Plenty to Worry About: Consent, Control, and Anxiety

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Patients frequently experience nocebo effects when taking active medications. These are side effects produced by negative expectations, rather than by specific pharmacological characteristics of the drug. Nonetheless, they add to the burden of illness and often motivate reassurance-seeking behavior that increases the costs of care. Studies show that nocebo effects can be induced by what doctors tell patients about a medication, and they are more likely to occur when facts about nonspecific side effects—for example, dizziness, nausea, and drowsiness—are disclosed to patients with high levels of somatization and anxiety. In order to reduce the likelihood of these harms occurring, Wells and Kaptchuk (2012) argue that the disclosure portion of the informed consent process should be modified in clinical care. They urge doctors to consider "the possible side effects, the patient being treated, the particular diagnosis involved to provide information tailored in a way that reduces expectancy induced side effects while still respecting patient autonomy" (22). In what follows, I argue that their proposal threatens to violate patients' autonomy rights, and may even negatively affect the very patients that it is designed to benefit.

Wells and Kaptchuk claim that "the chief motivation behind informed consent is the protection of patients" (22). If they are right, then their proposal allows doctors "to balance informed consent and nonmaleficence" (22). After all, the anxious patient's medical well-being seems to be protected when nocebo-inducing information is withheld. But the standard view tells us that the primary purpose of informed consent is the protection of patients' *autonomy* (Berg et al. 2001), and a cursory discussion of autonomy rights reveals a problem with the authors' approach.

Morally competent adults have autonomy rights. That is to say, they have rights to control certain aspects of their lives, and these impose duties on others not to usurp that control. If you visit your doctor with a suspected case of gout and she injects cortisone into your inflamed joint without your permission, she violates one of your autonomy rights—namely, your right to bodily integrity—by trespassing on your body without your permission. But when you grant another person consent, you exercise a right, thereby permitting that person to perform an action that would otherwise be impermissible. No rights violation occurs if you authorize the doctor's action after she diagnoses your condition, explains that in her professional opinion a steroid injection will ameliorate your pain, and adequately outlines the procedure, risks, and alternatives.

Unauthorized bodily trespass is not the only way a doctor can violate a patient's autonomy. Understanding autonomy rights as rights to control certain aspects of our lives reveals that whenever a doctor manipulates or withholds information that she knows and believes is relevant to a patient's treatment decision, the doctor exercises illegitimate control over the patient's decision by arrogating the patient's role as agent. The voluntariness of the patient's decision is undermined by control of this sort, and since voluntariness is a necessary condition of valid informed consent, it follows that this kind of control can invalidate consent to treatment (Bromwich and Millum in press; Feinberg 1986). For example, suppose that out of concern for your medical well-being your doctor decides to withhold a common reaction to the steroid injection—namely, a temporary period of intense and increased pain—for fear that if you knew about the potential for "cortisone flare" you would refuse the doctor's treatment plan. Even if you authorize the treatment, your consent is invalid because the doctor exercises illegitimate control over your decision by manipulating the information that you get to consider.

Unfortunately, Wells and Kaptchuk recommend withholding of this kind. When patients vulnerable to nocebo effects have conditions that require medication, they claim that doctors should "tailor the amount of information about medication side effects to these patients such that *only* the drug-specific effects are described" (22; my emphasis). But just as withholding the possibility of cortisone flare invalidates your consent to the steroid injection, so withholding the possibility of nonspecific side effects violates patients' autonomy rights by exercising illegitimate control over their treatment decisions and may even invalidate their consent to treatment (if the degree of control is sufficient to undermine the voluntariness of their consent).

Perhaps the information that Wells and Kaptchuk propose withholding is irrelevant to patients' treatment decisions since no reasonable patient would refuse treatment for a burdensome condition because of the possibility of a nonspecific side effect occurring. But nonspecific side effects experienced as side effects of the prescribed medication are often cited as reasons for nonadherence (Barsky et al. 2002), which implies that this kind of information is relevant to some patients' treatment decisions.

Wells and Kaptchuk are more likely to object that since "there is no abstract 'truth' about a medication's side effect profile independent of what the physician says or does not

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say" (22), no hard facts are withheld when doctors choose not to tell patients about possible nonspecific side effects. But data on nocebo effects do not license this conclusion. They just permit us to conclude that (1) what doctors tell their patients can make a therapeutic difference, and (2) it is difficult for doctors to know whether all side effects are the direct result of a drug's pharmacological action since the effects reported in clinical trials can sometimes be explained by negative expectations produced by the information disclosed to research participants during the consent process. Unless doctors have reliable evidence to support the authors' assumption that *all* nonspecific side effects are *not* caused by the pharmacological characteristics of the drug, they do withhold information that ought to be disclosed to their patients when they choose to remain silent about the possibility of these symptoms occurring.

It might still seem as if the authors' approach is justified by its expected practical effects. After all, the harms associated with the nocebo effect seem less likely to obtain if doctors withhold information about drugs' nonspecific side effects when treating particular patients. But there are reasons to doubt that contextualizing disclosure will achieve this desirable outcome.

First, those vulnerable to nocebo effects are likely to seek and find the offending information even if their doctor withholds it from them. Patients who want to know more about a medication can read the Food and Drug Administration (FDA) mandated package insert/label, talk to their pharmacist, or even look the drug up online. Wells and Kaptchuck plan to deal with "the possibility of patients learning of potential side effects from other source[s]" (22) in another paper. But the worry is not just about the availability of the information; it is that patients with high levels of somatization—patients especially vulnerable to the nocebo effect—are the very kinds of patients who are likely to engage in reassurance-seeking behavior that will motivate them to track this information down (Barsky et al. 2001).

Second, learning about possible side effects from other sources has the potential to damage the doctor–patient relationship in ways that might obstruct the healing process. Studies show that a warm, supportive, and empathetic clinical encounter can produce positive therapeutic outcomes (Benedetti et al. 2002; Di Blasi et al. 2001). However, as doctors repeatedly edit the information that they disclose to their patients and as patients start to notice that this information differs (sometimes significantly) from that gleaned from other reliable sources, trust will start to erode. Since patients cannot be expected to know that certain facts are being withheld for their benefit, they may seek to explain doctors' incomplete disclosure in less benevolent ways: Perhaps the doctor is incompetent, or has a conflict of interest, or is an old-fashioned medical paternalist. It is difficult to see how positive clinical outcomes can be produced by a relationship worn away by (albeit well-meaning) deception and mistrust.

Finally, when doctors "identify high risk patients and tailor the amount of information about medication side effects to these patients" (22), they may fail to optimally serve those they aim to benefit. Consider patients with somatoform and anxiety disorders. Studies show that such patients' irrational beliefs and thought processes often can be effectively altered by helping them to understand how misinterpreting information can lead to unhealthy patterns of response. Individual cognitive behavior therapy sessions have beneficial effects on the symptoms of somatoform disorders like hypochondriasis (Barsky and Ahern 2004; Greeven et al. 2007). These studies suggest that not all patients vulnerable to nocebo effects are best served by being sheltered from the kind of information that tends to induce these effects.

It is worth closing on a point of agreement: Data on nocebo effects give us reason to reflect on the practice of informed consent. But clinical research is the place to start. Most regulations and guidelines require that research participants be told a great deal about the possible risks of taking experimental medications. We now know that this information can induce side effects that are often attributed to the medications being studied. When these side effects are reported, doctors are obliged to disclose them, thereby possibly inducing the nocebo effect all over again. Future research should focus on what information ought to be disclosed to research participants about possible side effects.

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