

# **Rethinking Informed Consent: How Can Lay Patients Discern High-Tech Interventions?**

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*On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments*

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Sophia is finally taken in to see the doctor after waiting for almost 45 minutes. She has been complaining of neck and back pain since her car accident last month. Expecting a diagnosis of whiplash or – heavens forbid – a ruptured disk, Sophia is aghast when she is told, “We’ll need some scans to be sure, but it looks like you may have some sort of growth on your spine.” “How is this even possible?” she asks herself, holding back tears, “Cancer doesn’t even run in my family!” “Although this is rare, these things are often benign” the doctor assures her. He goes on to explain the next steps and then tells her what tests he is ordering. Sophia readily nods along, hardly processing a word. When the doctor presents her with forms to sign, she does so after briefly skimming, just as anyone else would have done in her situation.

This scenario represents an all-too-common occurrence in the modern medical setting: poor communication. Among those forms that were signed was “informed consent” literature. In its ideal form, this *principle* is meant to facilitate providing the patient with all relevant information (such as success rates, potential side effects, and alternative measures) necessary to decide on treatment strategy by weighing the risks and benefits; in almost ubiquitous practice these *documents* constitute a verbose headache for the patient and a liability release for the healthcare institution (*What Is Informed Consent?*, 2019). And who is to blame? Doctors are simply doing what is required, patients can be too emotional to inquire further or else ignorant of any alternative arrangements, and healthcare institutions do not necessarily have any institutional incentive to change their practice. Something is clearly disordered in this arrangement, but there are practical changes which can affect the situation positively; these mostly consist of simple behavioral changes as a result of shifted mindset. In this paper I will give a background of informed consent as a principle and law, show some problems with its current implementation, and then provide a framework for analyzing the landscape using “Engineering as Social

Experimentation.” I will finally illustrate some principles for helping the present situation. First, let us ask: how did we get here?

### **Who’s Informed, What Consent?**

Informed consent was not thought of overnight. It slowly developed along with many other cultural and societal realities over time, starting with seeds of the idea from ancient times. In early medicine, including traditional Indian systems and widespread practice in ancient Greece, undesirable customs prevailed such as paternalism, socioeconomic discrimination, and defensive medicine. This last practice is well illustrated in an example from Hippocrates’ writings: on multiple occasions, prominent physicians refused to operate on Alexander the Great out of fear unless the latter publicly stated his confidence in them and the incurability of his disease. This was to protect them in the event that they were unable to assist his condition – pay attention to the parallels with what informed consent has become. Nevertheless, certain figures were already promoting some recognizable features of modern medical ethics: “Hippocrates before Plato stated that information needed to be given to the patient to enable her/him to cooperate with the physician to give consent” (Kumar, 2013, para. "Ancient Greece").

Though the concept of informed consent has its origins in antiquity, the explicit definition thereof is a relatively recent phenomenon. In America, the codified right derives from a series of landmark cases throughout the 20<sup>th</sup> century in which plaintiffs sued their physicians for performing operations which were not approved in themselves or that deviated from the agreed manner. One example follows:

In the case of *Mohr v Williams*, the plaintiff, Mrs. Anna Mohr, consented to an operation on her right ear; however, once she had been anesthetized, the defendant physician changed the plan of surgery from the right ear to the left... Mrs. Mohr's hearing was further impaired by the operation, and she sued the surgeon for assault and battery... The Supreme Court of Minnesota agreed that the surgeon should have obtained consent before performing surgery on the opposite ear. (Bazzano et al., 2021).

In all these instances, the information regarding the procedure itself is obviously not central – the courts were not concerned with Mrs. Anna Mohr’s level of medical expertise – but only as a means to providing a basis of understanding for the patient’s decision-making process.

### **Flawed Inception – Informed Consent as Such Is Faulty (Problem Definition)**

The whole principle of informed consent is centered around the idea of personal sovereignty, that each person has a right to control his or her own body (Childress & Childress, 2020). “In its decision in favor of [one of the aforementioned plaintiffs] , the appellate court stated, ‘...under a free government at least, the citizen's first and greatest right, which underlies all others—the right to the inviolability of his person’” (Bazzano et al., 2021). Obviously, this right is not absolute – one may not, for example, use their body to harm another without just cause. But when it comes to the practice of medicine, which exists to promote health and wellbeing, it is each individual person who has ultimate authority to determine the best course of action for himself or herself. However, as described above, even since its establishment as binding for healthcare professionals, informed consent has not always been implemented most effectively: Bazzano et al. described how “empirical research has demonstrated that the informed consent process often fails to provide information in an understandable format to individuals with *low health literacy* and that the expectation of detailed information recall from a document that is often more than 20 pages is not realistic” (2021, para. "Introduction", emphasis mine).

As a side note, such an understanding suggests that in order to promote health equity, there must be an improvement in health literacy (Nutbeam & Lloyd, 2020). Though at the end of the day, if a certain medical intervention is simply too technically complicated for a certain individual to understand, then no amount of informative literature is going to help – in fact, it will probably only serve to make the patient more confused. Thanks to the internet, such

information *is* by and large readily accessible. Therefore, patients theoretically have the option to undertake study of their own to first comprehend the physiological mechanisms underlying their diseases and then discover the scientific principles governing the proposed treatment (i.e. become pseudo- doctors and engineers), but this is extremely time consuming and ultimately if they were able to do so it would remove much of the need for the doctor in the first place. Therefore, in the final analysis, I will not recommend diligent study on the part of busy patients as a definitive measure.

Further regarding health literacy, Betancourt et al., 2005 suggest that it is becoming increasingly obvious that one factor which is crucial in healthcare communication is adapting messages to be targeted to wider audiences in order to account for cultural differences as well as to provide effective care to diverse patient populations. This would require physicians, engineers, and any other actors involved in the creation and distribution of medical literature to be mindful not only of explaining technical matters comprehensively but also catering these documents and (hopefully) conversations to each individual, or at least discrete groups of individuals. The need for such skills would implicate a necessity for ongoing learning and development of skills, as it is unreasonable to expect this process to initiate itself (Campinha-Bacote, 2002).

However, as mentioned before, the primary aim of informed consent is not to make everybody a medical expert, but rather to ensure that individuals are equipped with the tools that they need to make good decisions regarding their own healthcare. Early on, neither of these ends were satisfied because “informed consent as a legal doctrine focused almost exclusively on the physician’s disclosure of information rather than on the patient’s understanding of that information” (Childress & Childress, 2020). So, neither the patients’ technical understanding of their conditions and the proposed interventions nor their decision-making competence were

ensured, which is obviously deficient if the whole purpose of the rule is to help the patients be able to make educated choices regarding their own treatment.

In practice, informed consent can very much resemble the heritage of defensive medicine whereby the doctor is simply trying to protect himself or herself from liability through the signing of a convoluted document rather than genuinely attempting to educate the patient. This unfortunate reality is a foreseeable possibility given our systems of economics and healthcare which mainly incentivize profits – for better or for worse – not positive patient outcomes. This tends to drive technological growth, but even that can actually contribute to the profit-centered model by providing increased diagnostic capabilities which translates to additional, costly testing to identify either the same conditions or new, lucrative ones:

In the contemporary neoliberal economies, **diseases** and **patients** are objects of business interest of the largely privatized for-profit healthcare industry. Profit from these objects emerges not only through sale of drugs or cure, but also from expensive hi-tech testing and “treatment” technologies... While technology-driven modern medical care tends to analyze the functionality of bodily organs to repair or restore them to the best possible level, it also reduces the human being into *biological machines in need of repair* (Hazarika & Dutta, 2012, emphasis mine).

Ironically, being able to treat patients “better” (medically speaking) often results in treating them worse (humanely speaking). Therefore, there must be some external driver for safeguarding patients’ legitimate comprehension.

There are some proposed changes which could indeed facilitate improved communication and transparency. Certain novel systems of medical decision making have been developed such as “shared decision making” (SDM) which emphasizes the joint effort of physicians and patients to determine the best therapeutic strategy. Although SDM can at times be “vague and imprecise because it encompasses so many different approaches,” practically its main encouragement is for increased and improved communication between patient and provider through more objective metrics: providing research-based information, collecting and considering patient values, asking

probing questions, etc. (Childress & Childress, 2020, paras. "Shared Decision Making" and "Narrow and Broad SDM"). This can make doctors feel more invested in the process and therefore take more responsibility for the outcome, leading to a closer collaboration and open expression of beliefs and concerns. Though no system is perfect: balances must be achieved between demands placed on doctors' limited time and patient needs, as well as other crucial factors.

### **Why Does One Need Permission to Cut Another Open?**

Apart from comparing communicative strategies and methods of decision making, it is important to consider why informed consent is necessary in the first place. Even if it were possible to achieve ideal patient-provider relations, this would not take away genuine risks that must be weighed regarding the interventions themselves. Many people want to withdraw from making difficult, impactful decisions or facing the hard reality of risk, but uncertainty is part of life. That is why, informed by the principle of personal sovereignty, informed consent demands assent to certain levels of medical intervention. "Valid consent can authorize another person to do something that would otherwise be impermissible. A clear example in the medical context is a surgical intervention: cutting on a person's body requires that person's consent" (Childress & Childress, 2020). On a healthy person, cutting would constitute an act of violence. In light of medical knowledge, however, we are able to use surgical, chemical, and other procedures to help cure illness.

At one point in time, certain medical procedures that are commonplace nowadays would have been seen as unquestionably harmful due to ignorance of medical developments. For example, chemotherapy – the circulation of indiscriminate poison throughout the body – would be inadmissible under basic ethical principles if not for scientific advances. The opposite is true

as well: there are practices once believed to be beneficial which are no longer. Think of widespread bloodletting, lobotomy, and certain obsolete pharmaceutical prescriptions to name a few. Despite major feats of the scientific revolution, many modern treatments' mechanisms of action are not even fully understood, and it is entirely possible that currently ubiquitous practices in the modern hospital will be unthinkable in the decades to come as a result of continuing progress in research. This is one of the main reasons why informed consent is an important factor: if we had perfect knowledge of physiology and medicine as well as specific individual's reactions, then there would be no need for a weighing of the risks, but, as it is, we have come to the conclusion as a society that the determination of these considerations is best left to the person affected.

### **Medicine, Like Engineering, is Risky (Research Approach)**

Research is, by definition, the act of assimilating the collective thoughts and ideas of other thinkers into a coherent framework for further expansion. In this process, it is essential to have one or two foundational sources to build upon because trying to respond to a swathe of sources as such would lead to a disjointed series of arguments which would not convey an integrated idea. The topic that I have chosen for investigation is considering how the principle of informed consent can be altered in practice to overcome some present issues and accomplish its intended purpose: namely, to allow nonexpert patients – who otherwise lack the necessary technical medical expertise – to be able to comprehend medical interventions in such a manner that they are able to form a reasonable plan of treatment. The foundational source I have chosen to use is “Engineering as Social Experimentation” by Martin and Schinzinger, which is itself a bit of a meandering though insightful exposition of the societal risks often unknowingly undertaken in the wake of technological advancement.



**Figure 1**

*The convolution of risk analysis*



*Note.* This comic attempts to point out some of the irony involved in the process of “foreseeing risk” on projects. The main point is if the mere exercise of trying to identify potential risks were sufficient to prevent catastrophe, then ostensibly a lot less catastrophes would happen. In fact, a lot of risk is unable to be predicted, which is what makes experimentation of any kind so dangerous. Copyright 1997, United Feature Syndicate, Inc.

Call to mind the story of the Titanic: an unsinkable ship sunken on its maiden voyage.

The irony of the whole situation, as this source so aptly elucidates, is that the “unsinkability” may have been a contributing factor to the catastrophe. “Buoyed by such confidence, the captain allowed the ship to sail full speed at night in an area frequented by icebergs, one of which tore a large gap in the ship’s side...” (Martin & Schinzingler, 1996). This mishap, combined with the fact that British regulations were severely inadequate in their lack of anticipation for vessels as large as the Titanic, resulting in a major shortage of lifeboats, led to 1522 people dying in terror in the freezing waters.

Now, accidents happen – that is certainly true regardless of how much planning and preparation go into something – but that is almost precisely the point they are trying to make: the release of new innovations is never a science in that nobody is perfectly able to foresee all of the possible consequences. Therefore, they argue, this should be made more explicit in the public perception so that true “societal” informed consent may be gained more broadly for the experiment that is engineering. If this were to take place, it would greatly contribute to a

collective mindset of taking very seriously the deliberation process between treatment options rather than passively and indiscriminately receiving whatever is recommended.

Essentially, what Martin & Schinzinger are attempting to do is make people really believe and act as if “each engineering project taken as a totality may itself be viewed as an experiment” (1996, p. 80). The basis of this claim is a set of undisputed facts regarding the engineering process: partial ignorance and inevitable uncertainties regarding the technical aspects; unpredictable broad-reaching final outcomes, such as occurred with the introduction of the cotton gin; and variation between laboratory testing and real-world application. One might argue that all of this could at least be dampened by not only accounting for isolated data but also factoring in all previous relevant attempts. While it is true that this may in fact mitigate risk, it would not completely eliminate it. And besides that, incorporating all previous data is very difficult, if not impossible, and even attempting is frequently neglected. Obviously, there is some difference between traditional laboratory experiments and engineering innovation. The former is explicitly intended to (dis)prove some null hypothesis under some controlled conditions of inquiry, whereas the latter is trying to avoid any uncertainty as much as possible and does not control conditions whatsoever. This just shows how much *more* of an experiment the latter can be, in the sense of being hazardous and unpredictable.

There is still room for legitimate consideration of the effects of released technology, as has been widely practiced by the proper sciences, social or otherwise. Additionally, and more relevant to my topic of interest, is that there is a lack of ethical obligation for the “experimenters” in the case of engineering to practice “safe” experimentation by, for example, obtaining informed consent. This would be almost impossible to execute perfectly, because there could hardly be an opt-in when many technologies have effects that go beyond the individual user, whether for good

or bad; however, this does not absolve the innovators from providing relevant information to make a reasonable decision and ensuring, as best they can, basic understanding of that information. The behavior and foresight of the engineers could be probed for adherence to a framework of engineering as social experimentation rather than a paradigm of certain benefit, and any positive or negative consequences resulting thereof could be considered. A thorough criticism could be accomplished rather than passive hindsight commentary which does not contribute much to the conversation.

This framework is extremely useful for analyzing the implementation of novel technologies, which helps when thinking about how to best navigate the associated risks. I think one of the strengths of this source is that it provides a novel yet relatively comprehensive framework for approaching engineering which has the potential to revolutionize innovation for the better through a humble acknowledgement of the unknown. In order for this source to be implemented, it would require a drastic change in mindset which admittedly could result in technological innovation coming more to resemble congressional impasse in the sea of risks to be considered. That is, innovation may slow down, but this is not necessarily a bad thing: if we acknowledge that engineering is inherently risky, would we not desire that our engineers take their time and exercise thoughtful hesitation? This could also help counteract the snowballing profit-centered principle informing modern American medicine as earlier discussed.

I think we must ask a crucial question: who do we want our engineers *to be*? Not just how do we want them to act, for isolated actions do not inform a character essence. This question may also be extended to our doctors and even patients. Martin and Schinzinger suggest four elements of responsible experimenters (1996, p. 89):

1. A primacy of obligation to protect the safety of human subjects and respect their right of consent.
2. A constant awareness of the experimental nature of any project, imaginative forecasting of its possible side effects, and a reasonable effort to monitor them.
3. Autonomous personal involvement in all steps of a project.
4. Accepting accountability for the results of a project.

All of these are either mindset aspects or foundational choices, and the expression of them can only be improved through practice. To use the language of virtue ethics, some pertinent values here are prudence, patience, diligence, and humility. A good innovator will not be blinded by the prospect of unrestrained technological growth or his or her own countless, taxing contributions as motivations to indiscriminately push innovation. Good physicians will likewise avoid pressuring their patients to accept treatments without fully and honestly presenting all risks and alternatives *in addition* to possible benefits. Patients ought to readily receive these presentations and actively ask questions to aid them in the process of discernment.

### **Improving on Informed Consent (Results)**

Short of reworking our entire medical-industrial complex and breaking down economic, intellectual, and political barriers, which is arguably impractical, a couple of simple prescriptions would appear to have profound benefits for the reformation of the practice of informed consent. Specifically, these recommendations are fostering a greater common awareness of the inherent risks of engineering (via the model of “engineering as social experimentation”) and encouraging those actors involved in the healthcare exchange to be formed as virtuous members of that network according to this model. Formation could include incentivizing doctors to have a more invested role in their patients’ outcomes and reforming the design process itself to include the perspectives of those who will actually be affected by its results, among other strategies. Admittedly, adoption of these strategies would not revolutionize the healthcare industry overnight, but they appear to be some modest yet effective ideas to benefit our current situation.

### *Risk Awareness*

It is very common for technological innovation to go unscrutinized by and large. The release of the newest iPhone marks a cultural landmark as people sleep outside for weeks in advance to be the first ones in line. Very rarely do people stop to consider potential risks associated with new technologies. Although it is a small example, the iPhone 12 was recently placed under a temporary ban in France due to excessive radiation levels emitted by the device (Williams, 2023). It is important that producers are vigorously attempting to regulate themselves through internal testing, and that consumers discipline their impulses towards a “latest-is-greatest” mindset. As a result, I would again challenge the primacy of profit and products.

### *Facilitating Patient-Provider Relations*

Doctors are the ones with the medical expertise. Grade-school teachers, plumbers, and say even rocket scientists simply will not have the toolkit to understand certain diseases and treatments, and therefore will be unable to fully comprehend the risks and benefits – at least to the same degree as the doctors. This will not change unless mandatory universal medical education is sponsored, which is plainly a poor policy proposal. So then, this implies that most of the reliable knowledge that patients have regarding their health will come directly from their doctors. For this reason, I suggest that one of the most beneficial actions doctors could do is to have more stake in this relationship, which will directly help their patients. They ought to make it their goal to learn about personal aspects of their patients lives and let that encourage their efforts of communicating effectively.

## *Rethinking the Design Process*

As an engineer, I have seen instances of the design process itself becoming very clouded due to a heavy reliance on an echo chamber of so-called “experts”. As a result, the designers get tunnel vision which results in neglect of oftentimes important considerations. If they were instead to bring in some prospective patients, doctors, and other disinterested yet ultimately affected individuals, it would serve as a sanity check on the engineering process, assist physicians and patients in use and understanding of the products, and foster a greater sense of collaboration, which could increase public opinion and trust.

The case has been made that the design process itself is not neutral, but actually embodies certain values and biases shaped by their designers and the social and cultural contexts in which they are developed (Brey, 2015). This has been described as technological artifacts being “morally loaded,” having important implications for society (Winner, 1986). If these values are not considered during the design phase, but only addressed after the fact or – even worse – completely neglected, then the populations intended to be served will be negatively affected by reduced access to care and decreased understanding of its mechanisms (Waren et al., 1967).

When it comes to novel, somewhat experimental medicinal techniques, especially those involving high-tech devices or methods, there will inherently be some obstacles to certain groups of people obtaining access. These will primarily revolve around what are referred to as social determinants of health (SDOH). These are social and economic circumstances which have been shown to have a large causation on people’s health outcomes; for example, race, class, and level of education (Braveman et al., 2011). It is crucial that these factors are taken into account not only ex post facto once products are on the market and organizations have spent the majority of their allocated resources, thereby informing the minimum necessary pricing in order to

recuperate their losses and turn a profit, but rather within the design process it is imperative that measures are taken to attempt a redirection of mindset from profit-oriented to patient-oriented. This could take the form of expanding the supporting literature to be catered to wider audiences, as mentioned before. Additionally, devices themselves could be designed to serve these very audiences. This could help us avoid blunders such as the neglect of dark-skinned individuals in the composition of sunscreen – its use is often avoided due to conflicting with pigment, and it is even seen as unnecessary, but darker people can develop skin cancer just like lighter-skinned people (*She Didn't Expect...*, 2023).

If patient-centered values are not prioritized during the engineering process, the whole enterprise of therapeutic innovation will be perpetually self-defeating by not serving those people it was created to but rather being subject to the desires of disinterested corporations. There has been much progress in recent years with awareness and activism pushing back against such unethical systems and practices. Examples from the 20<sup>th</sup> century include workers' attempts to establish medical cooperatives and clinics, civil rights activists' demands for greater racial equality in health care, feminist challenges to gender bias in medicine, and the activism of particular groups of patients, including people with AIDS breast cancer, and disabilities (Hoffman, 2003). I would like to further the positive aspects of these movements by suggesting further integration of nonexperts into the regular practice of design, which would of course also demand initiative on their part.

## **Conclusion**

Without engineering, the most practical of the applied sciences, I would not have been able to research or write this paper, not to mention that less people would be alive, healthy, and happy. Nevertheless, we must understand engineering for what it truly is, without naïveté.

Namely, it is a great way of taking the partial and limited natural truths that science uncovers and using them to optimize quality of life and productivity, but it is not a science itself. As with all other aspects of life, there are great inherent risks. Instead of propagating the legalistic info dump that informed consent has become, we ought to foster the development of the virtues of diligence in active initiative on part of the physicians, engineers, and patients; humility in seeking out the unknown and admitting mistakes; prudence in directing decisions regarding production, consumption, and application; and generosity with time and resources for the sake of understanding; all these among many others which can be extrapolated from this inquiry. The next time a technological breakthrough occurs, instead of wholeheartedly embracing it, take a more measured approach as if you have just become a subject in their global experiment. If such an attitude was adopted on a large scale, along with efforts to foster the necessary, corresponding character traits, then we could avoid a great deal of harm and continue to reap the innumerable benefits of such a great practice as engineering.



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