

Target Article

# To Tell the Truth, the Whole Truth, May Do Patients Harm: The Problem of the Nocebo Effect for Informed Consent

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The principle of informed consent obligates physicians to explain possible side effects when prescribing medications. This disclosure may itself induce adverse effects through expectancy mechanisms known as nocebo effects, contradicting the principle of nonmaleficence. Rigorous research suggests that providing patients with a detailed enumeration of every possible adverse event—especially subjective self-appraised symptoms—can actually increase side effects. Describing one version of what might happen (clinical “facts”) may actually create outcomes that are different from what would have happened without this information (another version of “facts”). This essay argues that the perceived tension between balancing informed consent with nonmaleficence might be resolved by recognizing that adverse effects have no clear black or white “truth.” This essay suggests a pragmatic approach for providers to minimize nocebo responses while still maintaining patient autonomy through “contextualized informed consent,” which takes into account possible side effects, the patient being treated, and the particular diagnosis involved.

**Keywords:** decision making, informed consent, professional ethics, professional–patient relationship

The ultimate goal of physicians is to help the healing process of their patients. In treating patients, physicians often recommend pharmaceutical agents and explain the medicines' benefits and risks, typically describing the possible side effects that could occur. However, in the very process of describing side effects, physicians may induce nocebo (negative placebo) responses and cause harm, rather than relieve suffering. Such a nocebo response is thought to occur because of patients' negative expectations, anticipations, and anxiety (Benedetti et al. 2007). Evidence suggests that the nocebo effect can significantly increase various nonspecific symptoms and complaints, resulting in psychological distress, significant excess costs because of increased medication nonadherence, extra treatment visits, and additional medicines prescribed to treat the nocebo effects (Barsky et al. 2002). Thus, the question arises: How much information should doctors provide to their patients about medication side effects? This question raises an ethical conundrum: On the one hand, full disclosure of possible side effects is required by the ethical norms of respect for persons and informed consent, yet detailed disclosure may produce harm. However, an examination of the extensive experimental research in nocebo effects may help attenuate this dilemma. This literature demonstrates that

the information provided to a patient regarding medication side effects is not an abstract neutral fact: The development of many medication side effects depends on what information is provided to the patient about side effects. For some patients, detailed information of every possible subjectively-assessed side effect (one version of fact) will create those very same side effects, many of which would not have occurred without the information (another version of fact). Adverse effects are ambiguous and chameleon-like, and information about adverse effects is itself an “active” component of the patient–physician encounter. There is no simple “truth” about adverse effects. Informing a patient about side effects is not a mere presentation of “facts” but is an important component of the art of medicine and requires the practitioner's clinical judgment. We propose what we call *contextualized informed consent* as an ethical procedure in clinical medicine whereby a provider considers the possible side effects, the patient being treated, and the particular diagnosis involved, to provide information tailored in a way that reduces expectancy-induced side effects while still respecting patient autonomy and truth-telling. We believe that such a strategy engages the physician's need to balance informed consent and nonmaleficence while upholding respect for person.

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