Placebos: some ethical considerations

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Placebo is usually understood to mean any substance, agent or procedure that is causally ineffective for the diagnosed condition but that nevertheless is used in such a way as to allow a patient to believe that it is specific for the condition.[1]

Placebos are an integral part of medical science. Without them research involving double-blind studies or similar techniques would be impossible. They are also an integral part of medical practice. Anywhere from 40% to 60% of medical interventions rely on the placebo effect,[1-3] and yet the acceptability of placebos remains a difficult and unresolved subject. In particular, it can be argued that by deliberately deceiving the patient the physician violates the patient's autonomy and desecrates the fiduciary nature of the physician–patient relationship. Other problems have also been reported; for example, the use of placebos may foster the mistaken and dangerous impression that medicine can cure all ailments,[4] and the discovery of the deception inherent in such use would seriously damage the reputation of the medical profession.[4,5]

Much of what these and similar objections convey is correct. However, for them to rule out the use of placebos altogether or to leave their use in an ethical limbo — necessary evils, as it were — is a mistake. The objections have a point, but it is of only limited validity. Rather than showing that placebos should not be used at all, they show that their use must be carefully circumscribed. A proper explanation of this, however, requires a brief look at placebo use in general.

It may be useful to distinguish between four types of placebo use: (a) for purely experimental purposes (e.g., double-blind trials), (b) for alleviating a patient's concerns or discouraging a "bothersome patient", (c) for eliminating possible causes of a particular condition and (d) for therapeutic purposes in which the patient must not know about the placebo use (e.g., in cases of addiction). This is not intended as an exhaustive distinction, but it does capture some of the more representative cases.

These types of placebo use are not only logically distinct but also present different ethical problems. The first involves the deliberate deception of a patient to satisfy the requirements of an experiment. However, if the experiment is properly set up, and the requirements of informed consent that govern experimentation among humans are adhered to, there are no ethical problems,[6] at least none over and above those potentially related to the subject matter of the experiment. If proper procedure is followed patients will be told that they cannot know whether they are receiving the drug or procedure in question or the placebo. The patients must consent to this before the experiment can continue. This works well in all but the psychiatric setting. For some non-therapeutic psychiatric experiments ignorance about being deceived might be an integral part of the study protocol. However, there are very few experiments like this. For those that do require such deception, both the experimenters and the ethics review board must determine whether the sort of information that can be obtained only through such a protocol is ethically worth getting. It is difficult to conceive of cases when the answer is Yes. Therapeutic psychiatric experiments — far-fetched as they may seem — might be the exception. However, because such experiments are therapeutic they might be better classified under the fourth rubric.

The second type of placebo use occurs when a patient with no discoverable illness and a well-established history of spurious symptoms requests medication and the physician prescribes a placebo to get rid of the patient or to meet the patient's

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expectations. This kind of use presents no ethical dilemma: it is always impermissible. There are several reasons for this. First, such use tacitly confirms the belief that medicine has an answer, if not a cure, for everything. It therefore sanctions a perspective on the appropriateness of medical intervention that is mistaken.[4,7] Second, it encourages the use of inappropriate medical services, with the attendant problems of time and resource allocation. Third, it does an incredible disservice to the medical profession. If such deception were discovered — which it usually is — the esteem in which medicine is or should be held by society would suffer irreparable harm.[4] Finally, it encourages a perception of medicine by patients that stamps every admitted limitation of medical science not as a limitation but as a failure.

The third type of placebo use is different. It usually takes place in an eliminative situation; for example, when a particular course of treatment has unexpected side effects and the physician wants to determine whether they are causally linked to the medication or to some other factor. An illustration of this is the extreme anxiety reported by a patient with acquired immune deficiency syndrome who had been receiving zidovudine therapy (see page 341 of this issue). It is important for the patient to know whether the anxiety is an idiosyncratic reaction to the medication or is triggered by something else. This sort of placebo use is very similar to the first type, and its ethical status is essentially similar: informed consent must be sought from the patient before the eliminative trial is started. The patient has the right to refuse the attempt to improve his or her condition — a right explicitly recognized in the Alberta case of *Mulloy v HopSang*.[8,9]

These three types of placebo use can therefore be dealt with in a rather straightforward fashion. However, uses of the fourth type are much more troublesome, as illustrated in the following case, condensed from the book *Who Should Decide?* [10]

A man who had been a military officer suffered from pain as a result of a wound he had received in action. Pentazocine had been prescribed for the pain, but the patient had become reliant on it even after the physical condition cleared up. The patient had adjusted to a self-administered dose of 1.25 ml intramuscularly six times daily. Over time, the resultant tissue damage made it difficult to find injection sites. He went to the physician for help with the problem but insisted that smaller doses were not the answer. He realized that he was dependent but saw no way to change the situation. The physician admitted him to hospital and began a program of self-controlled relaxation. Other techniques to control the pain were also taught. The patient was shifted to a pain-contingent medication schedule. In addition, unbeknownst to him the dose was reduced by 0.25 ml every day until it was 100% saline. The saline was given for 1 week, during which the withdrawal symptoms (such as diarrhea, nausea and cramps) were attributed to amitriptyline therapy, which had been started some time before the withdrawal program. During the same week the interval between injections was gradually lengthened to 12 hours. The patient was then told about what had been done in a special session with a psychiatrist. After an initial outburst of anger he accepted the fact. He remained in therapy for a while and was eventually discharged. Follow-up showed no relapse.

Although anecdotal psychiatric data indicate that a long-term cure cannot be effected in this fashion, for present purposes it will be useful to assume that in this case the cure was permanent. Thus, there is a dilemma. On the one hand, one could argue that the pragmatic success of the deception justified the nonconsensual use of the placebo because the patient did come to the physician to be cured. On the other hand, if this use is considered defensible, one is embracing the position that the physician may decide for the patient what treatment is appropriate. However, that would be advocating a paternalism of the very sort rejected in the leading Canadian case on informed consent, in which Chief Justice Bora Laskin stated that it is not the physician who is the arbiter of what treatment the patient should or should not undergo, it is the (competent) patient.[11] Therefore, if this sort of placebo use is accepted, the principle of patient autonomy appears not to be absolute. In fact, in certain cases, such as those that are *purely pragmatically determined*, it fails. If it is not accepted, then apparently the physician can never use deception for therapeutic purposes *even when there is every expectation of success.*

Which one of these alternatives is correct? The answer is both — and neither. The key to resolving the conundrum lies in the nature of the physician–patient relationship. Considered purely materially, the overriding characteristic of the relationship is that it is therapeutic. The patient comes to the physician for treatment, whether it be curative or palliative. At the same time the relationship involves an essential element of trust: *probably* on the physician's part — what the patient says is truthful, and the patient will comply with medical orders — but *certainly* on the patient's part. The patient comes to the physician in a compromised position that stems from an illness and perhaps a lack of knowledge about the condition; but, whatever the features, the patient has to trust the physician not to misuse his or her medical power to deceive the patient and not to misuse the information provided by the patient. Therefore, the dilemma can be restated as follows:

the therapeutic nature of the physician–patient relationship seems to require that its fiduciary nature be violated, whereas its fiduciary nature seems to require that its therapeutic aspect be abandoned.

But this is a spurious opposition, because it leaves out the very important fact that the physician–patient relationship does not develop in isolation. The physician enters the relationship with a particular view of the role of physicians in society, as does the patient. Furthermore, both the patient and the physician have their own psychologic perceptions and values. However, the fiduciary nature of the relationship requires that the physician submerge his or her personal values during the professional association or be excused from the case.[12] But this is not true for the patient. On the contrary, although it is the physician's duty to outline the medically appropriate options without letting his or her values influence the presentation, even though the physician's clinical preference may be revealed in a suitably noncoercive fashion, it is the patient's values that determine the direction that the professional action should follow within this domain.

It is this fact that opens up the option of the fourth type of placebo use in certain cases. In entering into a fiduciary relationship with a patient the physician acquires an obligation to determine the patient's *relevant* values — only those that have a bearing on the patient's health care decision-making. This obligation may be onerous in execution, but without it the patient cannot expect that the physician will not oppose what he or she considers important. This was again recognized by Chief Justice Laskin:[11]

> What the doctor knows or should know that the particular patient deems relevant to a decision whether to undergo prescribed treatment goes equally to his duty of disclosure as do the material risks recognized as a matter of required medical knowledge.

As far as placebo use is concerned, this means that the physician must determine where autonomy, health and truthfulness stand in relation to each other in the patient's scheme of basic values. If the patient values health and autonomy over truthfulness and comes to the physician of his or her own volition because of a particular condition, and if placebo use stands a statistically better chance of being successful than anything else available, then the physician may consider deceptive placebo use to be sanctioned by entailed consent: because the patient entered the therapeutic relationship not simply in the pursuit of health but more specifically to deal with what in effect is an autonomy-impairing condition.

On the other hand, if the patient values truthfulness over health and autonomy, then deceptive placebo use is impermissible. A statistically significant success rate would be irrelevant. The physician could not plead entailed consent because the value on which such an assumption could be based would be missing.

This brings us back to the beginning: there are some deceptive uses of placebo that are ethically defensible in medical practice, the fact of their deceptiveness notwithstanding. Of course, this assumes that the stringent conditions mentioned (congruence with the patient's value system and a statistically significant positive therapeutic rate that is better than the rates achieved with any other therapy) are met. If these conditions are not met, then even the fourth type of placebo use strikes me as ethically indefensible.

My opinions in this article are not intended as the final word on the subject. There is no final word in ethics or in medical practice; at best, there is an ever-closer approximation to an ideal. It is hoped that this editorial will stimulate debate on one of the most prevalent, and least-discussed, aspects of medical practice.

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