

Reformed Consent

A psychologist's perspective on what patients want to know and how physicians can meet these needs when making informed consent decisions

By Edward Johnson, PhD, C. Psych

Consider the following scenario: you have recommended a new treatment for your patient, Mr. Rodriguez, and sent him home armed with material (DVDs, pamphlets, etc.) from the pharmaceutical company that carefully and extensively presents the risks and benefits of the treatment. During his follow-up visit, Mr. Rodriguez mentions that he is afraid to take the medication and points to the pamphlet where two or three particularly serious, but rare, potential adverse events are circled in red ink. You proceed to explain that these events are very unlikely to occur and that this treatment has helped many patients. Mr. Rodriguez looks again at the adverse events, shakes his head and explains that he just is not willing to take that risk. Alternatively, perhaps Mr. Rodriguez initially agrees to treatment, but subsequently discontinues his medication for the same reasons.

Does this sound familiar? Do you ever wonder if there is a better way to approach the whole business of providing information and obtaining consent for treatment?

In this article, my goal is to offer new ways of thinking about informed consent that consider the psychological underpinnings of the process. Of particular importance in this approach is to identify emotional and cognitive factors that affect understanding of medical information and willingness to consent to treatment. Suggestions will be provided throughout the article to help you address these factors and improve your patient care.

Informed Consent: One-time Event vs. Ongoing Process

Usually, obtaining informed consent for treatment is conceptualized as a one-time event that occurs prior to the initiation of treatment. Although, since many patients exercise their right to discontinue treatment along the way, it is more helpful to think of informed

consent as an ongoing issue; like so many other things in life, it needs attention and periodic maintenance, just like changing the oil in your car's engine. From this perspective, both you and your patient may have good reasons to revisit the treatment plan. On the physician side, this may have to do with new information about the patient's medication, or the availability of better or less costly medication. On the client side, there may be concerns about the efficacy of the treatment, side effects, cost or treatment options.

Developing Understanding: Is Consent Informed?

The initial focus in informed consent is ensuring the patient is adequately informed about the risks and benefits of the various treatment options that are available, including the "no treatment" option. An important question is whether the methods used to present information to patients affect their comprehension and retention of the material. Principles of good pedagogy would suggest that this type of difficult material be simplified as much as possible; be presented in clear, jargon-free language; and be accompanied by a variety of visual aids (e.g., charts, graphs, pictures) to facilitate learning. Certainly, this would be important to ensure a clear understanding of the nature and consequences of various possible adverse events. Research on this topic, however, has not yet demonstrated a compelling or consistent advantage, or disadvantage, for using audio-visual materials in informing patients about treatments.¹

Information-processing considerations. In general, patients' understanding of treatment and disease-related information depends on the adequacy of the information-processing resources they apply to the task. Briefly, what patients need to do is to attend to and encode the relevant information (risks and benefits), holding this information in short-term memory while processing it (com-

paring risk:benefit profiles). Subsequently, after treatment is initiated, they need to be able to recall this information whenever re-evaluating whether they wish to continue taking the medication. As I will discuss, a variety of factors can interfere with the operation of these information-processing mechanisms, and thereby prevent a full understanding of the essential components needed for informed consent.

Understanding probabilities. A major part of the challenge of understanding the risks and benefits of a given treatment is that these are inescapably probabilistic. Not all patients will benefit from treatment or encounter adverse events. Consequently, the standard rational utilitarian decision-making model that underlies our informed consent procedures assumes that patients will assign, for each possible outcome, some quantitative value for how good or bad it would be were it to occur, and multiply this value by the probability of its occurrence. Summing these products yields a numeric measure of the net benefit of a given course of action, including no treatment, and allows the patient to make a rational choice by selecting the course of action with the highest value. At least, so the model would have us believe. Before we go on, however, ask yourself whether your patients—or you, for that matter—ever explicitly perform the full set of calculations needed to evaluate all possible outcomes for all relevant courses of action in the fashion just described. Ordinarily, few people actually do this.

Heuristics. In fact, considerable psychological research has demonstrated that people typically deal with probabilistic information informally, relying upon a variety of mental shortcuts known as heuristics.² Although heuristics allow for rapid decision-making in the face of uncertainty, they also can result in distorted understandings that significantly diverge from actual probabilities. In order to minimize these distortions, it is helpful to present probability information in both numerical (*e.g.*, proportions: a 1 in 1,000 chance) and verbal (*e.g.*, a very low probability) formats. It can also help to cite more familiar types of events to illustrate the rate of occurrence concretely (*e.g.*, about as often as you could expect to be struck by lightning in a given year). This kind of information allows patients to use their heuristic-based system with less distortion.

Emotional obstacles to understanding. Emotional and cognitive factors can seriously limit or distort patients' understanding of the risks and benefits of treatment alternatives. Fear and anxiety can cause people to attend



Meeting those needs: Dr. Johnson and his wife relaxing with a good book at one of their favorite spots near the Winnipeg river.

primarily to threat-related information, to the exclusion of benefit-related information. Moreover, fear can magnify or exaggerate the negative consequences of potential threats like adverse events while minimizing and underestimating the individual's ability to cope with

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such events. Depression and hopelessness, however, may cause individuals to underestimate the potential benefits of treatment and focus their attention on past treatment failures. Conversely, a sense of desperation can have the opposite effect of unrealistically magnifying potential benefits, while underweighting potential risks. As discussed below, identifying and addressing emotional influences is important for enhancing informed consent decisions.

Cognitive obstacles to understanding. Cognitive obstacles to understanding arise when there is a mismatch between the cognitive demands of the problem and the cognitive resources of the individual who needs to

understand the problem. As noted earlier, information presented in a way that is clear, simplified and readily understood can lower the cognitive demand. However, variability in the cognitive capacities of individuals will make even such accessible information challenging for some. Individuals who have limited education may not possess some of the basic knowledge and vocabulary needed to understand disease processes or the effects of medication. When limited education is compounded by limited intelligence, it may be difficult to successfully explain these concepts, though with patience and concrete analogies, much can be done even in these situations. Another challenge arises when English is not the native language; with individuals who have poor English skills, a good translator and/or translation of written material is essential for good understanding. Whenever doubts exist about patients' comprehension of consent-

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related information, having them share their own understandings can be very helpful for clarifying their level of comprehension and permitting you to correct any misunderstandings. It is encouraging to see a large majority of those surveyed in this issue's Joint Count indicated they at least "sometimes" utilize this practice.

Factors that May Affect Consent

Emotional and cognitive factors can also affect the process of making or altering consent decisions. Assuming that information and understanding precedes decision-making—an assumption that is not always tenable—any unchecked misunderstandings or distortions about consent-relevant information will affect the consent decision. It is worth noting that patients will encounter new information after consenting to treatment (e.g., from Internet sites, blogs, chat-groups, news

media, etc.) or may re-appraise the information they already have; this can result in patients altering their consent decision. If new understandings are distorted or inaccurate, this may lead to decisions to discontinue treatment. Accordingly, patients should be advised at the time of initial consent that they are likely to encounter further information about their disease and medication over time from a variety of sources. They should be advised to seek consultation with you or their family doctor whenever they have concerns about whether the treatment is working or whether there are likely to be serious side effects.

Culture and consent. In our increasingly multicultural society, we are more likely to encounter individuals for whom the concepts of individual rights and responsibilities underlying the practice of informed consent are less familiar; these concepts may even be at odds with their past experiences and expectations. For instance, individuals who have recently come from authoritarian societies may expect their physician to simply tell them which medication to take. They may become confused or anxious when presented with this as a health-related decision they need to make for themselves. Some explanation of Western norms of patient autonomy and socialization into the role of becoming an active, informed medical consumer, might be necessary. Even thoroughly Western patients may be surprised, and a little alarmed, when presented with a range of treatment options and told that there is no one "best" choice. In these instances, it may be helpful to remind patients that they are not necessarily choosing forever, and that some experimentation may be necessary to identify what works best for each person.

Emotional and interpersonal influences. Research on patients' concerns about medication shows that fears and worries about serious adverse consequences of medication use bother a great many patients.^{3,4} Some wonder if the medications they are taking to combat their disease will do as much or more damage than the disease itself, or if their medications may even kill them. With these worries, it may not take much for patients to begin panicking about worst-case scenarios, no matter how unlikely. This may cause patients to discontinue their medication or refuse to consent to it in the first place. Indeed, research on patient perceptions of adverse outcomes shows that there are a substantial number of patients who essentially ignore probability information when considering their willingness to take medication.

Summary of Recommended Practices

1. Disease and medication information is presented in a simplified, clear, and accessible manner and includes visuals (charts, pictures, graphs).
2. Probabilistic information is presented using equivalent words (*e.g.*, unlikely), numeric proportions (*e.g.*, 1 in 1,000 chance), and familiar, concrete illustrations (*e.g.*, as likely as...).
3. Factors that may interfere with understanding, such as limited education or intelligence, or poor English skills, are identified and accommodated appropriately.
4. Cultural-based differences in understanding and expectation are monitored and explored as necessary.
5. Emotional responses to disease- and medication-related information is monitored and explored. Patients should know that fears of adverse events are normal and that they can count on their doctor and healthcare team to work through any problems with them—they will not be abandoned.
6. Patients who exhibit signs of medical phobia should be referred for treatment to a psychologist or other behavior specialist.

The authors concluded that such patients consider certain adverse outcomes to be “protected values” they are unwilling to subject to considerations of trade-offs and probabilities.⁵ Although these authors have suggested that doing so results in suboptimal decisions, others have suggested that these decisions reflect patients’ desire to avoid future regret, and hence may be considered as having a rational foundation.⁶

Catastrophic Thinking

Although research has not yet identified what patients fear they will regret, I speculate that this fear has to do not only with incurring an irreversible adverse outcome, but that doing so would be catastrophic. In particular, I suspect their mental image is of their being not only physically disabled or disfigured in some way (as if that weren’t bad enough), but that they will be completely alone in having to cope with this circumstance. Consequently, they may fear their lives would be inevitably miserable as a result. This fear of social isolation is important for two reasons. First, chronic illnesses tend to increase social isolation, in that they impair mobility and can damage one’s sense of being worthy of social contact. Thus, it is natural for patients to fear that further physical damage or dysfunction may ensue from medication side effects, further increasing their isolation. Second, social isolation tends to be associated with a reduced sense of one’s ability to cope with problems. This sets up a vicious cycle in which fear of declining social support drives greater anxiety, which creates

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greater doubt about coping ability, which generates pessimism about outcomes, which increases worries about isolation, and so on. If this picture is correct, then no amount of reassurance that the feared outcome is very unlikely will assuage patients’ fears, since in their minds, any chance of this disaster occurring is unacceptable. Accordingly, what patients need in this context is to understand that, when worries or actual issues of adverse effects related to medication use occur, they will not be alone in dealing with them, for they will have the support of their physician and healthcare team. Moreover, it may be useful for patients to know at some point that even when individuals have experienced adverse events related to medication usage, it is typically much less troubling

than they feared. In sum, when fear of a particular adverse event appears to be weighing heavily on a patient's willingness to consent to treatment and they are not reassured by considerations of low probability, an alternative tactic to consider is addressing the worry head-on. By having the patient clearly describe what they fear, the physician will have an opportunity to open a dialogue about their worry of facing the problem alone. If done compassionately, I suspect that most patients will feel reassured by having their fears understood and having a greater appreciation of how their medical team can support them in avoiding or dealing with adverse events.

This approach will likely be helpful for many patients. However, there will be a subset of patients for whom you may find that any discussion about adverse events triggers panic, no matter how supportive and reassuring

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your manner. These individuals may have a medical phobia and may benefit from specialized psychological treatment designed to address these problems.

Medical Phobias

The results of this issue's Joint Count survey suggests that about half of the respondents believe 10% to 50% of their patients have a true phobia related to taking medication. The Diagnostic and Statistical Manual of Mental Disorders – IV (DSM-IV) indicates that a specific phobia has three central features: fear is directed at a limited set of stimuli; encountering these stimuli elicits intense fear and avoidance behavior; and the fear is unreasonable and excessive to a degree that it interferes with daily life. Recent population-health surveys in the U.S. and Netherlands indicate that specific phobias are among the most prevalent mental disorders, with 10%

to 12% of the population meeting criteria for a lifetime diagnosis of specific phobia.⁷ Age of onset is typically young, usually between 7 and 9 years, although claustrophobia begins later, around age 20.⁸ Of the five recognized subtypes of specific phobia, there are two, blood-injection-injury and situational phobias, which include fears of stimuli involving medical settings or procedures and which have the potential to interfere with obtaining necessary medical information or the use of certain treatments. As these two types of phobias have quite different physiologic responses involved, I will discuss them separately.

Situational phobias. The phobias in this category commonly involve claustrophobic fears associated with being inside an enclosed environment (e.g., airplane, movie theatre, elevator). In the medical context, these fears may include having to remain in an imaging device for an extended period of time without moving or leaving, such as a magnetic resonance imaging (MRI) scanner. If the environment is completely enclosed, there may be a fear of suffocation; otherwise the fear may be of "going crazy" or fainting as a result of being overwhelmed by panic without being able to escape the situation. Although persons with situational phobia may fear fainting, they do not actually faint because they experience an increase in blood pressure and heart rate.

Another situational phobia relevant to medication has to do with the fear many children and some adults have associated with swallowing pills (they fear they will choke or gag while struggling to swallow). A variant of this is found among patients who cannot bring themselves to consume medication for fear of experiencing an adverse event.

Blood-injury-injection phobias. In contrast, persons who fear blood, injuries or needles tend to experience an initial rise in heart rate, followed by a drop in heart rate and blood pressure, which could lead to fainting. Moreover, unlike other phobics who experience intense anxiety in the face of the feared object, those who avoid the sight of blood may be more likely to be disgusted or repulsed by an encounter with it and may be more likely to fear fainting.⁹ This type of phobia is more strongly heritable than other types of phobias, perhaps due to an inherited strong vasovagal response to bleeding, injury or the possibility of an injection.

Natural course. Left untreated, the natural course of most phobias is chronic, albeit with mild, rather than severe, symptoms of anxiety. In one study, only 16%

of cases remitted over a seven-year period.¹⁰ Many individuals with specific phobia simply avoid situations where they are likely to encounter what they fear; escape it quickly; or endure it with distress when they do encounter it. Depending on the nature of the phobia, the restriction on activities for the individual and the impact on family and friends can be significant (e.g., no air travel for flight phobics, no medical scans for claustrophobics).

Treatment of situational phobias. The treatment of choice for specific phobias is some form of cognitive behavioral therapy in which prolonged or repeated exposure to the feared stimulus is a central feature. Medications, including benzodiazepines and selective serotonin reuptake inhibitors (SSRIs), have generally not been found to be effective in the treatment of specific phobias. Technological developments in recent years now allow for many types of phobias to be treated using virtual-reality devices that simulate the experience of being in the feared environment. These are particularly useful when it is difficult to access the feared real situation (e.g., airplane, MRI). Unfortunately, equipment costs have limited the uptake of this procedure by therapists. Ideally, these in-office sessions are followed by in vivo sessions in which the patient encounters the feared situation directly and, with the therapist's support, remains in the situation for up to two or three hours. During the exposure, the therapist guides the patient to engage continually with the feared object (e.g., petting the dog, going up and down the elevator); these activities enhance the patients' sense of mastery or self-efficacy. Therapist-guided exposure has been found to be significantly more effective than simply encouraging patients to do exposure exercises on their own. Substantial reductions in fear and anxiety can be obtained in as few as one or two sessions. By using extended exposure sessions, patients get to experience their anxiety decreasing in the face of the feared object. This helps reduce patients' belief that their fear is a good indicator of objective danger in these situations.

Treatment of blood-injury-injection phobia. Applied tension, involving sustained tensing and releasing the muscles of the legs and arms, is the generally recommended treatment for this form of phobia.¹¹ This procedure allows patients to engage in exposure to the feared stimuli and avoid sudden drops in blood pressure associated with the sight of blood or venipuncture. This approach has been found to be quite successful.

Summary

Situational and blood-injury-injection phobias about medical equipment, procedures, or treatments can significantly interfere with medical investigations and patient adherence to treatment recommendations. Cognitive behavioral treatments that involve prolonged, guided exposure to feared stimuli, accompanied by applied tension for blood-injury phobics, has been found to be highly effective in treating these forms of phobia. Insofar as these phobias do not tend to remit spontaneously, patients with medical phobias should be encouraged to pursue treatment with a psychologist or a behavioral specialist, or with the aid of a credible self-help manual¹² in order to reduce avoidance and unnecessary suffering, thereby enhancing their ability to follow assessment and treatment recommendations.

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