

The Sin and Guilt of Inaction

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There is significant tension between the value of the individual and society within clinical research. While various deontological theories have argued for the necessity of informed consent, these theories have been repudiated by consequentialism. It is my position that neither deontological nor consequentialist theories are entirely erroneous. While investigating both sides, I will highlight the necessary requirements for ethical research as I examine the claims put forth by deontological and consequentialist theorists. I will first critique the arguments of two deontologists, Alan Donagan and Hans Jonas and then offer an argument for the necessity of informed consent, while borrowing from Leon Eisenberg and rule-utilitarian theory.

Both Donagan and Jonas argue for the necessity of informed consent. They defend the inviolability of individual agency and claim that any research done without consent, regardless of the outcome, would be coercive or deceptive. However, the authors disagree about the requirements for informed consent. Donagan argues that informed consent is sufficient, while Jonas pushes further. Jonas emphasizes the participants' 'thinghood' (i.e., an existence that is separate from the intended purpose) and claims that consent is not sufficient for ethical research; voluntary willingness is required.^[1] Before analyzing Jonas's claim that voluntary willingness is required for ethical research, I will first examine the issue of informed consent.

Informed consent requires both that instructive and accessible information is provided to participants and that they comprehend it. Informed consent is necessary for medical research for reasons highlighted by Donagan.^[2] First and foremost, the physician-patient relationship rests upon informed consent. Without transparency, there can be minimal trust. If informed consent is mandated, then the fundamental rights of the patient are secured along with trust. Additionally, the patient is assured the opportunity to decline to participate in an informed manner, rather than relying on a possibly biased researcher. According to Donagan, comprehension, assessment, and written consent must be obtained to guarantee that ethical informed consent has been secured for clinical research.

The field of bioethics was born of scandal and tragedy. Early clinical trials required minimal to no consent; when there was consent, it was often uninformed. Trials such as those in Tuskegee, which were conducted without any informed consent, engendered an ethos of mistrust in the American research community. Although many regulations such as the Nuremberg Code were drafted after this, regulation overall remained sparse. In 1966, Henry K. Beecher wrote about the lack of informed consent in clinical trials and noted 22 examples of unethical practice out of a sampling of 100. Throughout the latter half of the 20th century, concern was directed at the amount and quality of information being supplied for those consenting in trials. Research conducted abroad in developing nations was heavily scrutinized and many proposed that consent being attained from participants was uninformed. Critics claimed that the lack of knowledge regarding Western clinical trials and the duty the researcher had to the study (over the individual's healthcare) consequently misled participants about what type of care they were receiving. While some critics desired increased regulation, others demanded recruitment from highly able and educated populations.

While informed consent is necessary for ethical research, recruitment of highly able and educated volunteers may prove to be a significant hindrance to it. Jonas argues that when a researcher recruits participants for a study, he should search for subjects with whom a "maximum of identification, understanding and spontaneity can be expected."^[3] In typical deontological fashion, Jonas argues for the supremacy of the will and claims that a motivated and educated volunteer will ensure that his service is not

only permitted, but *willed*. Jonas calls this method of recruitment the “descending order of preference” and notes that it is an “inversion of normal market behavior.”^[4] Yet it is hardly believable that researchers would seek out the less-available and more-valuable participants, especially when funding is low. Jonas’s only reply to cases involving recruitment from the less-valuable and highly available populations is that the researcher must “sin and fall into guilt.”

Granting that Jonas’s method of recruitment is correct, and setting aside initial pragmatic concerns about his model, there are still concerns about the idiosyncratic selection of participants and the effectiveness of research. As Louis Lasagna writes, in an experiment in which postpartum patients, experiencing pain, were approached for a study, 80 percent to 85 percent of the patients refused to participate despite a minimal risk of harm.^[5] Utilizing Jonas’s volunteer-based requirements for informed consent could cause patient populations to be highly idiosyncratic, possibly damaging results. If a researcher is drawing his pool of participants from the most valuable and scarcest, then the sampling of the population would most likely be of a certain demographic, thereby skewing results. Although the efficacy of an intervention may be shown to be high in the test group, translating these results from a specific population to a worldwide demographic will most likely be difficult, and the intervention will have a decreased probability of effectiveness.

In addition to potentially biasing results, Jonas’s descending order of preference could create problems for research in developing nations. If only the scarce and valuable participants are allowed to participate, then participant pools will consist primarily of participants in developed nations. A variant of the RRV-TV vaccine was recently tested in the United States and demonstrated 49 percent to 68 percent efficacy in preventing diarrhea and 90 percent efficacy in preventing severe cases of diarrhea. However, it was quickly taken off the market, as it was shown to lead to intussusception.^[6] In some developing nations, one in 200 children die annually from rotavirus.^[7] Does one halt all randomized controlled trials of the vaccine if it is effective for those developed nations but risks intussusception? In cases similar to the RRV-TV vaccine case, the risk-benefit ratio may be seen as unethical in a developed nation while less dubious in a developing nation. If the risk-benefit ratio is deemed too harmful, then the research may never be performed, and many may die without the hope of research. Jonas’s order of preference would not only create discrepancies in effectiveness of research (due to creating a biased sample); it would also limit the potential benefits of research.

Flaws are present not only in Jonas’s framework but in Donagan’s as well. Donagan argues for the necessity of informed consent, but his methodology assumes a deontological moral theory, which I do not believe is necessary. Donagan provides no compelling reason why we should use a deontological theory, instead of consequentialism. The same protection of patient rights can be guaranteed using alternative theoretical approaches.

Employing rule-utilitarian theory, a form of consequentialism, one can come to the conclusion that informed consent is necessary. Supporters of rule-utilitarian individualism claim that research participants are the best judges of their own selves and interest. Evidence for this is provided by John Stuart Mill, who writes, “Over himself, over his own body and mind, the individual is sovereign.”^[8] Adapting this version of rule-utilitarianism ensures the most beneficial consequences for the greatest number of people, while respecting the individual. Individual-centered rule-utilitarianism maximizes the *summum bonum*, the highest good. With individual-centered rule-utilitarianism, society can be at ease, patients can be protected from abuse, and the individual’s choice remains paramount.

My position is in line with this rule-utilitarian theory. According to contemporary principlist concerns in bioethics, one must respect the individual while also promoting beneficent consequences. Adopting this position orients one to help the greatest number of people while still respecting the autonomy of the participant. The consent process can be undergone in a variety of ways, but the experimenter must ensure that it is instructive, accessible, and comprehensible. The rule-utilitarian framework allows clinical trials such as those in the aforementioned RRV-TV case to proceed in populations where interventions are desperately needed and clinical care is dangerously low. The consequences of this rule-utilitarian framework are that research is

devoted to populations in dire need without risk of coercion or compulsion. The goal of research is to yield new, generalizable knowledge. With a rule-utilitarian framework, results can benefit indigent populations while ensuring that tragedies such as Tuskegee never occur again.

This rule-utilitarian framework has the capability to help millions of disadvantaged humans. Jonas's model, on the other hand, cannot work in an international context. Drawing from solely educated and volunteer-based populations limits the amount of research, and thereby meaningful knowledge, that can be produced. The consequences of Jonas's model would be research confined specifically to smaller, more affluent populations. Restricting research to these populations could easily cause more research to be focused on chronic conditions found in developed nations rather than lifesaving treatments in developing nations. The rule-utilitarian framework avoids this misstep and favors helping those who need it the most, while still ensuring that each autonomous agent is consenting and is informed.

Upon adopting this rule-utilitarian theory, deontologists such as Jonas may still be wary of recruitment. Jonas claims that if a researcher recruits from the less-valuable and highly available populations, then that researcher must grapple with sin and guilt. Jonas may believe that researchers may sin and fall into guilt during recruitment, yet it is more likely that sin and guilt will be created through inaction. Inaction is a form of action; this is especially true when the resources to maximize health benefits and research are available. Eisenberg makes a strong case for directing medical research resources to the needs of the developing world, where infant mortality may reach 20 percent and life expectancy is limited to 30 years.^[9] It is clear that there is a moral justification for developed nations to focus on research that will prevent such horrific disease and death.

Contagion knows no political bounds and neither should advances in medical research. Jonas constrains his view to what a society can and cannot afford; however, once we expand our view to encompass the global community, it becomes clear that we cannot afford such death and disease. If there were a deadly ailment afflicting large populations of children in a developed neighborhood, research would begin immediately to eliminate the disease. Why hesitate when funding research that is beyond our local neighborhoods, in more remote, less developed nations? I see no moral difference, only a spatial difference. Despite distance, if it is possible to dedicate research to share in the freedom from death and pain, then it is justified that we do so. If one is more concerned with recruitment of lives than saving them, then perhaps this person too will experience graver sin and fall deeper into guilt. Instead of standing idly in the face of death, we can choose to act, while still protecting the individual.

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