Informed Consent: Its History, Meaning, and Present Challenges

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The practice of obtaining informed consent has its history in, and gains its meaning from, medicine and biomedical research. Discussions of disclosure and justified nondisclosure have played a significant role throughout the history of medical ethics, but the term ''informed consent'' emerged only in the 1950s. Serious discussion of the meaning and ethics of informed consent began in medicine, research, law, and philosophy only around 1972. In the mid-1970s medical and research ethics gradually moved from a narrow focus on the physician's or the researcher's obligation to disclose information to an emphasis on the quality of a patient's or subject's understanding of information and right to authorize or refuse a biomedical intervention. This shift was the real beginning of a meaningful notion of informed consent. However, it may be doubted that this notion has ever been put into real-world contexts of practice. Put another way, the bulk of consents given still today may not be sufficiently informed to qualify as *informed* consents.

I first discuss the early history of informed consent, including its critical landmarks. I argue that its arrival was sudden and impressive, but the path thereafter to high-quality consents has been rocky. I then explore two different meanings of ''informed consent'' at work in literature on the subject. The most established meaning derives from institutional and regulatory rules, although I give reasons to think that this meaning is morally suspicious. Finally, in the third part I discuss several contemporary challenges to informed consent that suggest we still have unresolved problems about whether, when, and how to obtain informed consents.

The Historical Foundations of Informed Consent

Classic documents in the history of medicine such as the Hippocratic writings (fifth to fourth century B.C.) and Thomas Percival's *Medical Ethics* (1803)[1] present an extremely disappointing history from the perspective of the right to give informed consent. The central concern in these writings was how to avoid making disclosures that might harm or upset patients. Physician ethics was traditionally a nondisclosure ethics with virtually no appreciation of a patient's right to consent. The doctrine of informed consent was imposed on medicine through nonmedical forms of authority such as judges in courts and government officials in regulatory agencies.

During the 1950s and 1960s the duty to obtain consent in a few medical fields, such as surgery, evolved through the courts into an explicit duty to disclose certain forms of information and to obtain consent in both practice and research. This development needed a new term, and so the word ''informed'' was tacked

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onto the word "consent," creating the expression "informed consent." This expression appeared publicly for the first time in the landmark decision in *Salgo v. Leland Stanford, Jr. University Board of Trustees* (1957).[2] The *Salgo* court said—prophetically, but probably incorrectly—that the duty to disclose the risks and alternatives of treatment was not a new duty, only a logical extension of the already-established duty to disclose the treatment's nature and consequences. In fact, *Salgo* not only introduced new elements into the law but initiated the history of informed consent. The *Salgo* court was not merely interested in whether a recognizable consent had been given. The court latched tenaciously onto the problem of whether the consent was itself *adequately informed*.

This development initiated a series of court cases that step-by-step added requirements into the doctrine of informed consent. For 15 years after *Salgo*, these changes came slowly and incrementally in courts of law. Then, suddenly, in 1972 there came down three court decisions in three separate state courts in the United States that would solidify the place of informed consent and advance to prominence the importance of its moral demands. The three landmark cases were *Canterbury v. Spence*, *Cobbs v. Grant*, and *Wilkinson v. Vesey*.[3] *Canterbury* had a particularly massive influence in demanding a more patient-oriented standard of disclosure. Judge Spottswood Robinson held that "[t]he patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice."[4] Informed consent would never thereafter lose its place as a significant legal doctrine, but it would soon be considerably expanded through discussions of the ethical demands of consent in both medicine and research.

Numerous articles in the medical literature on issues of consent were soon published, largely on the significance of the precedent cases. Doctors were fearful, and their articles functioned to alert physicians to informed consent as a worrisome new legal development with the potential to increase malpractice risk. A study done in the mid-1960s, conducted by a lawyer-surgeon team, showed that *consent forms* were not yet a ubiquitous feature even of the practice of surgery—let alone elsewhere in medicine.[5] This would change rapidly after the 1972 court decisions. During the years between 1972 and 1978, there was a dramatic solidification of the view that both physicians and biomedical researchers have a moral and legal duty to obtain consent for certain procedures. These developments prompted an explosion of largely negative commentary on informed consent in the medical literature of the mid-1970s. Physicians saw the demands of informed consent as impossible to fulfill and, at least in some cases, inconsistent with good patient care.[6]

We might ask why informed consent became so important and the focus of so much attention in case law, ethics, and biomedicine in the next few years. The most likely explanation is that law, ethics, medicine, and research were all affected by issues of individual liberty and social equality in the wider society. These issues were made dramatic by an increasingly technological and impersonal medical care. Informed consent was swept along with this tide of social concerns, which broadly propelled the new bioethics throughout the 1970s. As it happened, the arrival of informed consent and the birth of bioethics occurred at exactly the same time.

These developments, as thus far traced, tell us little about physicians' and researchers' actual consent practices or opinions, or about how informed consent

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was viewed or experienced by patients and subjects. The empirical evidence on this subject during the late 1970s and early 1980s is mixed. Perhaps the best and most interesting data on the subject are the findings of a national survey conducted by Louis Harris and Associates for a U.S. President's Commission on bioethics in 1982. Almost all of the physicians surveyed indicated that they obtained written consent from their patients before inpatient surgery or the administration of general anesthesia. Approximately 85 percent said they usually obtain consent—written or oral—for minor office surgery, setting of fractures, local anesthesia, invasive diagnostic procedures, and radiation therapy. Only blood tests and prescriptions appear to have proceeded frequently without some form of patient consent.[7]

This survey indicates that the explosion of interest in informed consent in the 1970s had an enormously powerful impact on medical practice by the early 1980s. However, evidence from the Harris survey and other sources also questions the quality and meaningfulness of this consent-related activity. The overwhelming impression from the available empirical literature and from reported clinical experience is that the process of soliciting informed consent often fell far short of a show of respect for the decisional authority of patients. As the authors of one empirical study of physician-patient interactions put it, "[D]espite the doctrine of informed consent, it is the physician, and not the patient, who, in effect, makes the treatment decision."[8]

To conclude this section, the history of informed consent indicates that medicine quickly experienced widespread changes under the influence of legal requirements of informed consent, setting in motion an evolving process in our understanding of informed consent and the moral demands involved in obtaining it. The 1970s framers of the rules wanted genuine informed consent, but that goal has been more difficult to achieve than was the impressive body of rules, court decisions, and books on informed consent that soon followed the early history. Practice has been slow to conform to abstract theory.

The Concept of Informed Consent

Accordingly, the claim that a signed consent form is evidence of an informed consent cannot always be taken at face value. Before we can legitimately infer that what is called an informed consent is truly an informed consent, we need to know what to look for. If one uses overly demanding criteria of informed consent—such as full disclosure and complete understanding—then an informed consent can hardly ever be obtained. Conversely, if underdemanding criteria such as a signed consent form are used, an informed consent becomes too easy to obtain, and the term loses its moral significance. Although a physician's or a research investigator's truthful disclosure to a patient has often been declared the essence of informed consent in legal and medical literature, mere disclosure is seldom evidence of an informed consent.

The question "What is an informed consent?" is complicated because at least two common, entrenched, and irreducibly different meanings of "informed consent" have been at work in its history. In the first sense, an informed consent is an *autonomous authorization* by individual patients or subjects. A person gives an informed consent in this first sense if and only if the person, with substantial understanding and in substantial absence of control by others, intentionally

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authorizes a health professional to do something. Here informed consent is fundamentally a matter of autonomous or self-determining choice.

In the second sense, informed consent is analyzable in terms of *institutional and policy rules of consent* that collectively form the social practice of informed consent in institutional contexts. Here "informed consent" refers only to a legally or institutionally effective approval given by a patient or subject. An approval is therefore "effective" or "valid" if it conforms to the rules that govern specific institutions. In this sense, unlike the first, conditions and requirements of informed consent are relative to the social and institutional context and need not be truly autonomous authorizations. Informed consent in the second sense has been the mainstream conception in the regulatory rules of U.S. federal agencies as well as in healthcare institutions, and this situation is not likely to change.[9]

However, literature in bioethics has increasingly maintained, as I would, that any justifiable analysis of informed consent must be rooted in autonomous choice by patients and subjects, because otherwise there is no truly informed consent. The first sense captures the morally best standard, because the whole point of the practice of informed consent is to protect and enable meaningful choice. Although living up to this standard has proved to be difficult in contexts of practice, informed consent as autonomous authorization arguably provides a model standard for fashioning institutional and policy requirements of informed consent. That is, truly autonomous choice can and should serve as the benchmark against which the moral adequacy of prevailing rules and practices are to be evaluated.

Current Challenges to Informed Consent

I turn next to some of the challenges we face today in the theory and practice of informed consent, with an emphasis on challenges in practice.

The Limits of the Law in Biomedical Ethics

A first challenge is how to understand the way the law should shape our understanding of informed consent. I maintained previously that the law has been more influential historically than any other field of thought in the United States. The doctrine of informed consent *is* the legal doctrine, and informed consent has often been treated as synonymous with this legal doctrine, which is centered almost entirely on *disclosure* and on *liability for injury*. This basis is unduly narrow for thinking about both research and medical practice, which is to say that the law is ill-equipped to help us in our thinking about informed consent beyond the restricted limits within which the law operates. Those limits can and often have misled us about our responsibilities to patients and subjects. American legal scholar and psychiatrist Jay Katz was appropriately unrelenting, throughout his career, in criticizing court decisions and the legal model. He regarded the declarations of courts as filled with overly optimistic and often morally empty and evasive rhetoric. The problem, in his view, is that the law has little to do with fostering morally required forms of communication in the clinic and in the research environment.[10]

The theory of liability under which a case is tried in American law determines the duty that must be fulfilled. In classic informed consent cases, negligence is the reigning theory of liability. This approach is itself a misleading and uninformative

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basis for thinking about informed consent in contexts of clinical practice and research. Negligence may be good for understanding what has gone wrong in some cases, but this rationale provides an inadequate framework for determining what we ought to be doing in soliciting consent or in waiving consent in institutions.

In the end, legal standards are not of major assistance in formulating a conception of informed consent for medicine and research. These standards do as much to distract us from an appropriate model as to contribute to the model, because they focus on illegal rather than unethical treatment. The heart of issues about informed consent is moral, not legal.[11]

The Quality of Consent

In discussing both meaningful choice and the limits of law, I have noted that problems about the quality and adequacy of consent probably cannot be resolved unless conventional disclosure rules are refocused so that we look instead at the quality of understanding in a consent as well as the rights of patients and their needs for information. This approach centers attention on the need for effective communication and genuine understanding by patients and subjects. Without a proper climate of exchange in the consent context, a request from a professional that the patient or subject ask for information is as likely to result in silence as to elicit the desired result of a meaningful informational exchange and consent. However, it is not clear how much progress has been made on this front in the last 20 years, and it is a good guess that relatively little educating and communication that conform to this model occur at present in either clinical practice or research. Achieving informed consent under the first of the two senses of informed consent discussed previously is still the principal challenge that we confront.

Problems of Broad Consent

A third set of challenges derives from contemporary concerns about broad consent. In Europe there is currently an active discussion of broad consent in settings in which obtaining consent is difficult or in which risk is extremely low. Although it is not as active, this topic haunts U.S. discussions as well. There has been a pervasive view in U.S. bioethics that if we must get consent, then it should be an *adequately informed* consent and that a broad consent is not an adequately informed consent. However, this view is now under pressure. I will approach the problem primarily through questions of the banking of biological samples.

The banking of samples. Certain advances in science have made efficiently promoting scientific advances while protecting the rights of donors ever more problematic. Samples collected for future—not merely present—research may not be adequately described in a protocol or consent form when sample collection occurs. How shall we understand what constitutes an adequately informed consent under these circumstances? The content of the consent will be roughly dictated by current and anticipated future uses of the samples. In giving consent, research subjects should be assured that sensitive personal information and data will be protected in a way that will not cause stigma or harm their dignity, will

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not violate privacy and confidentiality, and will not lead to discriminatory treatment.[12]

This challenge cannot be met merely by internal protections when obtaining consent. Biological samples and data from samples are often obtained from external sources such as industry, government, universities, or nonprofits. Here it must be ascertained whether samples were collected under valid consent policies. Surplus biological material that is often described as waste raises similar concerns. The use of a sample for purposes other than those specifically stated in the consent process is a violation of the trust that bonds the subject-investigator relationship and the original consent situation. If an investigator seeks to use a sample for purposes not originally stated in an informed consent form, the subject likely would have to be re-contacted and re-consented. However, there are exceptions to this rule—for example, when only minor departures are made from the original protocol and consent form and (in some cases) when samples cannot be linked with a donor. However, there seems to be only a narrow range of such valid exceptions. Even making samples anonymous is not a valid exception, because it may well violate the investigator-subject trust relationship.

These are just some of the problems that need to be addressed about the notion of broad consent. I will not try to resolve these issues here. However, I will follow up the challenges thus far noted with analysis of a case in which broad consent was used with disastrous consequences. This case beautifully exemplifies how morally complicated the informed consent process can be.

The Havasupai Indians and diabetes research. This case involves research conducted at the Arizona State University using as research subjects the Havasupai Indians of the Grand Canyon. Matters did not go well both because a broad consent was used by investigators when it was inappropriate and because university committee review of the research was ineffective. The case starts in 1990, when members of the fast-disappearing Havasupai tribe gave DNA samples to university researchers at Arizona State with the goal of providing genetic information about the tribe's rate of diabetes. Dating from the 1960s, the Havasupai had experienced a surprisingly high incidence of type 2 diabetes, which led to amputations and had forced many tribal members to leave their village in the Grand Canyon for dialysis.

The tribe's diabetes was examined in the research, but the blood samples that had been donated were then put to additional uses in genetics research, and here the trouble began. One use of the samples was to study mental illness (one professor had a special interest in schizophrenia). Another use was to study the tribe's geographical origins, which cast doubt on cherished tribal views about their historical origins. Approximately two dozen scholarly articles were published on the basis of research on the samples. Some of this research was judged by the Havasupai to be offensive, insulting, and provocative. For example, one study reported a high degree of inbreeding in the tribe.

A geneticist responsible for some of the research reported that she had obtained an adequate informed consent for wide-ranging genetic studies and defended her actions as late as 2009 as ethically justified. The problem was the use of broad consent. From 1990 to 1994, about 100 members of the tribe signed a broad consent that said the research was to "study the causes of behavioral/medical disorders." The consent form was intentionally confined to clear, simply written, basic information, because English is a second language for many

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Havasupai, and few of the tribe's remaining 650 members had graduated from high school. From the researchers' perspective, tribe members had consented to collecting the blood and to its use in genetic research well beyond the research on their particular disease. The Havasupai, however, adamantly deny that they gave permission for any non-diabetes research or that they were given an adequate understanding of the risks of the research before they agreed to participate.[13]

This case presents paradigmatic problems of human rights and informed consent. One reading of the case is that it is essentially about researchers' responsibility to communicate what might happen with the samples. The case also raises classic questions of whether scientists had taken advantage of a vulnerable population, and in this respect the case raises questions about exploitation that preys on ignorance.

Both the researchers and the review committee at the university overlooked the serious risks involved. One scholarly article eventually published by investigators theorized that the tribe's ancestors had crossed the frozen Bering Sea to arrive in North America. This directly contradicted the tribe's traditional stories and cosmology, which have quasi-religious significance for the Havasupai. Their history has it that they originated in the Grand Canyon and that the tribe had been assigned to be the canyon's guardian. To be told that the tribe was instead of Asian origin and that this was learned from studies on their blood, which has a special significance to the Havasupai, is to them disorienting and abhorrent. The account also introduced legal alarm. The Havasupai had argued that their origin in the canyon was the legal basis of their entitlement to the land, which is otherwise U.S. federal land.

Finally, in retrospect, there were significant risks for the university in the conduct of this research and in allowing a broad consent. In the end the university's Board of Regents agreed to pay $700,000 to 41 of the tribe's members, while acknowledging that the payment was to ''remedy the wrong that was done.'' The university spent $1.7 million fighting lawsuits by tribe members. The university had worked for years to establish good relationships with Native American tribes in Arizona. The reservoir of trust that had been established was seriously threatened by this case.[14]

This tragic case apparently happened with virtually no appreciation, during the course of ethics review, that obtaining a broad consent, under the circumstances, was an ethically dubious practice.

The Regulation of Consent and the Research-Treatment Distinction

A fourth type of challenge to informed consent requirements comes in how we should alter the ways in which consent is regulated.

I start with a basic distinction in bioethics, viz., that between clinical research and medical practice. This distinction has dominated how we think about biomedical ethics, including informed consent. Since the early 1970s it has been thought that research is risky, whereas accepted practice is aimed at the best interests of the patient. This belief is probably traceable to the history of abuses of subjects in biomedical research, and so there arose in the 1970s the assumption that research using human subjects is dangerous, exists for the benefit of future patients, and is aimed at scientific knowledge, not benefit for immediate subjects.

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Accordingly, it has been thought that the need for consent is more pervasive and the threshold of an adequate informed consent higher in research than in medical practice. But do we have good reasons to warrant this sharp distinction between research and practice—and the different levels of consent requirements that co-travel with it? And should the distinction between research and practice make any difference to requirements of informed consent? Perhaps today patients are underprotected, and research subjects overprotected, by our moral arrangements for consent. This matter will likely receive close inspection in upcoming years, and it presents an important challenge to current consent practices.

One central question will be whether we should have a moral system in which there is an intense, close ethical review of consent forms in research protocols and no close parallel attention given to consent forms in medical practice. One dimension of the problem is whether we should have government regulatory systems for research, but no comparable systems for the regulation of practice. In America, the vast differences in our systems rest on doctors' desires to not be regulated in the practice of medicine. But from the perspective of genuine informed consent, the U.S. system sometimes seems irrational, especially if there are dangers and risks in medical practice comparable to those in research. If so, then is it time for us to have comparable oversight systems in both research and practice?

Conclusion

I have been critical of various practices in the obtaining of and the failure to obtain informed consents. However, before we too sternly condemn defects in the judgments and practices of the past, we should remember that the history of informed consent is still unfolding and that current failures may be no less apparent to future generations than are the failures that I have found in the past and the present. Clearly we still face unresolved and critical moral challenges.

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