresses the process of the patient's reasoning, whereas the degree of defectiveness and
limitation of, competence depends in significant part on the likely harm to the patient's well-being
of accepting his or her choice. To the extent that they are known, the effects on the patient's well-
being should be evaluated in terms of his or her own underlying and enduring aims and values, or, where these are not known, in terms of the effects on life and health" (Buchanan and Brock, Ibid., p. 55).


20. Brock [(1991) "Decision making competence and risk" *Bioethics* 5(2):105-112] disputes this characterization of his position. See Wicclair "A response" (above) for a reply to these criticisms.


23. See Tobias and Souhami, *op. cit.* and Easterbrook and Houghton, *op. cit.*, for other examples of how much more difficult choices can be when they involve experimental therapies, particularly when they are made in an experimental context.

24. The author thanks Patrick Yarnell for this example.

25. See Cockling and Oakley, *op. cit.*