Special Section

The Nocebo Effect and Informed Consent—Taking Autonomy Seriously

SCOTT GELFAND

Abstract: The nocebo effect, a phenomenon whereby learning about the possible side effects of a medical treatment increases the likelihood that one will suffer these side effects, continues to challenge physicians and ethicists. If a physician fully informs her patient as to the potential side effects of a medicine that may produce nocebogenic effects, which is usually conceived of as being a requirement associated with the duty to respect autonomy, she risks increasing the likelihood that her patient will experience these side effects and therefore suffer (unnecessary) harm, a violation of the duty of nonmaleficence. If, on the other hand, she intentionally withholds side effect information in an effort to protect her patient from suffering unnecessary harm from side effects, which is consistent with the duty of nonmaleficence, she violates the duty to respect patient autonomy. In this paper, the author discusses several previous attempts to deal with the nocebo effect and explains their weaknesses. He then proposes a means of managing the nocebo effect and argues that it does not share the weaknesses found in previous approaches. He concludes with a discussion of a simple, yet practical tool that might help clinicians manage the tension resulting from the nocebo effect.

Keywords: nocebo effect; nocebo dilemma; patient autonomy; duty of nonmaleficence; side effects; duty of informed consent; withholding information

Introduction

Much has been written about the placebo effect, a phenomenon whereby a fake treatment—a biologically inert or inactive substance, like a sugar pill—improves a patient's condition. Recently, ethicists have turned their attention to the nocebo effect, the negative counterpart or mirror phenomenon of the placebo effect.[1] The nocebo effect is a phenomenon whereby learning about the possible side effects of a medical treatment increases the likelihood that one will suffer these side effects or that the side effects will be exacerbated. Presumably, the nocebo effect is triggered by the patient's anxiety or expectation that a negative effect will occur.[2]

The ethical problem associated with the nocebo effect is that it creates a tension between a physician's duty to respect patient autonomy and her duty of nonmaleficence. If a physician fully informs her patient as to the potential side effects of a medicine (or procedure) that may produce nocebogenic effects, which is usually conceived of as being a requirement associated with the duty to respect autonomy, she risks increasing the likelihood that her patient will experience these side effects and therefore suffer unnecessary harm, a violation of the duty of nonmaleficence. If, on the other hand, she intentionally withholds side effect information in an effort to protect her patient from suffering unnecessary harm from side effects, which is consistent with the duty of nonmaleficence, she violates the duty to respect patient autonomy or the duty to obtain informed consent. In short, the physician faces an ethical dilemma. She can either discharge the duty of nonmaleficence or the duty to respect autonomy, but she cannot discharge both duties.[3]

Numerous studies demonstrate that the nocebo effect is real. In a study of erectile dysfunction among patients being treated with beta-blockers, when participants were not told the name of the drug they were taking or the possible side effects, 3.1

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percent reported erectile dysfunction, a known side effect of beta-blockers. When participants were told only the name of the drug, the percentage of those who reported this side effect rose to 15.6 percent, and when they were told both the name of the drug and the potential side effects, 31.25 percent (a 1000 percent increase over the first group) reported erectile dysfunction.[4] In a different study, researchers investigated how mentioning the possible side effects of aspirin (to treat unstable angina) in the informed consent form would affect the rate of withdrawal from the study. Researchers reported that when the side effects were mentioned in the informed consent form, there was a six-fold increase in participant withdrawal "because of subjective, minor gastrointestinal symptoms."[5,6,7]

Some ethicists believe that the nocebo effect does not pose a problem or a dilemma for physicians, because informed consent and/or the duty to respect autonomy are best conceived of as being grounded in or motivated by beneficence or the patient's best interest requirement. Hence, there is not a conflict between autonomy and nonmaleficence. Those who believe that the nocebo effect creates tension between autonomy and nonmaleficence attempt to balance or manage the tension between the two competing duties. I begin this essay with a brief discussion of several previous attempts to manage the nocebo dilemma. I explain that these approaches share several weaknesses or flaws, including that they are overly paternalistic and may lead to a disparity of treatment resulting from implicit bias. I then propose a means of managing the nocebo effect and argue that it does not share the weaknesses found in previous approaches. I conclude this essay with a discussion of a simple tool that might help clinicians manage the tension resulting from the nocebo effect.

Previous Attempts to Manage the Nocebo Effect

As stated above, one way to deal with the nocebo dilemma is to claim that the nocebo effect does not create a dilemma for health care providers. Rebecca Wells and Ted Kaptchuk, for example, assert that the duty to obtain informed consent is grounded in or motivated by the principle of benevolence (or nonmaleficence). They explain, therefore, that there is not a nocebo dilemma, because in those instances in which informed consent will harm patients, the duty of beneficence trumps the duty to obtain informed consent, and physicians should not fully disclose the potentially harmful information.[8] Such an approach is dangerous, in that grounding informed consent in benevolence (or nonmaleficence), or defining autonomy in a way that conceptually subordinates autonomy to benevolence (or nonmaleficence), paves the way for the return to the days of medical paternalism. In addition, most ethicists (including myself) and many patients believe that the justification for informed consent is not merely that it protects patients. Rather, informed consent is justified by the duty to respect autonomy, and autonomy is separate and distinct from benevolence (and nonmaleficence). Tom Beauchamp and James Childress explain, "the primary function and justification of informed consent is to enable and protect individual autonomous choice."[9]

If we accept that autonomy is a distinct value that grounds the duty to obtain informed consent and that autonomy and nonmaleficence are in conflict when there is a potential for nocebogenic effects, the nocebo effect can be a true problem for physicians, who must choose between giving priority to autonomy or to nonmaleficence or must somehow balance these two values.

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Beginning sometime in the early to middle 1970s, in response to the paternalism that dominated the physician-patient relationship, respect for autonomy became an important topic of discussion among bioethicists. In the early 2000s, the pendulum had swung from an almost complete priority for paternalism to priority for autonomy. In 2003, Raanan Gillon famously stated: "I personally believe that emphasis on respect for autonomy is in many circumstances morally desirable and why I personally am inclined to see respect for autonomy as primus inter pares—first among equals—among the four principles."[10,11]

Subsequently, the pendulum began to swing in the opposite direction as ethicists began to question the prominence of autonomy and the strength of the requirement to obtain informed consent. Shlomo Cohen, Onora O'Neill and others point out that articulating what is the foundation of informed consent and defending the centrality of informed consent and full disclosure is extremely difficult.[12,13] Discussing the work of O'Neil, Cohen states:

> The list of the myriad irrationalities that people ordinarily exhibit in decision-making defies repetition, and this contradicts the presumption that the practice of obtaining informed consent, in its common universal form, rests on a duty to respect people's autonomous choice.[14]

Nevertheless, Cohen and O'Neill recognize that there is a duty to obtain informed consent, and following O'Neil, Cohen states that "its ethical point is indeed more elementary than respect for autonomous choice: it is to provide reasonable assurance that a patient has not been deceived or coerced."[15] Given this understanding of the duty of informed consent, Cohen concludes that there is a duty to provide information, but this duty is not so strict that a physician can never withhold information (or at least consider withholding information) if doing so is consistent with the duty of nonmaleficence.

For Cohen, the key to managing the nocebo effect is balance. Cohen concludes that when resolving the tension associated with the nocebo effect: "the duty to disclose should be directly correlated to the ratio between the probability of a specific side effect to occur after suggestion and the rarity of its occurrence as a result of the real drug or intervention."[16] Cohen believes, therefore, that more research must be conducted in order to determine the relative strength of the nocebo effect with respect to different treatments/medications. Cohen furthermore suggests that the justification for nondisclosure is strengthened when a patient is likely to be susceptible to nocebo induced effects. As Cohen explains, patients who score high on the Somatization Scale are more likely to be susceptible to the nocebo effect. Similarly, he surmises that optimists will be less likely to suffer nocebo effects, given that they are more likely to experience (positive) placebo effects. Possessing information pertaining to a given drug's nocebogenic potential and the likelihood that a patient is susceptible to the nocebo effect, the physician can attempt to determine whether disclosure is appropriate. For example, if a physician believes that a drug has a high nocebogenic potential and a patient is highly susceptible to nocebo effects, the physician should withhold (or be inclined to withhold) side effect information.

John Fortunato and colleagues, in a recent essay, suggest that Cohen's approach may be "ethically sound," but given the realities of clinical encounters, especially the lack of information concerning the nocebogenic potential of most drugs, Cohen's

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approach is impractical. That said, Fortunato and colleagues do adopt one element of Cohen's approach.[17] They suggest that in clinical situations, physicians should focus solely on the "likelihood of an individual patient to experience nocebo effects rather than on the susceptibility of a certain drug to nocebo effects."[18] If patients demonstrate a high likelihood of being susceptible to nocebo effects, they believe that withholding information is justified by the duty of nonmaleficence.

Fortunato and colleagues recognize that nondisclosure is inconsistent with the duty to respect autonomy, and they try to mitigate the lack of respect for patient autonomy (and/or the lack of informed consent) resulting from nondisclosure by requiring physicians to follow-up patients who were denied side effect information. This follow-up consists of asking patients, who already have begun taking a new medication, open ended questions or statements, like: "tell me about what you have noticed since starting this medication."[19] Fortunato and colleagues admit that this follow-up is not ideal, but claim that it will restore patient autonomy and provide physicians the information they need to determine whether they should disclose side effect information, while at the same time not induce nocebogenic effects (since physicians disclose limited side effect information and do so only when patients are experiencing specific side effects). Fortunato and colleagues believe that their approach, unlike Cohen's, is practical and could be utilized in real-world clinical situations.

Cohen and Fortunato and colleagues' approaches share several defects. As explained above, Cohen's approach is impractical in real clinical encounters, and this lack of practicality motivated Fortunato and colleagues to construct a new, more simple approach. Although I appreciate Fortunato and colleagues' approach, especially their attempt to salvage autonomy with a follow-up, I question whether it would, in fact, be practical or useful in many clinical situations. The only times in which their approach could be utilized is when physicians know (or can ascertain) the likelihood that a specific patient will experience the nocebo effect. They suggest that physicians can make this determination by looking at a patient's score on a Somatization Scale or by observing patients in an effort to discover markers for nocebo susceptibility, like a history of experiencing adverse reactions to drugs or medications. In an era in which patients are referred to specialists who don't know them or in which patients frequently change physicians and/or receive basic medical care from walk-in clinics or emergency rooms, it is likely that in many cases (perhaps most cases) physicians will be unable to acquire this information. Although Fortunato and colleagues' approach may be more practical than Cohen's approach (which suffers from this same defect), it will be unusable in many (or even most) clinical situations.[20]

A second defect associated with both Cohen and Fortunato and colleagues' approaches is that they have the potential to decrease trust in physicians. If patients (and the general public) learn that physicians withhold information when they believe that doing so will improve patient outcomes, patients (and the general public) may come to question whether physicians are telling the truth in many or most medical encounters. This lack of trust is especially relevant to the problem discussed in this essay. If patients come to believe that physicians may be withholding side effect information, they may conduct their own investigations in order to determine whether their treatments have undisclosed side effects, and they will do so after they have left their physicians' offices. This last is problematic in that physicians will not be present to put this newly discovered information into

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perspective. In addition, sophisticated patients who value autonomy and informed consent, and who are aware that physicians might withhold information if their patients have a high level of susceptibility to nocebogenic effects, may present themselves in a way that decreases the likelihood that their physicians will believe they are susceptible to these effects. Even worse, highly anxious patients, who know that their physicians might withhold information if they somehow reveal that they are anxious, might try to hide their anxiety in order to receive complete information. This would be unfortunate, as these patients might benefit from physician interactions that are aimed at informing their patients and reducing patient anxiety.[21]

The third defect associated with both Cohen and Fortunato and colleagues' approaches is that their approaches may allow for significant implicit bias, which may result in differential treatment along the lines of race, ethnicity and gender (and other characteristics). Although I am unaware of the existence of any studies exploring whether implicit bias might affect a physician's judgment when attempting to determine whether a patient will be susceptible to the nocebo effect, given the numerous empirical studies that demonstrate that implicit bias affects physicians' treatment decisions, it is reasonable to assume that implicit bias could potentially affect these judgments as well.[22]

As I explain in the final section of this essay, research suggests that implicit bias can be mitigated by implementing strict protocols that encourage agents to treat everyone in the same way (or consider the same information) when making decisions. Cohen and Fortunato and colleagues' approaches require physicians to determine whether patients are highly susceptible to the nocebo effect, even if physicians have had little or no prior interaction with patients. Physicians must decide, often times quickly and based on the way patients present themselves, whether their patients are highly excitable or anxious. This is the sort of activity that allows implicit bias to affect physician-patient interactions.

The final and most profound defect associated with both Cohen and Fortunato and colleagues' approaches is that they do not instruct physicians to take into account how much value patients attach to autonomy and informed consent. Surely, there are patients who attach significant value to autonomy and informed consent, and who want to be informed of side effect information, even if being informed has the potential to increase the likelihood that they will suffer nocebogenic effects. Cohen and Fortunato and colleagues would withhold information from these patients if their physicians believe that they are likely to suffer nocebogenic effects.

Although Cohen and Fortunato and colleagues recognize the danger of imposing a paternalistic relationship on patients, their approaches nevertheless run this risk. Empirical evidence reveals that we ought to be concerned about medical paternalism. In one study, researchers found that although 93 percent of the physicians studied believed that patients' expressed wishes and values deserved at least "a lot of weight," only 40 percent believed that patient autonomy should be the dominant concern.[23] The authors conclude: "While autonomy is regarded highly, doctors often give equal weight to other considerations, such as their perception of what is in the patient's best interest and guidelines from professional bodies."[24] In a different study, researchers discovered that physicians treating some medical conditions are likely to decide what treatment is best for their patients without providing patients information concerning different treatment options or dangers associated with the treatment the physicians want their patients to undergo. In this study of patients who elected to undergo cardiac stenting, when a more conservative treatment was a

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viable option, only 10 percent of the stent patients reported that they had discussed an alternative to stenting as a serious option.[25] Furthermore, only 19 percent of stent recipients "said their physicians" spent much time discussing "the reasons they might not want the procedure."[26] And "only 16% said that they were asked about their own treatment preference."[27]

Clearly, the danger of medical paternalism is alive and well, and any approach to managing the nocebo effect must recognize this reality. As Colloca asserts when discussing Fortunato and colleagues' approach to managing the nocebo effect: "forestalling the principle of autonomy to promote nonmaleficence has the risk of imposing the traditional paternalistic approach."[28]

Authorized Concealment

I suggest that it is imperative that physicians take into account patients' values and preferences when determining whether to disclose possibly harmful side effect information. Not doing so may result in physicians subordinating autonomy to nonmaleficence or beneficence (a return to paternalism) while many of their patients may not support this subordination.

Before proposing my own approach to managing the nocebo dilemma, I discuss an approach that does take seriously patients' values with respect to autonomy. This approach, known as authorized concealment, instructs physicians to ask patients if they would like side effect information to be withheld if this information has the potential to harm them. Luana Colloca and Franklin Miller, who support this approach, assert: "Authorized concealment constitutes a valid waiver by the patient of the right to receive information about certain types of treatment risks, making it consistent with autonomy."[29,30]

Authorized concealment does allow patients to be involved in the decision as to whether side effect information should be disclosed. However, as Fortunato and colleagues explain, there is a practical problem with authorized concealment. Asking a patient to consent voluntarily to nondisclosure may increase patient anxiety, and therefore have the effect of increasing nocebogenic effects. This is especially true of highly anxious patients and those with high levels of somatization, as these patients are likely to engage in behaviors like exploring the Internet to learn about a medicine they are taking in an effort to find reassurance. Thus, "overt nondisclosure could still carry, or even increase, the likelihood of nocebo responses in the portion of the population that is most susceptible to experiencing nocebo effects."[31]

To Disclose or Not to Disclose

When looking for an approach to manage the nocebo dilemma that takes into account nonmaleficence, respect for autonomy, and physician trust, it is helpful to distinguish between two types of cases. The first type of case (Type 1) involves patients who know (or should know) what treatment they desire. Typically, these are cases in which there is only one plausible treatment option (one option is far superior to other options) or cases in which patients have more than one plausible option, but they have already decided which option they will pursue. The second type of case (Type 2) involves patients who have more than one plausible option and have not yet decided which option to pursue. Below, I look at both types of case and explore how the duties of nonmaleficence and autonomy might affect informed

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consent and the decision to withhold or disclose side effect information. In addition, I explore how nondisclosure might affect physician trust in both of these types of cases.

In Type 1 cases, providing full disclosure has no medical value for the patient. In fact, full disclosure only carries additional risks, in that full disclosure increases the likelihood that patients will suffer from nocebogenic effects. Hence, nonmaleficence provides an argument for withholding information.

Although withholding information is usually inconsistent with the duty to respect autonomy, this is not true with respect to cases of the first type. If, as Rebecca Wells and Ted Kaptchuk assert, informed consent is motivated by the obligation to protect patients, there is little justification for full disclosure in cases of this type. If, as Cohen asserts, the point of informed consent is to provide assurance that patients are not being coerced, in Type 1 cases autonomy provides little or no justification for full disclosure. Patients do not have a real choice because there is only one option, or they have already decided whether to undergo a course of treatment. Hence, one can hardly say that withholding information is coercive.[32]

One might believe that even if nondisclosure in Type 1 cases is consistent with respecting autonomy, nondisclosure may be dangerous in that it has the potential to undermine trust in physicians.[33] Trust can be undermined in at least two different ways: (1) Patients (and the general public) might come to believe that physicians withhold information in order to steer patients to what physicians believe is best for patients—paternalism; or (2) Patients (and the general public) might come to believe that physicians withhold information in an effort to steer patients to what physicians believe is in their own interest. In Type 1 cases, it is unlikely that trust will be undermined in either of these ways. The physician is not steering the patient toward any treatment option; patients have already decided on a treatment option (or there is only one option). In fact, although there may be exceptions, patients (and the general public) may welcome nondisclosure in this type of case in the same way that they welcome other behaviors that contribute to patient well-being, like a warm smile or, in the case of an overly anxious patient, a consultation that puts the risks in perspective.

We see, therefore, that nonmaleficence, autonomy and concern for physician trust weigh in favor of nondisclosure in Type 1 cases. Let us look at Type 2 cases.

In the same way that nonmaleficence motivates nondisclosure in Type 1 cases, it does so in Type 2 cases. Autonomy, on the other hand, is more complicated. If autonomy is conceived of as being motivated by patient protection (Wells and Kaptchuk), nondisclosure may be justified. If, on the other hand, the point of informed consent is to ensure that patients are not being coerced (Cohen), then nondisclosure may be unjustified. If a patient has the choice of several potential treatments, and the physician does not disclose the side effects of the different treatment options, patients are not in the position to make an informed choice. This is especially true if well-informed patients (perhaps in consultation with their physicians) are in the best position (or at least a better position than physicians acting on their own) to determine how different side effects might affect their own well-being. Not knowing, for example, that erectile disfunction is a side effect of a medication may be an important piece of information for some patients and not others. Presumably, the patient (perhaps in consultation with his physician) is in the best position to determine whether the benefits from a medication or treatment outweigh the risks, and patients who are not given the information to make an

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informed choice may believe that they were coerced or deceived (deception by omission).

In addition, nondisclosure in Type 2 cases may undermine physician trust in the two ways mentioned above. If physicians withhold information in Type 2 cases, the patient (and the general public) may come to believe that physicians cannot be trusted because they withhold information in order to steer patients to what physicians believe is in their patient's best interest (paternalism), or even worse, that physicians withhold information because doing so is in their own best interest.

Up to this point, the focus has been only on the instrumental value of autonomy; that is, full disclosure is valuable in those instances in which learning about side effect information can help the patient make a decision that is in his own best interests. But for some, autonomy also has intrinsic value. It is not unheard of or illogical for a patient to claim that he wants to be fully informed, even if full information might decrease his physical well-being. That is, patients who value autonomy may believe that autonomy has intrinsic value, and its intrinsic value can trump the instrumental value resulting from decreased autonomy. For example, a patient may claim that he wants to be fully informed and make his own medical decisions as opposed to having his physician make decisions for him, even if doing so increases the likelihood that his physical wellbeing will not be maximized. For patients who believe that autonomy has significant intrinsic value, autonomy weighs in favor of full disclosure in both Type 1 and Type 2 cases. Of course, in the same way that it is difficult for a physician to determine whether her patients are susceptible to nocebogenic effects, it will be difficult for physicians to determine how much value patients attach to autonomy.

The Clinic

This section examines the practical aspects of what has been discussed above and describes an approach that physicians can use to manage the nocebo dilemma.

I suggest that withholding side effect information must meet a high justificatory standard. Several concerns (discussed above) motivate this claim. First, allowing exceptions to full disclosure may not adequately respect patient autonomy or a patient's desire to be fully informed (and has the potential to take us a significant way along the path to medical paternalism). Second, exceptions to full-disclosure run the risk of decreasing trust that physicians will tell the truth. In addition to these concerns, any approach to managing the nocebo dilemma must take into account clinical realities; that is, it must be practical and workable in the clinic. This last includes limiting implicit bias.

As explained in the previous section, in Type 1 cases, nonmaleficence and autonomy (when taking into account only the instrumental value of autonomy) justify nondisclosure of nocebogenic effects. Furthermore, it is unlikely that nondisclosure in Type 1 cases will decrease trust in physicians. Thus, I propose that in clinical situations the default associated with Type 1 cases should be nondisclosure.

Type 2 cases are more complicated. Nonmaleficence justifies nondisclosure. However, since patients in Type 2 cases have not decided on a treatment, the duty to respect autonomy (when focusing only on its instrumental value) may justify or encourage full disclosure. In addition, in Type 2 cases, withholding information has the potential to decrease trust in physicians. I suggest that the default in Type 2 cases should be disclosure.

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Like other defaults, the defaults proposed here can be overridden. If a physician is involved in a Type 1 case, and the physician knows that the patient attaches a lot of value to autonomy, the physician may consider overriding the default. Similarly, in Type 2 Cases, if the patient attaches little or no value to autonomy and prefers medical paternalism, the physician may consider overriding the default.[34]

Allowing these defaults to be overridden is consistent with shared decision making. Although shared decision making usually pertains to the process of deciding a course of treatment, my focus is on providing an approach that involves both patients and physicians in deciding the nature of the physician-patient relationship, specifically of whether physicians should disclose side effect information that will potentially increase the likelihood that patients will experience nocebogenic effects.[35] In order to accomplish this last, the physician needs to know how much value patients attach to autonomy before deciding whether (non) disclosure is appropriate or whether to override one of the defaults. As explained above, one means of acquiring information pertaining to how much a patient values autonomy is to discuss authorized concealment with one's patients. However, this approach is risky and may unnecessarily harm patients, especially patients who are likely to suffer nocebogenic effects.

A different way to acquire information pertaining to how much weight patients attach to autonomy and informed consent is to utilize a tool that can help patients communicate this information. Physicians can then take their patients' values and preferences into account and decide whether to override the defaults associated with each type of case, without explicitly asking patients to consent to nondisclosure.

Most of us are familiar with the Universal Pain Assessment Tool, a chart that assists physicians in assessing the severity of pain their patients are experiencing. Patients are shown the chart and asked to point to a number that best describes their level of pain. One of the most well-known, the Wong-Baker FACES Pain Rating Scale, shows a series of faces, rating pain from zero to ten (using only even numbers) and contains pictures of a smiling or frowning face above each of the numbers. Under the zero are the words "No Hurt" and above the zero there is a smiley face. Under the ten are the words "Hurts Most" and above the ten is very sad face, with tears.[36]

I suggest that a similar tool could be used to assess patient attitudes toward autonomy.[37] Although more research is necessary in order to determine what this chart might look like or how it might work, imagine a simple scale from zero to ten, just like the pain chart. On the far left, just above the zero, there would be a picture of someone surrounded by books and looking at a computer with a smile on her face. On the far right, above the number ten, the same picture would appear, but the person would have a frown or an expression of pain or disapprobation. The pictures might include a few words to help patients express their attitudes. Underneath the zero, below the smiley face, would be the words: "I want to know the details, regardless of the consequences." Underneath number four would be the words "Unless the potential harm is great, I want to know the details." Finally, underneath number ten would be the words: "I don't want to know the details. Tell me only what I need to know."[38]

Before discussing treatment options (or perhaps at the beginning of an appointment, depending on the type of practice or specialty) a clinician could ask her patient to select the number that best describes how he feels (or what he believes) about learning about the details of different medical treatments or detailed medical information.[39] The clinician might preface this question with a short description

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of what she is trying to discover: "We know that some patients like to learn about all the details associated with different treatment options, while others do not want to learn this information. Knowing that different patients have different preferences, our office makes it a practice to ask patients how much information they want to be provided. Point to the number that best describes your attitude."

Just to be clear, I recognize that development of a tool to measure how a patient values autonomy is not an easy endeavor. Furthermore, I am not suggesting that every physician should (or must) utilize an autonomy assessment tool in order to determine whether the defaults should be overridden. Rather, I am suggesting that the tool would be useful for those physicians who believe that a patient's values should drive the decision concerning whether to override the defaults. Physicians who chose to use the tool and thereby learn about their patients' values with respect to autonomy and the sharing of information can make an informed decision as to whether to override the defaults suggested above; that is, physicians can determine whether nondisclosure, partial disclosure or full disclosure is appropriate for each individual patient. I do not think it is a stretch to say that by providing the autonomy chart to their patients, physicians are engaging in robust shared decision making. Patients' values are being taken into account when physicians consider whether to share side effect information, thereby decreasing the likelihood that unwelcome paternalism will infect the physician-patient relationship.

This tool is also helpful in that it will help limit the number of cases in which physicians withhold information and patients seek the information in other places. Avoiding this problem is important, because if patients discover side effect information while searching the Internet at home, for example, there is no health care provider present to put this information into context and thereby decrease the likelihood that patients will become overly anxious (which, as stated above, may increase the likelihood or severity of nocebogenic effects).

Regardless of whether a physician chooses to use an autonomy assessment tool, abiding by the defaults has the potential to limit implicit bias. Utilizing defaults (or some other fixed structure) decreases the likelihood that a physician's decision to disclose or not to disclose information will be influenced by a patient's race, gender, or sexual orientation. And in those situations in which a physician uses the autonomy chart, her decision pertaining to whether she should override the defaults will be not be guided solely by her own subjective impressions of the patient, but rather by information the patient communicates to his health care provider.[40]

It should go without saying that when physicians do disclose information, they should do so in a way that is least likely to result in harmful side effects. Luana Colloca makes a similar point:

> Clinical strategies to minimize the occurrence of nocebo effects should include avoiding negative phrases when explaining interventions or medical treatment, emphasizing the positive effects of the medical treatment, taking time to allow the patient to ask about previous and actual negative aspects of the medication, and providing adequate time for the patient to internalize the information that has been given. [41]

Finally, in those instances in which physicians choose to withhold information, patient follow-up, like that suggested by Fortunato and colleagues, is appropriate.

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As explained in their essay, this is a means of respecting autonomy and obtaining informed consent, albeit not the best way of doing so.

Although the approach I propose is similar in some ways to authorized concealment, it is different. As explained above, authorized concealment is dangerous in that asking patients if they want their physicians to withhold side effect information may increase patient anxiety, especially in the case of those patients who are most susceptible to the nocebo effect. Utilizing defaults and the autonomy assessment tool is less likely to increase the anxiety of patients in that patients are not explicitly told that information will be withheld. (And if a physician knows or has reason to believe that her patient is extremely anxious, she may decide not to use the tool or abide by the defaults.) Rather, patients are told that their health care providers want to provide the amount of information their patients desire, without explaining that they may withhold information in order to protect them from side effects. In addition, patients are not asked to make a choice (whether they want their physicians to withhold information), thereby avoiding the anxiety associated with choosing a specific option.

Conclusion

There is no easy way to manage many of the tensions arising out of the relationship between a physician and a patient. Although at times we may be tempted to try to eliminate these tensions, I suggest that physicians and ethicists strongly resist this temptation. We must remember that every physician and every patient is unique, and the values, needs, desires, goals, etc., of every physician and patient contribute to a unique couplet when a physician and patient decide to work together.

In this essay, I take the above seriously when I propose a means of managing the nocebo dilemma. I suggest that physicians employ a system of defaults. In Type 1 cases, the default should be to withhold side effect information when doing so has the potential to decrease the likelihood that patients will suffer nocebogenic effects. In Type 2 cases, the default should be to disclose information pertaining to side effects, even if doing so may increase the likelihood that patients may suffer these side effects. Like most defaults, I suggest that these defaults can be overridden. Whether to do so depends on both the patient's and physician's values pertaining to autonomy and informed consent, and I propose a tool that physicians can use to ascertain what her patient's values are. Possessing this information can help physicians manage the nocebo dilemma in a practical, workable way that takes seriously their patients' values with respect to autonomy, paternalism, and informed consent, and balances these values with their patients' desire not to be harmed (and their own desire not to harm their patients and to respect their patients' autonomy). Finally, unlike other approaches to managing the nocebo dilemma, this approach attempts to mitigate implicit bias and is unlikely to undermine public trust of physicians.

Notes

1. In an essay discussing the nocebo effect, Shlomo Cohen states that a search for 'nocebo' in the Philosopher's Index "yields a striking *zero* result." See Cohen S. The nocebo effect of informed consent. *Bioethics* 2014;28(3):147–54, at 147.
2. Benedetti F, Amanzio M, Vighetti S, Asteggiano G. The biochemical and neuroendocrine bases of the hyperalgesic nocebo effect. *Journal of Neuroscience* 2006;26(46):12014–22.

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3. A related problem associated with the nocebo effect is that when patients suffer side effects (as a result of the nocebo effect) or are aware that they may suffer side effects, the likelihood of nonadherence and/or discontinuation of treatment increases. See, Barsky AJ, Saintford R, Rogers MP, Borus JF. Nonspecific medication side effects and the nocebo phenomenon. *Journal of the American Medical Association* 2002;287(5):622–7.
4. Silvestri A, Galetta P, Cerquetani E, Marazzi G, Patrizi R, Fini M, Rosano G. Report of erectile dysfunction after therapy with beta-blockers is related to patient knowledge of side effects and is reversed by placebo. *European Heart Journal* 2003;24(21):1928–32.
5. Wells RE, Kaptchuk TJ. To tell the truth, the whole truth, may do patients harm: The problem of the nocebo effect for informed consent. *American Journal of Bioethics* 2012;12(3):22–9.
6. Myers MG, Cairns JA, Singer J. The consent form as a possible cause of side effects. *Clinical Pharmacology & Therapeutics* 1987;42(3):250–3.
7. Although this study focused on participant withdrawal from clinical trials, it is reasonable to conclude that the same (or similar) results would obtain with respect to clinical encounters.
8. Wells and Kaptchuk, state: "Since the chief motivation behind informed consent is the protection of patients, then through the principle of beneficence, withholding self-fulfilling nocebogenic information may be appropriate through contextualized informed consent" (see note 5, Wells 2012;25). Although Wells and Kaptchuk imply that the principle of beneficence trumps the principle of autonomy because latter is motivated by the former, in their essay they describe a nuanced approach to informed consent–contextualized consent–that takes seriously both of these principles. They claim that the key to resolving (managing) the nocebo effect dilemma is balancing informed consent and nonmaleficence.
9. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 4th ed. New York, NY: Oxford University Press; 1994, at 142.
10. Gillon R. Ethics needs principles–four can encompass the rest–and respect for autonomy should be "first among equals." *Journal of Medical Ethics* 2003;29(5):307–12, at 310.
11. Daniel Callahan, who was critical of the prominence placed on autonomy, nevertheless recognized the role it played among ethicists: "Autonomy is, then, in fact given a place of honour because the thrust of individualism, whether from the egalitarian left or the market oriented right, is to give people maximum liberty in devising their own lives and values." Callahan D. Principlism and communitarianism. *Journal of Medical Ethics* 2003;29(5):287–91, at 289.
12. See note 1, Cohen 2014, at 149–52.
13. O'Neill O. Some Limits of Informed Consent. *Journal of Medical Ethics* 2003;29(1):4-7.
14. See note 1, Cohen 2014, at 150.
15. See note 1, Cohen 2014, at 150.
16. See note 1, Cohen 2014, at 153.
17. Fortunato JT, Wasserman JA, Menkes DL. When respecting autonomy is harmful: A clinically useful approach to the nocebo effect. *The American Journal of Bioethics* 2017;17(6):36–42.
18. See note 17, Fortunato et al. 2017, at 40.
19. See note 17, Fortunato et al. 2017, at 40.
20. Luanne Colloca makes this same point: "Having an 'identikit of the nocebo responder' is far from becoming clinically available." See Colloca L. Tell me the truth and I will not be harmed: Informed consents and nocebo effects. *American Journal of Bioethics* 2017;17(6):46–8, at 47.
21. Hadley Bryan and Veljko Dubjevic make a similar point and claim that distrust of medical personnel may have the effect of increasing nocebogenic effects. See Bryan H, Dubljevic V. To disclose or not to disclose: When fear of nocebo effects infringes upon autonomy. *American Journal of Bioethics*. 2017;17(6):50–2, at 51.
22. Hall WJ, Chapman MV, Lee KM, Merino YM, Thomas TW, Payne BK, Eng E, Day SH, Coyne-Beasley T. Implicit racial/ethnic bias among health care professionals and its influence on health care outcomes: A systematic review. *American Journal of Public Health* 2015;105(12):e60–e76. The authors conclude: "[I]mplicit bias against Black, Hispanic/Latino/Latina, and dark-skinned individuals is present among many health care providers of different specialties, levels of training, and levels of experience." In an earlier study, focusing on racial bias, social class bias, and gender bias, Howard Garb concludes that some (but not all) of the widespread beliefs concerning bias are, in fact, false. Garb H. Race bias, social class bias and gender bias in clinical judgment. *Clinical Psychology Science and Practice* 1997;4(2):99–120.
23. Lawrence RE, Curlin FA. Autonomy, religion and clinical decisions: Findings from a national physician survey. *Journal of Medical Ethics* 2009;35(4):214–8, at 218.
24. See note 23, Lawrence, Curlin 2009, at 218.

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25. Fowler FJ, Gallagher PM, Bynum JP, Barry MJ, Lucas FL, Skinner JS. Decision-making process reported by Medicare patients who had coronary artery stenting or surgery for prostate cancer. *Journal of General Internal Medicine* 2012;27(8):911–6, at 914.
26. See note 25, Fowler et al. 2012, at 914.
27. See note 25, Fowler et al. 2012, at 914.
28. See note 20, Colloca 2017, at 46.
29. Colloca L, Miller F. The nocebo effect and its relevance for clinical practice. *Psychosomatic Medicine* 2011;73(7):598–603, at 602.
30. Hadley Bryan and Veljko Dubljevic make a similar proposal. They assert that physicians should ask patients whether they want to know side effect information and then explain the nocebo effect. If patients want to be fully informed, physicians should attempt to minimize the possibility that patients will suffer nocebogenic effects. "One such method includes prescribing additional medication such as cholecystokinin (CCK) antagonists, which have been found to block certain nocebo effects. The prescription of CCK antagonists would offer a possible solution without sacrificing patient autonomy, increasing the complexity of provider–patient interaction, or causing any additional harm." See note 21, Bryan, Dubljevic 2017, at 50.
31. See note 17, Fortunato et al. 2017, at 37.
32. I realize that at this point I am treating autonomy as having only instrumental value. Later in this essay I discuss how autonomy may have intrinsic value and how this affects Type 1 and Type 2 cases.
33. Significantly, if trust in physicians suffers as a result of nondisclosure, patients may be more inclined to do their own research (on the Internet). Hence, patients who do not learn about harmful side effects in their physicians' offices will learn about them anyway. This last is dangerous in that no one is present to put this information into perspective, and patients (especially those with high somatization likelihood) may suffer harms from side effects that are of a greater magnitude than they would suffer if they obtained the information in a physician's office.
34. I am confident that there are some other situations that may warrant overriding the default. This is unsurprising, given that medicine is an art form, and being a good artist or creating a fine piece of art cannot be reduced to a simple set of rules or algorithms.
35. In an essay addressing the issue of nudging and informed consent, I make a similar suggestion. See, Gelfand S. The meta-nudge – A response to the claim that the use of nudges during the informed consent process is unavoidable. *Bioethics* 2016;30(8):601–8.
36. The Wong-Baker FACES pain scale is preferred by both parents and children. Chamber CT, Giesbrecht K, Craig KD, Bennett SM, Huntsman E. A comparison of faces scales for the measurement of pediatric pain: Children's and parents' ratings. *Pain* 1999;83(1):25–35.
37. I want to thank Mary Arpe for this idea.
38. As suggested above, this is a *very* rough sketch. Presumably, developing an autonomy scale would require significant empirical research, as some words or descriptions would likely be more anxiety producing than others. Clearly, the autonomy scale should not significantly increase anxiety in the way that 'authorized concealment' does.
39. It may be the case that patients would be more willing to share their honest beliefs if someone other than their physicians administered this test.
40. Although numerous studies have been conducted in an effort to discover ways to decrease implicit bias, there remains much to be learned. That said, research pertaining to decreasing implicit bias in hiring interviews suggests that structured interviews are beneficial. In one study, the authors conclude: "the unstructured interview tends to be where job-irrelevant information tends to emerge to influence interviewer decisions." Purkiss SLS, Perrewé PL, Gillespie TL, Mayes BT, Ferris GR. Implicit sources of bias in employment interview judgments and decisions. *Organizational Behavior and Human Decision Processes* 2006;101(2):152–67, at 164.
41. See note 20, Colloca 2017, at 47.

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