

COMPREHENSION IN INFORMED CONSENT: IMPROVING DISCLOSURE TO EMPOWER CHOICE

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Abstract

This project incorporates legal, ethical, and social analyses in an attempt to synthesize a clear picture of current problems with comprehension of informed consent disclosures in order to determine possible avenues of procedural improvement. To that end, a series of semi-standardized interviews with professionals involved in informed consent proceedings were conducted. Responses were used in conjunction with prior research to develop a comprehensive perspective on current issues in biomedical disclosure comprehension.

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1. Introduction

Decision-making processes involving competing valuable interests require employment of analytical systems in order to optimally resolve the conflict. Perhaps nowhere is this concept more central than in the area of informed consent, one of the most important yet least clearly understood bioethical doctrines of the present day. Broadly, informed consent refers to the positive duty of those who would interfere with a person's recognized rights of bodily integrity and self-determination to inform that individual of the possible consequences of the particular interference proposed and to obtain consent before proceeding. The concept of informed consent finds applications in diverse areas, but most frequently, discussion of informed consent is limited to medical and research contexts.

In both areas, there are three analytical systems by which one can make an assessment as to possible courses of action. These three systems fall into a continuum of specificity, and in general the functional importance of each as regards informed consent is directly proportional to the degree of specificity in the system. The least specific of these, ethical analysis, can be applied to any decision. In the middle is the legal system, which prescribes laws and regulations that apply only to certain areas of decision making and indeed only to certain questions in informed consent. While, due to the coercive

power of the state, law may be invested with the most power of these systems, in practice the law often acts in deference to the third system. This third and most specific analytical system is that of clinical practice in informed consent, which refers to the aggregate of customs, policies, and regulations that physicians and researchers respectively apply in the course of their duties.

Often, these three systems overlap and interact, sometimes in a contradictory fashion. This contradiction may be counterintuitive, since at first apprehension it would seem that each system is derived from the previous. However, while law is theoretically founded upon the common ethics adopted by a society and can thus be conceived as a type of intermediary between ethics and clinical practice, the vagaries and technicalities of law combined with barriers to its change prevent it from perfectly representing the ethical sensibilities of the citizenry at large.

Clinical practice, though based heavily on the various laws binding doctors and scientists participating in human research,^{*} also takes into account many of the everyday realities in these fields which may be too complex or may require too much expert knowledge for the law to consider. While the ultimate decision in a question of informed consent may be determined by which system supersedes the others in a specific case, all

^{*} Hereafter, terminology referring to the practitioner and beneficiary of informed consent will be frequently abbreviated to the medical context. The material should be understood as also applicable to researchers and subjects in an experimental context.

three systems should always be explored in order to increase surety in achieving the best result.

2. Ethical Foundations

Great advances in bioethics have occurred due to the augmented public and scientific interest over the course of the past two decades, and one of the most notable trends is the increasing popularity of a consensus-based approach to ethical dilemmas. It has become evident that no single ethical theory thus far devised is sufficient to analyze the myriad, diverse ethical dilemmas that confront today's researchers and medical practitioners. To better address these problems, the thorough bioethicist must draw from multiple moral traditions to build an "ethical consensus" that may serve as a more effective guide to the complex issues presented today.¹ This wisdom certainly applies in the area of informed consent, where some of the most challenging ethical issues are often encountered. Endeavoring to follow Martin's advice, the following two sections of this paper will approach several of the most prominent ethical influences upon the practice and analysis of informed consent practices.

Though informed consent is now an international phenomenon, the focus of this research project is on the theory and practice of informed consent in the United States, and thus the Western moral derivation of informed consent is of prime interest

here. The roots of informed consent stretch back to the fundamental ideals upon which American society was formed. Embedded in the moral traditions of the West, and especially those of the United States, are core principles of personal autonomy and self-determination. From these foundations arose the patient or subject's right to informed consent, to which the doctor or researcher's duty of informed consent is a corollary.

The supreme masterpiece of Western theory on autonomy is the moral philosophy of Immanuel Kant, who suggested autonomy as the supreme principle in all moral actions.² Kant's moral philosophy was both original and profound in this matter, providing a new conception of humans as rational, self-governing moral agents.

According to Kant, the ability to impose one's will and act towards one's own benefit is the most important factor separating human beings from animals and objects, which are by comparison mere tools by which humans may seek to further their goals.³

Kant's autonomy has two parts: self-imposition of values, and effective self-government in accord with these values. Since morals are requirements that we impose upon ourselves, Kant argues, a person is always the final arbiter of his own morality and therefore the first part of Kant's definition is always satisfied. The moral laws that people thus create are obligations, and the fulfillment of these obligations is the supreme duty. Kant proposes that this moral duty to oneself must trump all other influences upon our decisions, including desires, which Kant views as entirely separate from morals. The

ability of someone to correctly prioritize and act upon his self-imposed ethical guidelines is Kant's depiction of virtue, which he equivocates with "moral strength of will."

In his notes on Jean-Jacques Rousseau's *Social Contract*, Kant makes a specific argument against paternalism, no matter how benevolent.⁴ Above all, the independence of autonomous beings must be maintained; else their very nature is compromised. Kant reviles the air of servility that he sees as inseparable from a situation in which humans are dependent upon the beneficence of others. He further condemns systems and situations in which things deserved by right are granted only in submission: "It is not all one under what title I get something. What properly belongs to me must not be accorded to me merely as something I ask for."⁵

A common objection to this Kantian theory comes from the voice of history: Kant's real break with tradition in this new moral philosophy was that he asserted that human beings were indeed capable of self-governance through self-motivation to self-imposed moral action. Prior philosophy, with the notable exception of Rousseau (who influenced Kant deeply in this matter), held that one or more parts of this self-governance must be delegated to an external authority in the form of the law, a god, or nature.⁶

Kant rejected these theories, which he termed heteronomous, since they lead to a viewpoint in which quantifiable good, or "moral rightness," is existent independently of

the only beings capable of moral judgment—humans. Kant insists that moral necessities can and must be purely a priori, as good and evil are concepts which describe an action's relation to the moral law. Kant thus avoids the problem of incomplete knowledge cited by several naturalists and theists, in which it is claimed that humans cannot be morally autonomous since a given human is highly unlikely to know all of the repercussions of an action and what moral requirements may apply. In acting as rational agents and applying our wills, we are implicitly forced to make moral decisions, as morality is part of the rational will. Thus, an action can only be properly judged within the context of the principle it was based upon, and extent of knowledge is obviated.

Kant concedes that humans may not always apprehend the correct moral principles on which to base decisions, and often will not take the path they know is right. However, it is the creation of the known right path, the "ought," which is of prime importance to Kant's theory—if we know what we should do and do not do it, we are still capable of ruling ourselves through autonomous will, but are merely imperfect. Kant ennobles this human imperfection in the concept of virtue, as previously mentioned. The struggle for moral rectitude is the proper station of humans in Kant's eyes, and this very battle of our moral and rational wills against our base impulses and desires is what makes our moral decisions meaningful; a perfectly good being would not need to exert any effort to act on morals over impulses, and so those actions would not deserve the same praise.

Kant also elaborates on the process of moral decisions and gives a guide to action which, in addition to instructing the reader in how to act morally, further elucidates the Kantian perspective on the framework of moral action. In his syntheses of morality, Kant invented several concepts which have become cornerstones of Western moral philosophy: maxims, the hypothetical imperative, and the categorical imperative.

Recalling Plato and other ancient philosophers, Kant insists that moral laws must be classically formal. Classical formality implies a differentiation between form and matter; form is a sort of universal organization that gives objects and ideas their essential character while matter is the “filler” or detail. In the context of Kantian morality, that distinction leads one naturally to Kant’s own concept of maxims, which are essentially purely formal, generalized moral prescriptions. It is through maxims, Kant argues, that we can both understand morality and act morally, even though the intellect (or will) will need to adapt these maxims to individual situations as necessary. Kant’s maxims are generally conditionally willed future actions, e.g. “If it is cold out, I shall put on a jacket.” The particular jacket, temperature, or any other details are not important or relevant to the maxim, and through that very absence of detail maxims become easily morally evaluable.

Kant’s two imperatives are what he considers the two basic laws of rational will. He deems it evident that a rational will working towards an end must take action towards

that end, and Kant's hypothetical imperative states little more than that: "Whoever wills an end ought to will the means." This statement is conditional, as the imperative ("ought") portion depends upon the willing of the end, and thus it earns its title as hypothetical. Kant's categorical imperative, perhaps his most often-cited philosophical doctrine, can be construed as the "conscience" of the rational will, and creates a necessary inclusion of morality into all actions of a rational will.

The basic form of the categorical imperative, which Kant outlined in his *Groundwork on the Metaphysic of Morals*, is "Act only according to that maxim through which you can at the same time will that it should become a universal law."⁷ This is Kant's ultimate statement on morality and his definition of lawfulness itself, and Kant views it as obviously necessary in a society in which there are many agents of rational will. This imperative creates two requirements in the analysis of the maxim underlying a potential action, as Kant later describes: one must both be able to conceive of a world in which this maxim is universal law (alternately, a "law of nature") and rationally will its existence. If it is not possible to do both, then the potential maxim fails the moral test and must be discarded as immoral.

J. B. Schneewind, in *The Cambridge Companion to Kant*, proposes testing a maxim first by the hypothetical imperative, and then the categorical imperative, as a maxim must meet both criteria to be acceptably rational and moral.⁸ This is intuitive;

one must essentially decide whether an action is moving oneself towards the achievement of a goal, and then whether the underlying principle of the action is universalizable and therefore right and lawful. This is a convenient and practical way to quickly discard some actions with an easier test in the hypothetical imperative, but a proper understanding of the categorical imperative would necessarily imply the hypothetical imperative, as one could not rationally will a world in which all beings acted irrationally.

The categorical imperative's logic is further clarified through extension to Kant's concept of right, "the totality of conditions under which the will of one person can be unified with the will of another under a universal law of freedom."⁹ Kant also described how this concept should be applied in testing maxims or actions: "Every action is right which, or the maxim of which, allows the freedom of the will of each to subsist together with the freedom of everyone."¹⁰ This addition completes the rudiments of Kant's logical moral system, and one may understand how each part of the system, which is derived from pure rationality, depends on each other part. Fundamental to all parts of his moral philosophy is the overriding perception of human beings as moral agents acting according to rational wills. It is clear that any morality compatible with Kant's would need to respect this autonomy as without that autonomy, there could be no moral judgment, and no right; we would be cast adrift in a sea of amorality.

Kant's influential philosophy has a multitude of implications towards informed consent. In order to respect the autonomy of persons, we must trust in their rational wills and allow them to make their own decisions, so long as that decision will not interfere with the freedom of others. In the case of a medical decision or the decision to participate in scientific research involving human subjects, an individual's choice regarding participation will not impact the freedom of others and therefore must be preserved. If it is not, the individual is stripped of his moral and rational agency, which in turn deprives that individual of all freedom and dignity.

A decision made under undue pressure, of course, would not be autonomous as it does not embody the unfettered will of the decision maker, instead it would create a heteronomous dependency on an external source of decision. A medical decision made wholly by a doctor on behalf of a patient would be yet worse; the physician in that case would, by ignoring the patient's will, be treating the patient as an inanimate object for the purpose of fulfilling the doctor's goals. Despite the fact that the patient's and the doctor's primary objectives are presumably both the patient's well-being, it is the patient's subjective view of his benefit that is of importance to the concept of autonomy and thus is a basis for moral action.¹¹ As discussed in the next section, this beneficent instrumentalization, known as medical paternalism, was standard practice for the majority of medical history.

Noted English moralist John Rawls disagreed with Kant on several points, though in the end the implications of Rawlsian moral theory for informed consent are similar to those of Kantian theory. While Rawls was not read, nor even alive, at the time of the founding of the United States, he followed in the same liberal tradition of the philosophers who influenced the founders of the USA. Rawls had a great advantage, however, in terms of the amount of prior thought readily available to him. As a result, Rawls had the ability to compare and contrast a great deal of others' moral philosophy in the synthesis of his own. The works that Rawls thus created have now become cornerstone of modern liberal political philosophy.

In his aptly-named, quintessential work, *A Theory of Justice*, Rawls focuses on the principle of justice as a foundation for moral philosophy. In doing so, he takes a fundamentally different approach to Kant: instead of focusing on an individual code of ethics and then deriving societal implications from these personal morals, Rawls jumps straightaway to a national viewpoint. To determine these societal principles, Rawls applies a theory which amounts to a reformulation of Kant's categorical imperative for better application to policymakers. Rawls advocates discussing what is right for a country to do under a "veil of ignorance," in which one must make decisions blind to one's own position in a hypothetical society.¹²

Relying on the principle of rational minds making self-interested decisions, Rawls reasons that if one were making rules for a society without knowledge of one's place in this society, one would not wish to make unfair rules, lest one risk falling victim by chance to a disadvantaged position. Rather than leaving it up to one's own conscience to decide whether an action is truly representative of a universal maxim, Rawls chooses to use this "ignorant" viewpoint, called the "original position," in order to ensure easily recognized universality.¹³

Indeed, Rawls himself seems to view his postulated perspective and the famed principles of justice that he subsequently derives as deepening and extending Kant's theory. Remarking that the original position may be conceived as a procedural interpretation of Kant's model of autonomy, Rawls writes that the principles which would derive from his original position are the same as those that would regulate a kingdom of ends (Kant's term for a society in which each member acted according to the Categorical Imperative.)¹⁴

Utilitarianism, another eminent school of ethical theory in the Western tradition, differs greatly from Kantian ethics in its moral perspective. Invented by English philosopher Jeremy Bentham, Utilitarianism dictates that the best action is the one which produces the greatest amount of happiness for the greatest number of people. This moral rule is known as the greatest happiness principle and is considered to be the

foundation of Utilitarianism. As with any ethical analysis system, detractors pose a number of challenges to Utilitarian theory, chief among which is that great harm might be done to a few for the sake of obtaining a small amount of good for the masses.

Extending and crystallizing Bentham's theories, John Stuart Mill popularized the doctrine further in works including *On Liberty* and *Utilitarianism*. In these essays, Mill recalls Aristotle in arguing that there are different types of freedom and happiness, and in his indication that a given amount of superior happiness may trump a greater amount of lesser happiness. Echoing the Declaration of Independence, Mill suggests that all men must be free to pursue happiness in their own ways. This respect for autonomy as personal freedom was Mill's counter to criticisms of Bentham's work as being subject to mob rule and to schadenfreude, the taking of pleasure at another's misfortune.

Without Mill's supplement, Utilitarian theory might justify practices such as ancient Roman gladiatorial games: since the pleasure derived by many spectators at such a game might be greater than the amount of suffering that the gladiators undergo, especially since part of the excitement (which, for the sake of argument, can be assumed to be the source of pleasure in the context of gladiatorial combat) for the crowd is dependant upon the struggle and fear of the combatant. With the addition of respect for

autonomy, the whims of the crowd would be inferior in moral stature to the personal liberty of the gladiator.

In *On Liberty*, Mill strictly stated this “liberty principle” of societal respect for individual autonomy: “...the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others.” It is thus evident that despite the fairly large differences between the moral theories of Mill and Kant, they would reach the same conclusion: in the contexts in which informed consent is discussed, individual autonomy must be held in the highest regard and must not be violated except in exceptional cases. Mill clearly agrees:

The only freedom which deserves the name is that of pursuing our own good in our own way, so long as we do not attempt to deprive others of theirs or impede their efforts to obtain it. Each is the proper guardian of his own health, whether bodily or mental and spiritual. Mankind are greater gainers by suffering each other to live as seems good to themselves than by compelling each to live as seems good to the rest.¹⁵

These various ethical perspectives that have been discussed do not stand alone as abstract philosophies; to the contrary, they reflect and have influenced the progression of liberal ideals in the Western world. Perhaps no country exhibits this trend more than the United States, as exemplified in both the Declaration of Independence and the U.S. Constitution. However, a far older British document, the Magna Carta, was a harbinger for the evolving respect for autonomy present in diverse Western moralities.

The Magna Carta, issued initially in 1215, set a new standard for protection of individuals from government in creating the right of *habeus corpus*. Although a specific procedure was not codified until the Habeus Corpus Act of 1679, the Magna Carta declared the right by stating that the sovereign had the right to determine why the “liberty of any of his subjects was restricted.” After the Habeus Corpus Act was passed, the original intention of the statement—to protect citizens from wrongful detainment—was implemented by allowing prisoners to submit a petition to the Court, which would hold proceedings to determine the lawfulness of the petitioner’s imprisonment.

This guiding principle of the Magna Carta was clearly on the minds of United States founders when the Declaration of Independence was issued. Too familiar with the injustices and abuses that arise when a government possesses tyrannical authority over its citizens, they boldly declared that all men are created equal and are endowed with unalienable rights to life, liberty, and the pursuit of happiness. Further, they declared

that it is the right of individuals to structure a government in whatever way seems, to them, most capable of guaranteeing their safety and happiness.

This definitive adoption of autonomy as a chief principle of United States society was later incorporated into the United States Constitution, which includes the right of *habeas corpus* in the Suspension Clause, located in the first section of the Constitution. Perhaps of greater import, though, is the right to due process codified in the Fourteenth Amendment to the Constitution: "...nor shall any state deprive any person of life, liberty, or property, without due process of law..." Despite the wording "any state," subsequent judicial interpretation has held the text of this Amendment to apply more universally to all levels of government.

By specifically recognizing individual liberty—one formulation of autonomy—as inviolable except when a formal legal proceeding based upon the laws of a representative democracy has removed that liberty, this Due Process Clause serves as the foundation for a great deal of the personal protections that United States citizens enjoy today. Frequently cited in discussions of the legal foundations of the rights to informed consent and personal privacy, the essential character of this passage is the protection of personal autonomy. This inclusion of enforced protection of the autonomous freedom of individuals in the very bedrock of United States jurisprudence leaves no doubt: the Constitution and the ethical philosophy which it was based upon demand that everyone,

due to conscience of the principles of the foundation of the United States and due also to legal obligation, must respect the autonomy of persons in informed consent proceedings.

3. Contemporary Bioethics

In their seminal text *Principles of Biomedical Ethics*, Beauchamp and Childress offer a broad picture of the field of bioethics, including informed consent practices. In their noteworthy ethical analysis of the relevant issues, they propose a new ethical perspective specific to dealing with these issues. Their viewpoint, dubbed principlism, puts forth four basic principles as central tenets of bioethical analyses upon which relevant dilemmas may be judged. Despite the fact that this is no longer considered a wholly adequate approach to bioethical problems, the value of these principles is beyond question. Two of these principles are autonomy and justice, which have been often explored by classical ethical theorists such as Kant and Rawls. The other two principles, nonmaleficence and beneficence, are more application-specific normative cornerstones of medical morality originating from Hippocratic tradition and continuing through to the present day.

The conception behind these two principles can indeed be gleaned from Hippocrates himself in his *Epidemics*: “The physician must...have two special objects in

view with regard to disease, namely, to do good or to do no harm.”¹⁶ Respectively, these two “special objects” constitute the principles of beneficence and nonmaleficence. Despite their seeming similarity, these two goals are distinct principles which may sometimes even conflict.¹⁷

Beneficence, the *raison d'être* of physicians, is an affirmation of the purpose of their profession—to help. The doctor does good when he cures, enhances the quality of life for, or otherwise treats a patient. In order to do the most good, then, the doctor must use his training to choose the most effective medical treatment. If a patient might elect to choose another option, then that would compromise the completion of the physician’s objective of beneficence. This conflict leads to a phenomenon known as medical paternalism, in which medical practitioners assume the totality of the decision-making process on the assumption that their training will allow them to make the best judgment and thus produce the most good.

Medical paternalism, however, fails to take into account many factors, including respect for individual autonomy, personal beliefs, and the patient’s assumption of risk. Further, the credibility of medical paternalism has been tarnished by atrocities such as Nazi medical “experimentation” at Nuremburg and the Tuskegee syphilis study. Increasing public awareness and skepticism of pharmaceutical corporate interest and

involvement in biomedical research has also contributed to a lack of trust in the biomedical establishment.¹⁸

The other duty that Hippocrates places upon physicians, that of nonmaleficence, is more subtle but also more applicable to a present-day informed consent discussion. The prominence of respect for autonomy and related rights, including those of privacy and self-possession, in modern ethical discourse impels biomedical ethicists to consider a violation of those rights to be a form of harm. As a result, allowing medical paternalism to trample these rights is a violation of the duty of nonmaleficence, which is regarded as being a duty of greater priority than that of beneficence.

Despite the historical constancy of medical paternalism, it is crucial for ethical practice of medicine in the United States to consider these mores which are so entrenched in American culture. However, autonomy is not to be construed as the sole factor which should influence medical decision-making, including informed consent procedures. Rising trends of medical consumerism threaten their own harms, including forcing patients to make decisions that they do not wish to or cannot handle and devaluing the expertise of medical practitioners.

There are certain situations in which complete, direct autonomy does not serve towards the benefit of the patient or, indeed, the patient's wishes. The obvious

exceptional case is that of the incompetent patient, incapable either of making any decision or at least of making a rational one. The topic of incompetence will be covered in greater detail in a later section. A less severe case in which total autonomy is not desirable is when the patient does not wish to make his own medical decisions. One of the most important roles of a doctor is to counsel patients in medical matters, and patients may often feel unable to make decisions due to their illness, or may simply feel that reliance upon a doctor's expert judgment is in their best interest. Even in these cases, the patient's autonomy is preserved in the form of the delegation of authority for actual decision-making to the doctor. The origin of the authorization of treatment remains the patient's will, which entrusts the care of that patient to the physician to whom the patient has delegated decision-making authority.

4. Legal Basis

To some degree, medical consent (although not specifically informed consent) has always been required under common law due to the principle of battery. One early case involving this legal precept is *Slater v. Baker and Stapleton* (1767), an English case in which a surgeon was found liable for not obtaining his patient's consent before breaking one of the patient's bones in order to reset a partially healed fracture. However, in

keeping with their tradition of medical paternalism, doctors often misrepresented treatment in order to obtain the patient's consent which might have been withheld had the patient been told the truth. During the beginning of the twentieth century, this practice was abolished when rules were enacted around the country requiring any information that a physician provides to his patient to be truthful. Physicians still did not have a positive duty to disclose information, however.

A transition from this simple form of consent to informed consent began in 1914 with *Schloendorff v. Society of New York Hospital*. In this case, the Court held that consent must be given freely, recognizing the principle of autonomy. *Salgo v. Leland Stanford Junior University Board of Trustees* (1957) was a Californian case in which the decision created the first requirement of informed consent while coining the very term. Salgo was a patient who suffered permanent paralysis as the result of a diagnostic test and then filed suit against his doctor, alleging that his doctor had provided him with inadequate information regarding the procedure.

Legal requirements of informed consent were further shaped by subsequent cases in various state courts across the country, notably in *Mitchell v. Robinson* and *Natanson v. Kline*, both 1960 cases. Both cases involved patients who suffered major negative health consequences pursuant to prescribed medical treatments. In *Mitchell*, the court held that it was a physician's duty to inform the patient of possible negative

outcomes of treatment. The *Natanson* decision went further, with the court stating that doctors must inform patients not only of possible negative consequences, but also of the goals of treatment, chances of success, and alternatives to the recommended course of treatment. These criteria laid out in *Natanson* have stood the test of time and are the core elements of disclosure required for informed consent today.

Still, as with almost any legal issue where the majority of the law is crafted by the states as opposed to the federal government, there are substantial differences in the requirements of informed consent across the country. One particularly notable difference in standards of disclosure arises from a disparity in the perspective from which the courts evaluate the information presented. Approximately half of U.S. states follow a professional standard of disclosure, meaning that a physician must communicate such information as would be considered professionally appropriate or customary by other doctors. This doctrine has been implemented to some degree throughout history; in the 1767 *Slater v. Baker* case mentioned earlier, the court's rationale was indeed based on the fact that other surgeons considered it fitting to inform patients of the procedure they were about to undergo.

A professional standard has some clear limitations. First, other doctors may not want to receive or disclose all of the same information that a patient would need or desire. This inclination is likely to give too much power to the practice of "therapeutic privilege,"

a paternalistic idea of exception to informed consent in cases where the physician deems that disclosure of information would work at cross purposes to the treatment. Second, in cases in which there is no established practice or custom of disclosure, a professional standard would seem to exonerate physicians from any duty of disclosure at all. Finally, in order to actually seek compensation for a failure of disclosure under a professional standard, would-be plaintiffs need to secure the testimony of another doctor against the doctor that they allege violated their right of informed consent. Physicians are frequently reluctant to testify against their own. Often, the expert witness would need not only to be a doctor, but specifically to be a doctor familiar with the same locality in which the case took place, placing a further barrier in front of patients seeking legal remedy.

In response to these challenges, some courts decided over the course of the 1970s that the more appropriate perspective from which to judge the information disclosed is that of the patient, creating what is known as a lay standard of disclosure. Utilization of juries to determine whether a physician has conferred the information that a patient would want to know imposes a greater requirement of disclosure upon the physician, hopefully further protecting the patient and the patient's autonomy. Too, this increased obligation does not impose an undue burden on doctors: education, training, and professional circumstances all make it fairly easy for physicians to ascertain what information patients would require in a given situation.

However, a lay standard also has significant drawbacks. One such drawback is the possibility of what Berg, et al., refer to as “hindsight abuse.” In a case that has not been previously tested in a court of law, the jury has considerable freedom to impose a broad range of requirements of disclosure upon the physician. In some cases, the elements of the disclosure may seem obvious in the aftermath (of course, all such judicial questions are decided *post facto*, in the context of a malpractice suit, rather than as prescriptive law) while it may not have seemed necessary beforehand, such as in the case of an infinitesimal risk of severe side effects from a treatment.

Another drawback is that such general standards are based upon “reasonable person” logic, and may not take into account the specific information that a particular patient would find relevant that might not be of interest to the average patient. For example, a dancer advised to have surgery to remove a benign mass on her brain might be particularly fearful of a risk of decreased balance and coordination following the procedure, whereas an average patient could be significantly more concerned with the health risks of the mass itself. A few states have attempted to correct for these drawbacks in lay standards of disclosure by implementing hybrid or subjective standards of disclosure, but in many cases these requirements can be too nebulous for a physician to properly interpret.¹⁹

5. Special Issues

It is apparent by its very name that informed consent is a bidimensional requirement. In order to determine that patients or subjects have given informed consent, it must be established that they have been adequately informed and also that they have, of their own free will, given consent. In order to verify the degree to which patients are informed, standards of disclosure have been implemented which prescribe the types of information which physicians must pass on to their patients.

Commonly, relevant court decisions, statutes, and regulations call for disclosure elements including the nature of the procedure, risks of the procedure (including the nature, gravity, chance, and immediacy of the risk), alternatives to the treatment, and sometimes the benefits of the treatment. The requirements of consent are fewer; a practitioner need only make sure that the patient understands the information he has been given and that the patient makes a free choice to undergo the treatment.

Despite their face-value simplicity as compared to the requirements of disclosure, the elements of consent have spurred far more controversial cases and issues due in large part to the clinical occurrences of emergent exceptions to informed consent as well as patient incompetence. Doctors are generally permitted to render urgent care on a relatively short-term basis in an emergency situation without first obtaining consent,

due to the immediate health risks involved. Patient incompetence is a related exception to the laws of informed consent in which an individual, due to any number of factors, is legally deemed to be unable to participate rationally and meaningfully in his medical care.

6. Comprehension in Informed Consent

Given the ethical basis of informed consent procedure, a patient's comprehension of the information relevant to making the decisions at hand is a *sine qua non* for meaningful choice. If a patient does not understand the disclosure he is presented with, then his autonomy is only negligibly more protected than if he was not offered any information to begin with.

Questions have been raised as to whether any success in meeting a standard of comprehension might be realized. Disclosure forms are often riddled with both legal and medical jargon, and those reading these forms are often untrained in these matters. Sickness, anxiety, and pressure often further burden a patient's ability to internalize the facts at hand, both on an intellectual basis and in terms of grasping personal relevance and impact.

Comprehension of informed consent has more pragmatic necessity, as well. The perception of ignorance can lead to a feeling of helplessness, especially when an individual is undergoing a medical treatment, whether experimental or therapeutic in nature. Disclosure aimed primarily at fostering comprehension and therefore empowerment in the patient will aid in creating a relationship of trust between the practitioner and the patient, which in turn will benefit both parties. Indirectly, this relationship of trust may reduce the risk of litigation to the practitioner.

Ironically, many informed consent disclosures today seem to be aimed at minimizing risk to litigation through contract theory.²⁰ Even if this legal theory is successful in the courtroom, the practitioner and his sponsoring institution, if any, would still be subject to financial and time expenses associated with the legal proceedings. Furthermore, a patient's signature to a questionably comprehensible form would be far from a bulletproof defense, especially in the context of a jury trial for medical malpractice.

For the above reasons, it can be stated that comprehension of informed consent disclosures will lead to pareto-optimal outcomes and should thus be the primary target of any biomedical disclosure practices. To marginalize this confluence of ethical and practical impetuses towards comprehension is to jeopardize the welfare of not only an individual patient or subject, but also the medical institution or research project. A lack of public trust in biomedical establishments also has the potential to cause negative media

publicity, to degrade the standard of healthcare, to increase mental anguish in the sick, and to slow biomedical research through restrictive legislation, increased scrutiny, and decreased participatory willingness.

Despite these compelling interests in comprehension of informed consent disclosure, evaluative studies have found great deficits in patient understanding and retention of information related to treatments for which the patient has given consent. As summarized and referenced in a recent article²¹ for *Patient Safety and Quality Healthcare*, the research is quite conclusive of these deficits. Eighteen to forty-five percent of patients are unable to recall major risks of surgeries they will undergo,^{22,23,24} many patients cannot answer even basic questions regarding their treatment,^{25,26} and many patients do not even read the informed consent disclosure form with which they are presented.²⁷

Such figures are discouraging in light of the large amounts of effort and money expended by practitioners involved in the administration of informed consent disclosures. While the ideas of informed consent and shared medical decision-making are very new relative to the ancient practice of medicine and its historical viewpoint of beneficent paternalism, the progress of these liberalized practices does not seem commensurate with the accelerated development of progressive societal and ethical ideals and of scientific progress that has occurred in the past few decades. Research in this area, especially in the

area of comprehension, is essential to determine what is retarding more ubiquitous implementation of true shared medical decision-making.

7. Investigational Method

A number of investigational strategies were employed for this project, which was conceived as an interdisciplinary overview of the status of informed consent comprehension and an inquiry from which some meaningful suggestions or at least clarity might be drawn. The goals of this project necessitated a combination of both retrospective and original research.

The ethical analysis above was drawn from both primary texts and secondary sources, with a consideration of the interplay between Western moral philosophy and shifting societal norms. Legal research was undertaken through news, law journal, law review, and court opinion sources, utilizing research tools available at WPI and also at the Worcester County Law Library. Information relating to the specific topic of comprehension of informed consent was drawn from a number of medical journal articles and peer-reviewed studies.

For the original research component, this project involved a series of anonymous, semi-standardized interviews conducted with medical professionals and members of institutional review boards. These interviews were aimed not to glean statistically

supported quantitative information, but rather to uncover the perspectives and personal experiences of individuals most closely involved in performing informed consent disclosures. The hope of this project is that the qualitative information obtained in these interviews might provide valuable insight towards new or little-known strategies to improve comprehension in the informed consent disclosure process.

8. Responses and Discussion

The primary finding in the interviews conducted for this report was that despite greatly varying perspectives among various personnel conducting informed consent disclosures, all respondents were in consensus on a few key problem areas impeding comprehension in informed consent procedures: inadequate public medical literacy and health-related education, language barriers, and monolithic, impenetrable disclosure forms.

Another recurrent theme in the responses to interview questions was the highlighted importance of an individually tailored disclosure based upon a personal relationship with the patient. Both a medical practitioner in the field of obstetrics and a sociologist with a significant background in informed consent scholarship expressed views that no matter how clearly worded an informed consent disclosure document might be,

such a one-size-fits-all approach would never suffice to adequately empower an individual to make reasoned medical decisions.

Two respondents involved in psychosocial research felt that informed consent regulations for human subjects research could be overly restrictive to relatively innocuous studies. Both of these respondents also cited famous experiments on obedience conducted by Dr. Stanley Milgram in which subjects were deceived into thinking they were giving electric shocks to another volunteer to test the relationship between learning and punishment.²⁸

In reality, the other volunteer was an actor, and the experiment was designed to test the subject's obedience when commanded to inflict pain on another. Though Milgram alleged that "procedures were undertaken to assure that the subject would leave the laboratory in a state of well being"²⁹ and that "an effort was made to reduce any tensions that arose as a result of the experiment,"³⁰ his own study records subject reactions including extreme anxiety, fear, and "striking reactions of tension and emotional strain."³¹ Milgram wrote of one observer's notes regarding an initially smiling and confident businessman being "reduced to a twitching, stuttering wreck, who was rapidly approaching a point of nervous collapse."³² Specifically noting "tension [that] reached extremes that are rarely seen in sociopsychological laboratory studies," Milgram writes of subjects sweating, trembling, stuttering, groaning, and having fits of uncontrollable

nervous laughter. Three subjects in this experiment were under such strain that they collapsed in uncontrollable seizures.

To justify such an experiment might be possible under teleological utilitarian ethical theory, but it is clear that it would fail a test of ethical consensus, owing to its disregard for autonomy and the well-being of human subjects involved. Recent insight into post-traumatic stress disorder that was not available when Milgram was conducting this experiment further underlines the point that no matter how great the scientific benefit that Milgram's study may have conferred, it came at an unconscionable risk to the rights and health of those subjects involved. Perhaps the real lesson to draw from the Milgram experiments is that researchers must not discount seemingly intangible harms to subjects, for they may have ethically unjustifiable consequences not immediately obvious to the researcher.

9. Policy Recommendations & Conclusions

Reform in law and policy may be an avenue to partial remediation of some of these issues plaguing comprehension in informed consent. In the interviews conducted for this project, the most frequently cited obstacle to comprehension was a perceived lack

of public background medical knowledge. Examples given of this type of background knowledge included basic understandings of anatomy and physiology, common illnesses and types of treatments, and good health practices.

An Institute of Medicine study³³ has called the type of knowledge “health literacy,” though that term is also used in other literature to mean more basic background skills (reading, arithmetic, etc.) necessary as a foundation to this type of understanding.³⁴ The IOM study cites a wealth of research showing deficiencies in public health literacy and connecting failures of communication and comprehension in medical contexts to adverse outcomes of treatment. This agrees with the perspectives of interviewees, and this information makes a compelling case for increased efforts to educate the public in this area. Enhanced health education in public schools and greater implementation of public health awareness programs may be able to combat this lack of health literacy.

In order to tackle comprehension problems related to language barriers, the only clear solution pathway is widespread dissemination of convenient and speedy medical translation services. Significant research would be needed towards finding an effective and unobtrusive way to implement these services so that they would be available not only to patients in hospitals, but also to patients in private medicine and prospective research subjects.

The final problem universally recognized in the interviews was that of dense informed consent disclosure forms which include large amounts of information often not relevant to a particular patient's decision. This excess of information is included more to guard against legal liability for the medical practitioner rather than to truly inform the patient. Unfortunately, it seems unlikely that any legal recourse will have the necessary effect of shifting disclosure practices from goals of legal risk management to goals of communication, comprehension, and shared decision-making.

Further state adoption of patient-based disclosure standards, combined with guidelines from medical associations stressing personalized disclosure and open communication between physicians and patients might be able to ameliorate some degree of the disclosure form issues. However, as one researcher interviewed pointed out, it comes down to as much a question of cultural practice as anything else. Constant fear of legal liability combined with a still-present attitude of medical paternalism leads to unproductive, impersonal disclosures that are not likely to produce satisfactory comprehension in the patient. Further research must be undertaken in this area to solve these problems if the quality of informed consent disclosure comprehension is to be improved.

10. Appendices

10.1 Appendix A: Questionnaire

The below questions are substantially similar to those posed to each subject interviewed in connection with this study. Due to the anonymous nature of the study along with the details involved in this study, it is impossible to disclose raw transcribed responses to these questions. Note that since the interviews were conducted with semi-standardized technique, questions were added, modified, or omitted as appropriate with each individual interview. As stated in the above method section, the goal of each interview was not to obtain a quantitative set of responses to standard questions, but rather to ask questions that seemed most likely to prompt interviewees to relate wisdom and insights that they had acquired in the course of their duties.

SECTION I: ALL INTERVIEWEES

1. To communicate information to your (patients/subjects) necessary to obtain their informed consent, do you use a standardized form, a verbal explanation, a combination of the two, or some other technique?

2. What are the key elements that you describe to (patients/subjects) about a given treatment, procedure, or study? Are there any additional factors that you might disclose only under certain circumstances?

3. What percentage of your (patients/subjects) would you estimate fully understand the applicable information after your normal disclosure? Do you ever take special measures to ensure comprehension if you do not believe the normal disclosure procedure has been effective?

4. What are the major factors preventing comprehension of risks, benefits, etc. in the remainder of your (patients/subjects)? Could anything be done to eliminate some of these factors?

5. Are there any current problems with the system of informed consent and disclosure as you participate in it? What steps could be taken to address these problems?

6. How frequently, in your experience, does a dispute arise with a patient, a subject or the family of a patient or subject with regards to the practice of informed consent?

7. Have the legal requirements of informed consent ever impeded you in obtaining the optimum health for your patients or optimum data for your research?

8. From what sources do you receive input, guidelines, forms, or other information or documentation relating to informed consent procedures? Could this be better handled by another entity such as a professional organization?

SECTION II: MEDICAL/CLINICAL INTERVIEWEES

9. Do you view informed consent more as a giving of permission by the patient for the pre-selected treatment that you suggest, or as a shared decision-making process in which you and the patient together decide on a treatment option?

10. Does the current practice of informed consent provide for too much or too little patient autonomy? Is it more important for patients to more trustingly accept professional medical counsel, or for doctors to be more respectful of patient autonomy?

11. How have you dealt with your ethical and legal obligations to informed consent and disclosure in cases where a patient is temporarily or permanently incompetent to comprehend your disclosure or to give consent?

SECTION III: REVIEW BOARD / RESEARCH INTERVIEWEES

12. Do you feel that the aims and methods of research frequently conflict with the personal best interest of research subjects? If so, what are the most significant points of conflict?

13. Do current procedures for informed consent provide for pareto-optimality in research contexts (optimizing the combined benefit to both the researcher and the subject)? If not, which side has a disproportionate amount of power in the research relationship and in what manner is this exhibited?

14. What procedures do you undertake in cases where incomplete disclosure is essential to the scientific integrity of a research project? How might we better protect those subjects without seriously impeding human subjects research?

15. The bioethics of informed consent in human research can be very complex and conflicting. Do you feel that, in certain circumstances, potential for societal or scientific benefit from research can outweigh the value of respecting a subject's autonomy? Under what circumstances might this be the case, and what degree of deception or undisclosed risk might be permissible?

10.2 Appendix B: References

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- ⁴ *Ibid*, p. 311.
- ⁵ *Ibid*.
- ⁶ *Ibid*, pp. 311-313.
- ⁷ *Op. cit.* 2, p. 97.
- ⁸ *Op. cit.* 3, p. 320.
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- ³⁰ *Ibid*.
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- ³⁴ Cite health literacy