

JUSTIFYING DECISIONS WHEN VALUES CLASH*

James M. DuBois

In the article, “A Framework for Analyzing Ethics Cases,” it was noted that there are three common sources of uncertainty or disagreements in ethics:

1. Different people are involved who have competing interests (e.g., a participant may seek therapeutic benefits in research, whereas a researcher may seek new knowledge)
2. Uncertainty or disagreement exists about relevant facts (e.g., about the probabilities and magnitude of harms resulting from an intervention)
3. Uncertainty, conflict, or disagreement exists regarding ethical norms (e.g., a beneficial action will violate the principle of autonomy)ⁱ

This conception of how ethical problems originate yielded the “So Far No Objections” framework for analyzing cases in terms of stakeholders, facts, norms and options. Once we have analyzed a case and clearly identified sources of disagreement and options, we need to decide upon a course of action. But how do we know which course of action is ethically best, all things considered? Are their criteria for ethically justifying a decision?

How we justify decisions will differ depending on what the source of a disagreement is. The following reflections provide guidelines on resolving different kinds of disagreements. No set of guidelines will provide a magic algorithm for generating one right answer. Prudence is always needed to take into account the specific details of a case. Moreover, answers can only be generated from a specific perspective. This specific perspective involves a view of human nature (e.g., of what it means to flourish as a human being), of one’s profession (e.g., of whether the people one serves are best understood as free-market consumers of products or as people to whom special fiduciary obligations exist), and of the hierarchy of values (e.g., of whether protecting health is more important than respecting autonomy or vice versa). Nevertheless, guidelines can provide time-tested means of *ruling out bad decisions* even while leaving room for disagreements across worldviews. (For example, no decision is good if it is known at the outset that it will trample on other values even while failing to achieve the good it is intended to achieve.) Moreover, a framework can structure public deliberations and ensure that important considerations are not ignored.

The [Hepatitis Studies at the Willowbrook State School for Mentally Retarded Children](#) will be used to illustrate the various issues involved in justifying a decision. Although we will consider the actual course of events, the key question we will ask – albeit with the advantage of hindsight – is whether we would approve such a study if it were proposed today under similar conditions.

DISAGREEMENTS INVOLVING COMPETING STAKEHOLDERS

When disagreements revolve around the fact that different people have competing interests, we have to ask two questions:

1. Do reasons exist for giving priority to the interests of one party over another? For example, in the research context the safety of individual participants is generally put above the interest society has in gaining new knowledge.

* This article is based on Chapter 4 of (DuBois, forthcoming).

2. Who is invested with decision-making authority? For example, the legal and ethical doctrine of informed consent gives participants the right to make the decision whether or not to participate in research. Institutional Review Boards have decision-making authority to prevent or stop a research study that appears overly risky. And researchers have the authority to determine whether potential participants meet inclusion criteria.

Dilemmas arise when each party has legitimate claims to competing goods or when decision-making authority is unclear in a specific realm. Resolving such dilemmas will typically involve examining laws (statutes, regulations, and cases) and professional codes for guidance; considering whether mediation would be helpful; and asking whether some parties should recuse themselves.

Simply becoming aware of the various stakeholders in a given situation may raise awareness of competing but legitimate goods that should be considered. Perhaps above all, it reminds one of the need for ethical processes like community consultation and IRB review, processes that frequently force one to clarify goals and to compromise so as to balance competing interests.

As we have seen, the Willowbrook study involved several key stakeholder groups: the children, their parents, the researchers, and society from a public health perspective. But as a matter of historical fact, various stakeholders did not generate much disagreement. The authority of parents to decide whether their children should participate in the hepatitis studies was uncontested. The fact that the interests of parents – e.g., in placing a mentally retarded child who needs tremendous time and energy from caregivers – did not always coincide with the interests of the children was not considered. Here we see that IRB review using publicly developed guidelines might have introduced a “disinterested” third party that could assess whether or not the study was safe enough (or at least that the risks really were similar to those encountered in daily living at Willowbrook) to justify even approaching parents for permission.

DISAGREEMENTS INVOLVING FACTS

The term “facts” is being used in a very broad sense here to include mundane facts (e.g., the dose of an investigational drug), as well as probabilities (e.g., of benefits or harms resulting from participation), and controversial worldview beliefs (e.g., that society will only be improved by regularly subjecting humans to harms in research).

Disagreements over mundane facts are perhaps the easiest to resolve, as long as people are committed to empirical methods and data exists.

Disagreements over probabilities are far more difficult. The reason why research is proposed is precisely because we do not typically have many answers about the topics under investigation prior to conducting a study. Moreover, the significance of a probability (which may be very low) increases as the magnitude of a benefit or harm increases, and this is often a determination that depends on individual values (e.g., how highly one values privacy). Committees that review research should have members with expertise in the areas of research they review and should consult scientific literature as necessary.

Disagreements over worldview beliefs are often the most difficult to resolve. Again, this points to the need to have ethical processes in place to ensure that such differences are aired and solutions are negotiated.

The Willowbrook studies definitely involved significant disagreements over facts. Saul Krugman, the principal investigator, firmly believed that the probability of harms for the children in his study were lower than the probability of harms for children outside of the study because the unsanitary living conditions at Willowbrook meant that nearly all children would become infected with hepatitis and those in the study were at least monitored and in a sanitary environment. More controversially, he believed that his research would eventually lead to a vaccine that would directly benefit the population to which the participants belonged and society at large. While he was in fact right, most clinical research never yields such major breakthroughs – so detractors were not without factual arguments of their own. Moreover, other methods for providing more sanitary living conditions (and thereby reducing the risk of contracting hepatitis and other diseases) clearly existed.

DISAGREEMENTS INVOLVING CLASHING ETHICAL NORMS AND VALUES

The last observation – namely, that there were other ways to benefit the children at Willowbrook – allows us to recognize an important point as we turn to disagreements that revolve around values. A decision cannot be justified without first clarifying what are our goals. Clearly, as a medical researcher rather than a personal physician, Dr. Krugman's primary goal was not care of the children, but rather gaining new knowledge that would serve science and the public's health through the development of vaccines. This led him to seek to justify decisions that others – e.g., child advocates – did not seek to justify.

In stating that we first have to know what our goals are, we are not embracing a crude utilitarian philosophy of the end justifies the means. Such a philosophy sanctions ignoring other values and ethical norms in the pursuit of worthy goals. Yet there are at least two kinds of ethical norms, and neither should be ignored even when they conflict with worthy goals.

Moral absolutes constitute the first kind of norm. Examples of such norms are “it is wrong to coerce sexual relations” or “it is wrong to kill a human for personal gain.” Some people deny that there are any moral norms that apply everywhere, at all times, under all conditions. Nevertheless, professional codes and laws often treat certain behaviors as prohibited under all conditions. Thus, when a worthy goal conflicts with a moral absolute, the absolute trumps the goal. In the Willowbrook study, some have argued that the infections were not in fact part of a “natural experiment”; rather they were knowingly caused by the researchers (Rothman, 1982). If “thou shall never knowingly infect another with a disease” were a moral absolute, then our deliberations might end here.ⁱⁱ

Prima facie norms are the second kind of moral norm we encounter. These are norms that express commitment to a value that deserves respect and should always be taken into account. Ordinarily, prima facie norms should be followed. An example might be “protect the confidentiality of data” or “obtain informed consent.” The values that underlie these norms are important and always deserve regard. However, sometimes a breach of confidentiality is appropriate (e.g., to prevent a suicide due to depression) and sometimes informed consent should be waived (e.g., in directly beneficial research with young children – here parental permission might suffice). One might argue that the prohibition against knowingly infecting someone is similarly prima facie; for we knowingly infect people whenever we use a live virus in a vaccine. That being the case, we need to explore whether a decision to conduct research that involves knowingly infecting participants with hepatitis can ever being ethically justified. Similarly, we need to explore whether conducting research with mentally retarded children who cannot grant consent could be justified.ⁱⁱⁱ

In an article, “Public Health Ethics: Mapping the Terrain” (Childress et al., 2002), a group of ethicists, scientists, and policymakers presents a framework for justifying ethical decisions that is attractive for two reasons: first, there is precedence for using each of its conditions in the long history of applied ethics (e.g., in natural law and casuistry); and second, observation of applied ethics committees (like IRBs) and policy groups reveals that these are intuitive criteria that are commonly used by people as they debate moral issues (albeit sometimes tacitly and frequently unsystematically). What follows is a framework largely based on the one presented in Childress et al (2002). While I have retained the basic framework presented in Childress et al (2002), it is important to note that the first four tests can be conceptually reduced at least to two. The “least infringement” test encompasses the “necessity” test: if a choice does not minimize infringement of other values insofar as possible, it clearly fails the necessity test; if it does minimize it insofar as possible, then it passes the test. Similarly, the “proportionality” test includes the “effectiveness” test: if a choice will not be effective in achieving its aim, it necessarily fails the proportionality test. While some users find the separation of steps helpful, others find the redundancy of tests confusing and may prefer to refer only to proportionality and least infringement.

When a proposed action conflicts with certain legitimate values or prima facie norms, it may nevertheless be justified if it meets the following criteria:

1. **Necessity:** *Is it necessary to infringe on the values or norms under consideration in order to achieve the intended goal?* Or would an alternative action achieve the same good aim without infringing on those or other equally weighty values? For example, in the Willowbrook study one might argue that more research could have been conducted with animals or that adult volunteers

could have served as participants. However, Dr. Krugman countered that research with animals could not replace research with humans. Moreover, adult volunteers were likely to become more seriously ill than children; and it was far from inevitable that they would become infected. Thus, adults would clearly be taking on a risk of harm that was well outside those encountered in daily living.

2. **Effectiveness:** *Will the action be effective in achieving the desired goal?* This question forces us into the realm of prediction, which can range from near certitude (e.g., that something won't work based on past models) to tremendous uncertainty. Krugman argued that his design was rigorous enough to yield knowledge of the different strains of hepatitis and to contribute to the development of a vaccine. Based on the successes in vaccine development witnessed in the 1960's, many were highly optimistic that his goals would be met.
3. **Proportionality:** *Is the desired goal important enough to justify overriding another principle or value?* Clearly, if the only outcome of the Willowbrook study were to generate data needed for a dissertation, the risks would not be justified. However, given that the risks were lower than might initially be imagined (*vis-à-vis* normal living conditions at Willowbrook) and that the potential benefits would be tremendous (and in fact were) it is easy to see why some believed the Willowbrook studies passed this test. However, we will revisit this criterion below.
4. **Least infringement:** *Is the policy or action designed to minimize the infringement of the principle or value that conflicts with it?* As we saw, Dr. Krugman made efforts to address the absence of informed consent and to minimize the risks to his participants. He sought parental permission (though critics noted that there were flaws in the process); he only exposed children to strains of hepatitis that were present in Willowbrook; and he provided monitoring and a sanitary environment. Additionally, nature provided that children typically experience far fewer symptoms than adults.
5. **Proper process.** *Has the decision been made using proper processes?*^{iv} Sometimes this involves nothing more than being transparent, i.e., not covering up decisions so as to allow public scrutiny. Sometimes it involves submitting a study to IRB review or obtaining community input. Most frequently proper process in research minimally involves obtaining informed consent from participants. In the case of the Willowbrook study, it is reasonable to assume that the review processes used were less structured than those that would be used today given that research regulations were nearly non-existent, IRBs were not widely used or mandated, and community consultation was not common. However, Krugman's studies were reviewed by the Armed Forces Epidemiological Board, which approved and funded the research (Advisory Committee on Human Radiation Experiment, 1995).

This analysis illustrates several things. First, it illustrates that the Willowbrook studies were ethically far more complex than suggested by the cursory presentation they typically receive in ethics texts that use it as a landmark case of research misbehavior (Shamoo & Khin-Maung-Gyi, 2002). This is often the case when researchers are motivated by noble aims and not merely personal gain. Nevertheless, these noble aims do not cause ethical issues to disappear. Second, it shows that clear criteria can be used to explain why such studies are or are not acceptable. Third, it shows that even with clear criteria disagreement is possible. People will disagree about whether alternatives or options are really viable; whether success should really be expected; whether the anticipated benefits are proportionate to the risks; whether harms have been minimized as far as possible; and whether the processes used to arrive at the decision were adequate.

Perhaps the most common source of disagreement is over the proportionality test. Our analysis of the Willowbrook studies illustrates why this is the case. The proportionality test reintroduces the issue of stakeholders: Can anticipated benefits to society be measured against harms to participants? (In the Willowbrook studies, the participants themselves were not expected to benefit from vaccines.) Moreover, comparing values is often like comparing apples and oranges; the value of liberty and the value of health are quite different and cannot be added or subtracted from each other to come up with a value sum. Finally, determining the significance of specific risks and anticipated benefits requires us to consider both their probability and expected magnitude, thus thrusting us into the realm of speculation (National Commission for the Protection of Human Subjects of Biomedical

and Behavioral Research, 1979). Dr. Krugman did not know his research would be successful in contributing to the development of a vaccine; he simply had good reasons to believe it.

Despite the ethical plausibility of the Willowbrook studies, it is highly unlikely that any IRB would permit such research to be conducted today. The reasons concern primarily proportionality and process. Given a history of exploitation of vulnerable populations and the ongoing risk that history could repeat itself, our current regulations require that additional protections be afforded to vulnerable populations. The participants in the Willowbrook studies were triply vulnerable: they were children, with mental retardation, living in an institution. Part of what it currently means to offer enhanced protections is that IRB members and researchers are not ordinarily allowed to consider benefits to society in an attempt to justify exposing vulnerable participants to greater than minimal risks. Such research could only be justified if the Willowbrook participants were expected to receive direct, significant benefits. The only benefits that were directly offered to participants involved basic care that should have been a standard part of care at the school (e.g., basic hygiene).

Moreover, the permission of parents was unduly influenced by a variety of factors that interfered with the proper process that was meant to replace the informed consent of subjects. In order to enable truly voluntary permission, parents should not have been asked to enroll children in the study until after they were admitted to the school, and basic benefits like adequate hygiene should not have been held hostage to participation.

BEYOND ETHICAL UNCERTAINTY

The process of analyzing cases and justifying decisions is clearly a highly reflective exercise undertaken in response to cognitive uncertainty or social disagreement. The frameworks that were illustrated can be helpful in navigating these waters. There is some evidence that the social process of debating and analyzing cases can also have a positive effect on ethical sensitivity, moral reasoning, and even professionalism (Bebeau, 1995; J. Rest, Narvaez, Bebeau, & Thoma, 1999; J. R. Rest & Narvaez, 1994). This is consistent with evidence that the process of adult learning is correlated with the readiness to challenge assumptions and a growing tolerance for ambiguity (Brookfield, 1998).

However, studies of moral exemplars – of people who were selected because they were identified by others as highly moral, self-sacrificing people – indicate that they frequently act out of a sense of moral certainty and view their actions as fulfilling; that is, they do not experience a lot of cognitive or volitional dissonance (Colby & Damon, 1994). How can we reconcile these two competing images of the moral life?

Perhaps an analogy is helpful. Frankl (1997) discusses a psychological case in which a violinist became obsessive about consciously analyzing the most trivial detail of technique, which eventually led to a complete artistic breakdown. Frankl acknowledged that consciously analyzing technique has its place, especially in addressing problems. However, the ultimate goal of musical education is to allow the artist to use his or her technique spontaneously, creatively, and unreflectively. Something similar could be said of ethics education. Its ultimate aim should be the development of moral character that enables persons to do what is right habitually, creatively, and with a sense of integration.

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ⁱ As noted above, capturing the complex reality of a moral situation in a framework is always somewhat artificial. The distinction between these three sources of uncertainty is often gray; and interrelationships between them are important to notice. Identifying stakeholders inevitably means identifying those who will be affected by the action in a variety of ways, and thus identifying competing interest and values. Likewise, morally relevant facts are seen as value-laden or related to the respect we accord to persons, e.g., the fact that a law exists requiring informed consent, the fact that a population has been exploited in the past, or the fact that a group of potential participants cannot grant consent.

ⁱⁱ Whether we are ever obliged by one moral absolute to violate another is debated; but most traditional ethicists who accept the existence of moral absolutes say no because (a) there are extremely few moral absolutes and (b) they are all negative (e.g., prohibitions on actions not positive duties) (Finnis, 1980). However, were the law or a professional code to treat certain positive duties as moral absolutes (e.g., save a life when possible) it would inevitably set up intractable moral dilemmas.

ⁱⁱⁱ While other ethical norms and concerns were relevant to the Willowbrook studies, I will focus just on these two in order to illustrate clearly the process of justifying a decision.

^{iv} This last criterion is a development of the "transparency" criterion presented in Childress et al (2002).