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Target Article

When Respecting Autonomy Is Harmful: A Clinically Useful Approach to the Nocebo Effect

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Nocebo effects occur when an adverse effect on the patient arises from the patient's own negative expectations. In accordance with informed consent, providers often disclose information that results in unintended adverse outcomes for the patient. While this may adhere to the principle of autonomy, it violates the doctrine of "primum non nocere," given that side-effect disclosure may cause those side effects. In this article we build off previous work, particularly by Wells and Kaptchuk (2012) and by Cohen (2013), to suggest ethical guidelines that permit nondisclosure in the case when a nocebo effect is likely to occur on of the basis of nonmaleficence. We accept that that autonomy vis-à-vis informed consent must be forestalled, but salvage much of its role by elaborating a practical clinical approach to postencounter follow-up. In doing so, we reconcile a clinically practicable process of determining conditions of disclosure with long-standing ethical commitments to patients.

Keywords: nocebo effect, placebo effect, disclosure, informed consent, ethics

While a plethora of research has been published on the placebo effect, substantially less work has been done exploring its negative counterpart, the nocebo effect. The placebo effect describes a desired clinical effect that arises solely from the patient's positive expectations. A classic example includes the prescription of physiologically inert agents (e.g., sugar pills), to a cohort of subjects who manifest the same benefit as a similar cohort who is given an actual therapeutic agent. In contrast, nocebo effects, which have been reported in both clinical and research settings, occur when negative effects arise out of a patient's or participant's negative expectations (Hahn 1997; Levine 1987; Cohen 2014). This presents an ethical dilemma, particularly for clinical practitioners, who have competing prima facie duties both not to harm patients (a function of the principle of nonmaleficence) and to insure that the patient is fully informed regarding the risks of particular treatments (a function of the principle of autonomy). This article builds on important previous work, but also articulates a proposal that both extends the ethical analysis of nondisclosure and also meets the prerequisites of clinical practice wherein patient-centered care requires balancing disclosure against the harms that might result from disclosure-induced nocebo effects.

BACKGROUND: THE LANDSCAPE OF ETHICS, NOCEBO EFFECTS, AND DISCLOSURE

Patient consent is undeniably important in the ethics of clinical practice. But when unintended adverse effects can and do occur directly as a result of disclosure, providers are faced with a dilemma of two competing principles: autonomy and nonmaleficence. For its part, autonomy assumed an almost sacred role in the clinical ethics landscape from the 1970s to the early 2000s, as a counterbalance to the antecedent practice of paternalism. More recent work has suggested that more extreme forms of laissez-faire autonomy may actually be counterproductive to the patient-practitioner relationship (Hans et al. 2016). An emerging literature on the ethics of persuasion (or nudging) implies that some impediment or influence leveraged against a patient's purely self-determined choices (if such a thing even exists) can be ethically appropriate when exercised in that patient's best interests and with particular limits (Cohen 2013; Thaler and Sunstein 2008). Following similar logic, similar limitations on autonomy exercised in a patient's best interests should also be ethically permissible.

In those patients who will experience a nocebo effect, the adverse effects derive from the patient's own negative

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expectations and not from the actual therapy. Importantly, this means that disclosure is the root cause of the adverse event. Additional consequences also follow, such as a patient failing to adhere to an otherwise beneficial medical regimen.

Published data indicate that nocebo effects are real and significant. A study involving the use of aspirin to treat unstable angina reported a sixfold increase in participant withdrawal from the study when the possibility of gastrointestinal (GI) disturbances was disclosed to the experimental cohort as compared to the control group (Wells and Kaptchuk 2012; Myers, Cairns, and Singer 1987). In another study, patients with food allergies were misinformed that they had been injected with an allergen when they had actually been injected with an inert saline solution, with the result that allergic symptoms were experienced by 25% of the subjects (Jewett, Fein, and Greenberg 1990). In a report authored by Schweiger and Parducci, more than two-thirds of patients reported a headache when they were falsely led to believe that electrical currents were being passed through their skulls (Cohen 2014; Schweiger and Parducci 1981). A study involving the use of finasteride to treat benign prostatic hypertrophy reported a threefold increase (15% to 44%) in erectile dysfunction (ED) when this potential side effect was disclosed (Mondaini, Gontero, and Giubilei 2007). Similarly, in a study involving the use of beta-blockers, only 3.1% of men reported ED when they were not told the drug name, 15.6% when they were told the drug name but not the risk of ED, and 31.2% when they were told both the drug name and the risk of ED (Silvestri, Galetta, and Cerquetani 2003). These diverse reports indicate that for some kinds of side effects, disclosing a possible adverse event significantly increases the probability of such an event occurring. Thus, clinicians face an ethical dilemma of whether or not to disclose side effect information in cases where negative effects are engendered by the disclosure itself.

Dilemmas of disclosure are often discussed within the bioethical community. For example, many would argue that the nondisclosure of minor side effects is appropriate when patients are in extreme distress. It has been deemed ethically acceptable to withhold some information from these patients until they regain the capacity to make fully informed decisions. Temporary nondisclosure of the purpose of certain diagnostic tests, performed to rule out serious conditions so as not to alarm the patient, is also common (Wells and Kaptchuk 2012). Thus, not only is there precedent for mitigating autonomy in favor of best interest in adult patients (as previously stated), but considering the patient's mental state and psychological tendencies has been legitimized as relevant in this regard. In the previous example, withholding information is presumed to be temporary, but its temporal nature corresponds to the temporal nature of patient distress. Therefore, more durable psychological tendencies that produce similarly adverse effects would not necessarily need to be time-limited in order to be ethical.

One potential resolution to the nocebo dilemma suggests that physicians and patients should come to an agreement in advance on a reasonable level of permissible information. This draws on the more general concept of the Ulysses contract (Barilan 2012). It has also been articulated as "authorized concealment"(Colloca and Miller 2011; Miller and Colloca 2011), wherein "the patient has given consent to not being fully consented" (Howick 2012). However, this fails to satisfy the ethical dilemma posed by nocebo effects, particularly if the mystery of undisclosed potential side effects nonetheless causes the patient to experience substantial anxiety about a treatment. Patients with high levels of somatization are at greater risk for experiencing nocebo effects (Bromwich 2012; Barsky et al. 2001). Further, these patients are the ones who are most likely to engage in reassurance-seeking behaviors, such as investigating the adverse reactions to a drug on the Internet (Barsky et al. 2001). In this way, 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.

There are two more significant previous attempts to justify nondisclosure as a means of reducing nocebo effects (Cohen 2014; Wells and Kaptchuk 2012). Cohen argues that level of risk of harm is a relatively unimportant consideration, since nocebo effects can be significantly harmful in themselves (e.g., elevated blood pressure can be significantly risky and result from negative expectations) (Cohen 2014). Instead, he conditions nondisclosure of side effects on the degree to which they might be caused by suggestion, measured in concert with the patient's predisposition to suggestion (i.e., the extent of disclosure should consider whether the patient is optimistic or has a propensity for somatization). While ethically sound, this would be clinically impractical, given the time constraints of a clinical visit. The average clinical practitioner would find it hard to navigate all of these conditions in a manner nuanced enough to accurately, and therefore ethically, calibrate disclosure to the propensity for nocebo effects for every patient. In a subsequent section, we extend part of Cohen's analysis about the relevance of drug-specific propensity for nocebo effects, but ultimately propose a less stringent methodology for making determinations of nondisclosure, bolstered by a short follow-up that can capture side effects occurring in the absence of suggestion.

Wells and Kaptchuk address not only the ethics of disclosure in light of nocebo effects, but also provide a clinical approach for navigating these conditions (Wells and Kaptchuk 2012). They argue that nonspecific symptoms are candidates for nondisclosure, while more specific side effects, often being more severe and less suggestible, ought to be disclosed. We agree with Cohen and others that creating a distinction between specific and nonspecific symptoms fails to resolve several clinical and ethical issues related to nocebo effects (Cohen 2014; Miller 2012). First, determining what constitutes a nonspecific versus a specific symptom creates its own inherent dilemma. Second, nonspecific symptoms may be perceived by the patient to

be so significant that they result in nonadherance to treatment (Barsky et al. 2002). A nonspecific symptom is not synonymous with a less severe symptom (e.g., severe headaches can be debilitating). In the end, the degree of specificity appears to have little bearing on the ethicality of nondisclosure, since the degree of harm from nocebo effects, whether specific or not, is contingent on the degree to which any sort of side effect can result solely from suggestion. As both Wells and Kaptchuk and Cohen point out, the nocebo effect is highly individualized and patient specific, something that is particularly cumbersome for a clinical practitioner to navigate (Cohen 2014; Wells and Kaptchuk 2012).

Wells and Kaptchuk ultimately argue for "contextualized informed consent," which "involves taking into account the possible side effects, the person being treated, and the disease involved, to tailor the information about the medication side effects to provide the most transparency with the least potential harm" (Wells and Kaptchuk 2012). Similarly, some have suggested that the proper framing of nocebogenic information can mitigate the nocebo effect (Colloca and Miller 2011; O'Connor, Pennie, and Dales 1996). However, it could be argued that informed consent should always be "contextualized," and properly framing information should always be a component of clinical medicine, regardless of the nocebogenic potential. While contextualized informed consent and proper framing may mitigate some nocebo effects, it cannot be assumed that they would eliminate nocebo effects altogether. Thus, while this may mitigate the dilemma, it does not, in effect, resolve it. That is, even if we accept that context is relevant in determining when the harms of nocebo effects might justify nondisclosure, one still must address the fundamental ethical question about whether harm from disclosure can ethically supersede a widely recognized commitment to autonomy vis-à-vis informed consent.

Additionally, Wells and Kaptchuk state that the role of informed consent ultimately is the protection of patients, thereby aligning the autonomy qua informed consent with the principle of beneficence (Wells and Kaptchuk 2012). Of course, in some contexts, there are clearly articulated links between autonomy and best interest. For example, the American Academy of Pediatrics views parental autonomy as primarily of instrumental value in pursuit of the best interests of the pediatric patient. However, among adults, autonomy is not clearly linked to best interests. Rather, the exercise of autonomy among adult patients is based upon their own beliefs and thus may not align with what their providers believe to be in their best interests. One could propose that this is a form of autonomy tethered to "best interest," only if we define the latter very broadly, which is atypical. A justification of nondisclosure instead may need to sacrifice one competing principle or the other, as dilemmas often require. In the following, we discuss why autonomy need not be valued above nonmaleficence in the ethical analysis of nondisclosure in cases with nocebogenic potential, though it can be recovered in a secondary phase of patient care such that it is forestalled rather than discarded.

While the articles described in the preceding section make strides in addressing the nocebo dilemma, both arguably leave too great of demand on clinicians to navigate the nocebogenic potential of various side effects, along with the specificity of these potential side effects and placing this in relation to each individual patient's personalities and dispositions. Based on Cohen's and on Wells and Kaptchuk's analyses, decisions to disclose potential nocebo effects require an assessment that is nuanced to a degree that is challenging to say the least, particularly in time-sensitive clinical encounters. In the following, we propose a way to soften the amount and type of information clinicians must ascertain to make a decision to not disclose on grounds of nocebogenic potential. First, however, we wish to highlight that such assessments are even more complex than outlined so far.

As Wells and Kaptchuk opined, information about adverse effects is an "active" component of the physician/patient relationship (Wells and Kaptchuk 2012). Therefore, there is no simple "truth" about the actual risk of adverse effects when the probability of their occurrence is derived from population data such that the denominator must be taken into consideration. Restated, the "true incidence" of side effects is best determined when the potential side effects and their probabilities are not known in advance. Once the incidence rate is known, the likelihood of occurrence for a particular patient may actually increase through nocebo effects. Therefore, the epidemiological data does not predict an accurate likelihood for any given patient. Rather, the "truth" regarding the likelihood of experiencing an adverse effect is often co-created by both the physician's presentation to the patient and the patient's perception of that presentation. This underscores the significant moral liability among providers when they induce nocebo effects, along with the gravity of their moral responsibility to minimize it, but also the difficulties of achieving informed disclosure for risks that can be compounded by nocebo effects (Cohen 2014). That is, even if full disclosure of risk is one's ethical standard, which is a cornerstone of informed consent, it may not even be possible due to the highly dynamic nature of risk and the causal involvement of disclosure itself in nocebogenic situations. For these reasons, the nocebo dilemma cannot be accurately discussed within a paradigm that presupposes that knowledge about the side effect profile of a treatment is static.

The discourse about nocebo effects so far has yielded neither consensus about ethical best practices, nor corollary clinical approaches to nocebo dilemmas. While framing and contextualized informed consent could mitigate some nocebo effects, in clinical medicine these are common practices that do not fully address the problems associated with the dilemma. The distinction between specific and nonspecific symptoms provides little momentum toward a resolution, as the decision to not disclose information could be consequential and carry moral weight in either condition. Finally, the use of "authorized concealment" may be viable for those with low somatization scores.

However, there is reason to believe that those with high somatization levels (i.e., those likely to experience nocebo effects) could experience anxiety from such explicit nondisclosure and also would be likely to engage in reassurance-seeking behavior by searching for information about the undisclosed side effects on their own. This is especially true in the "Internet age," which bypasses the physician's former role as "gatekeeper of information" (Meynen, Swaab, and Widdershoven 2012). Finally, it must be acknowledged that even under ideal conditions, where a physician employs appropriate framing and contextualization skills, nocebo dilemmas can still occur with ensuing specific and nonspecific symptoms. In the next section we continue this discourse to suggest and justify an approach that is responsive to the practical clinical scenario.

RECONSIDERING ETHICAL OBLIGATIONS AND NOCEBO RISKS: A CLINICAL PERSPECTIVE

We propose simply that nondisclosure of side effects for treatments with nocebogenic potential is ethical on the grounds of nonmaleficence, even at the expense of autonomy qua full informed consent at the initiation of treatment. In cases where side effects are not disclosed, appropriate follow-up can maximize patient protection and informed decision making about the continuation of treatment, should adverse events arise through a natural physiological course. A follow-up appointment or phone interview (as appropriate) can be used to collect both physiological and self-reported data in order to determine the side-effect experiences of the patient and then to discuss continuation of the treatment under the auspices of that information. Not only is this already common practice for many physicians, it means that full disclosure is effectively only forestalled until certain side effects are experienced. Wells and Kaptchuk make a similar, though arguably more modest, proposal, advising physicians who do not disclose nonspecific side effects to suggest that patients call about any experiences with symptoms. However, we argue that autonomy can be salvaged to an even greater degree by a more active follow-up protocol where physicians (or their designees) use nonleading open-ended questions to solicit such important information. While not ideal in terms of protecting autonomy, we argue such a delay is ethical when balanced against the need to not cause undue risk of harm to patients. Additionally, the information discussed with the patient at this point in time would be of higher quality and more responsive to their experience—that is, more informative. As previously stated, a discussion with a patient in advance about risk of a treatment with nocebogenic potential borders on a disingenuous form of informed consent in the first place, given the unpredictable nature of nocebo effects.

There are additional justifications and precedents for this proposal. First, while the guiding principles of informed consent have historically been rooted in a commitment to patient autonomy, recent arguments have been made that reframe this mainstay of bioethics. Instead, some argue, informed consent is less clearly founded on the promotion of autonomy, in the sense of maximizing a patient's self-determination (a very high standard indeed), and more simply linked to providing assurance that the patient has not been deceived or coerced (Cohen 2014; O'Neil 2002). Such articulations soften the requirement for disclosure to meet the relatively high, arguably impossible, burden of enabling a patient to make fully autonomous decisions. Therefore, not only may withholding self-fulfilling nocebogenic information be beneficial for the patient, it may also be in accordance with the fundamental premise of informed consent, or at least a more practical interpretation of it.

The trend away from paternalism toward autonomy coincided with a period of advancing technology, but largely in a landscape of relatively predictable consequences. Today, there is an exponentially larger range of potential pharmacological therapies and an even larger, more complex and unpredictable set of potential side effects. Compound this with the influence of each patient's individual psychology and one is confronted with an infinitely more complex medical landscape than the one from which laissez-faire autonomy grounded on complete and total disclosure emerged. The complexity of this landscape renders informed consent a matter of communicating complex probabilities even under optimal conditions. With treatments that carry high nocebogenic potential, predicting risks using best evidence is virtually impossible, given the confounding variables engendered by the patient's individual dispositions.

Data suggest that some patients are more likely than others to experience nocebo effects (Wells and Kaptchuk 2012), especially those patients with higher levels of somatization (Bromwich 2012; Barsky et al. 2001). Studies highlighted in a review by Enck and colleagues demonstrate the role that "expectation-induced activation of the brain reward circuitry, Pavlovian conditioning, and anxiety mechanisms," along with sociological factors such as gender, all contribute to nocebo effects (Enck, Benedetti, and Schedlowski 2008). Spiegel suggests that there are three social contributions that can activate nocebo, including " (1) negative messages from the health care environment, (2) negative messages from the patient's social and psychological milieu, and (3) secondary gain." These and other similar processes serve to highlight that the causal pathways to nocebo effects constitute a very complex set of vectors that amplify or attenuate nocebogenic probability in any particular patient (Spiegel 1997). Importantly, this means that determining an individual patient's nocebogenic potential for any particular treatment is challenging. Moreover, this suggests that the manner in which individual treating physicians craft messages of disclosure represents only a small proportion of the influences that can promote nocebo effects. Thus, strategies to improve the quality of disclosure do not sufficiently address the problem, such that nondisclosure under certain conditions remains necessary.

In an effort to mitigate nocebo concerns, Cohen suggests an "ethical calculation" wherein the probability of nocebo side effects is weighed against the probability of the drug causing side effects. These concerns must be weighed in light of patient-specific characteristics that can either attenuate or amplify the likelihood of nocebo effects (Cohen 2014). While this articulation is philosophically sound, it is clinically challenging. Although there are data for the nocebo effects of some drugs (e.g., finasteride), a practical clinical application of this criterion would require similar data for all existent therapies. There is a nascent literature on treatments with nocebogenic potential and the rates at which nocebo effects are experienced. While this literature may increasingly empower physicians to know which treatments require careful consideration of nondisclosure of particular associated side effects, it is currently underdeveloped.

As an alternative, we propose that both future nocebo research and clinical decision making regarding nocebo dilemmas focus on the likelihood of an individual patient to experience nocebo effects rather than on the susceptibility of a certain drug to nocebo effects, but with the caveat that determining individual likelihood needs to be operationalized in such a way that it is practicable in the clinical context. It is likely that human nocebogenic traits (e.g., somatization), are more contributory to nocebo effects than are drug-specific nocebogenic traits. Therefore, human nocebogenic traits could serve as a "biomarker" for nocebo susceptibility. High formal somatization scores (Barsky et al. 2001) might be ascertainable, but an observed clinical history of somatization could substitute for those, along with a prior history of experiencing adverse reactions to drugs (Barsky et al. 2002) and a baseline of nonspecific symptoms (de la Cruz et al. 2010). All of these portend a higher likelihood of the nocebo effect. These are all easily accessible data points for a clinical practitioner making a decision regarding nondisclosure. Indeed, these constitute information that most practitioners have by virtue of their clinical relationship with patients, and while to some degree they leave the determination of nondisclosure to clinical judgment, this is not unique to clinical decision making but rather is part and parcel of most practice decisions. Additionally, given that physicians can and do often follow up with patients starting new treatment regimens, the occurrence of physiological side effects can be ascertained using basic communication "best practices" (e.g., asking open-ended questions such as "tell me about what you have noticed since starting this medication").

This approach advances previous suggestions in a more practical direction, against the backdrop of reasonable ethical analysis that prioritizes nonmaleficence by forestalling autonomy qua informed consent, though then maximizing the latter in a follow-up process that is arguably even more responsive to the individual patient's experience (Cohen 2014; Wells and Kaptchuk 2012). Still, nondisclosure to prevent nocebo effects arguably remains relatively paternalistic in nature. There are at least two responses to this concern. First, determinations about nondisclosure can only reasonably be made in clinical situations because nocebo effects are heavily dependent on an individual patient's characteristics. Second, if one accepts that it is legitimate to withhold certain side-effect information because it is significantly likely that disclosure will *cause* the effect, then we must also provide a clinically practical mechanism for meeting the standard of nonmaleficence. It is unlikely that we will ever have nocebo effect data on a substantial portion of available treatments. After an extensive search by the authors and colleagues in the pharmaceutical field, no study has been found assessing the prevalence of nocebo effects in clinical trials and their effect on adverse reaction reports. It is known that phase IV drug trial participants are told of the anticipated side effects in their study. In effect, reported side effects in phase IV trials may be due to nocebo effects (resultant of their disclosure during informed consent). This jeopardizes the validity of side-effect data for approved pharmaceutical therapies. Even if such data existed, it remains unrealistic to assume that given this data, physicians can take the time to perform an ethical evaluation that includes these drug-specific data representing the nocebogenic tendencies found in aggregate study samples of highly variant individuals.

While the proposal here requires some navigation, it mirrors the decision-making process in which physicians already engage. It affirms the ethicality of a clinician's best clinical judgment based on readily available patient information (e.g., previous adverse drug events, tendency toward somatization, etc.). This approach permits a physician to refrain from disclosing certain side effects in advance, but to help patients make increasingly informed decisions as the effects of their treatment are interpreted individually. This strategy is responsive to the patient's experiences without playing a causal role in inducing adverse side effects.

Both Cohen and Wells and Kaptchuk have noted that violations of patient trust represent a significant limitation of their own proposals, and this extends to our proposal as well. Certainly an emerging side effect that was not disclosed could be frustrating for a patient, but this might be mitigated in the follow-up discussion with a laying bare of the reasons for nondisclosure, which after all was done in the patient's best interest. Nonetheless, there could be patients who would react negatively to nondisclosure. At the same time, distrust and frustration might arise either way. If one must provide full information regarding risk, one would arguably be compelled to disclose both the raw physiological rate of an adverse event and the probability of the nocebo effect, which is difficult to quantify. A patient may have difficulty understanding the nocebo effect and may take umbrage at the concept that a physician would significantly amplify the risk of a treatment by disclosing it to them. It also may be more important for a patient to have a positive perception of the provider's commitment to that patient's best interests rather than an extreme commitment to that patient's autonomy. Indeed, trust in the medical encounter is significantly contingent on a patient's perception of how much their doctor cares about him or her

(and conversely, perhaps, less contingent on adherence to stricter standards of autonomy qua informed consent) (Lupton 1996). Many patients state that they appreciate the discussion, but that their ultimate decision is based on the physician's judgment with the expectation that he or she has their best interest in mind. Nondisclosure of side effects for treatments with nocebogenic potential, particularly when executed in deference to nonmaleficence and with appropriate follow-up with the patient, fits the parameters of a caring, beneficent, and engaged practitioner.

A final and particularly challenging limitation to our proposal concerns cases where serious, undisclosed adverse events might occur. Indeed, this is problematic in the current legal environment, but this does not mean it is unethical. Most adverse effects that have additional nocebogenic potential appear to be less serious. For example, a drug might have a risk of headache at a particular rate, and when this is disclosed, the rate is significantly higher. But as Cohen points out, some nocebo-induced side effects can be more serious, yet following the principle of nonmaleficence we would also not disclose those because we would only be amplifying the rate at which they occur. In many of these cases, the serious side effects typically have precursor symptoms (elevated blood pressure that might lead to stroke). These can be accounted for with more intensive follow-up monitoring based on the potential symptoms. Nonetheless, it is likely that at least some individuals will experience serious adverse events that were not disclosed to them in an effort to mitigate their likelihood. However, despite some adverse experiences, there likely will be net benefit to patients overall. Moreover, it certainly is not our intention here to advise physicians to undertake new protocols that are not currently legal, even though we believe the proposal remains ethically sound. Instead, we believe that the evolution of legal frameworks to meet the complexity of contemporary clinical practice in this and other situations needs to be preceded by a careful ethical discourse.

Future research could provide confirmatory data that will address the effectiveness and feasibility of this proposal. A future study, for example, might attempt to determine whether there is a positive correlation between self-reported allergies, high somatization scores, and baseline nonspecific symptoms. Determining the relative contributions of these factors in a predictive model of nocebo effects would inform a more specific clinical protocol, which would assist for treating providers by evaluating the nocebogenic potential of patients facing particular treatments and assist in their ethical decision about nondisclosure.

CONCLUSIONS

Nocebo effects likely will occur despite proper framing and contextualization efforts employed by the physician. Nondisclosure can be justified in these situations, particularly on the grounds of nonmaleficence, coupled with a clinical protocol that salvages much of the informed consent process post facto (and arguably with higher quality information). To increase the clinical practicality of assessing when nondisclosure is warranted, we suggest shifting focus from the drug to patient risk factors. This will reduce the likelihood of inducing a nocebo effect and subsequent nonadherence to an otherwise beneficial treatment plan. This approach is compatible with the recent trends toward "patient-centered care," wherein patient-specific factors are given more weight in health care decision making. Moreover, given an appropriate follow-up protocol, the decision of nondisclosure need not be based on an unrealistic amount of psychosocial data, but rather on the kinds of information clinicians already have and use in treating patients. Previous attempts to justify nondisclosure of side effects for treatments with high nocebogenic potential have attempted to reframe autonomy or relied on unavailable data on nocebo effects. We argue instead that nonmaleficence can justifiably outweigh autonomy qua informed consent at the initiation of treatment, though much of it can be salvaged with appropriate follow-up. Similarly, requiring drug-specific nocebogenic potential is clinically challenging, given a dearth of reliable data. Rather, nondisclosure under particular conditions of patient risk factors for the nocebo effect balances the need for informed consent against the need to not cause harm. By utilizing clinically available information and making an informed clinical judgment, backstopped with a postassessment visit, our proposal should prove effective in routine clinical practice.

CONFLICTS OF INTEREST

Daniel Menkes declares he served as a consultant for Neurotron, Inc., which manufactures electrodiagnostic devices. ■

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