2.1.4 Use of Placebo in Clinical Practice

A placebo is a substance provided to a patient that the physician believes has no specific pharmacological effect on the condition being treated. The use of placebo, when consistent with good medical care, is distinct from interventions that lack scientific foundation.

A placebo may still be effective if the patient knows it will be used but cannot identify it and does not know the precise timing of its use. In the clinical setting, the use of a placebo without the patient's knowledge may undermine trust, compromise the patient-physician relationship, and result in medical harm to the patient.

Physicians may use placebos for diagnosis or treatment only if they:

(a) Enlist the patient's cooperation. The physician should explain that it can be possible to achieve a better understanding of the medical condition by evaluating the effects of different medications, including the placebo.

(b) Obtain the patient's general consent to administer a placebo. The physician does not need to identify precisely when the placebo will be administered. In this way, the physician respects the patient autonomy and fosters a trusting relationship, while the patient may still benefit from the placebo effect.

(c) Avoid giving a placebo merely to mollify a difficult patient. Giving a placebo for such reasons places the convenience of the physician above the welfare of the patient. Physicians can produce a placebo-like effect through the skillful use of reassurance and encouragement, thereby building respect and trust, promoting the patient-physician relationship, and improving health outcomes.

AMA Principles of Medical Ethics: I,III,V,VIII

Background report(s):

CEJA 3-A-16 Modernized *Code of Medical Ethics*

CEJA 2-I-06 Placebo use in clinical practice

CEJA 3-A16 Modernized *Code of Medical Ethics*

2.1.4 Use of Placebo in Clinical Practice

A placebo is a substance provided to a patient that the physician believes has no specific pharmacological effect on the condition being treated. *The use of placebo, when consistent with good medical care, is distinct from interventions that lack scientific foundation. [New content clearly distinguishes placebo from invalid, scientifically unfounded interventions.]*

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AMA Principles of Medical Ethics: I,III,V,VIII

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2-I-06

Subject: Placebo Use in Clinical Practice

Presented by: Robert M. Sade, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Francis X. Van Houten, MD, Chair)

INTRODUCTION

The use of placebos in research has received much more attention than has their use in clinical practice. This report is intended to guide physicians' clinical use of placebos in ways that respect patients' autonomy by allowing them to participate actively in the medical decision-making process.

For the purposes of this report, a placebo is defined as a substance that the physician believes has no known specific pharmacological activity against the condition being treated. Placebos can be therapeutically beneficial to some patients, when they give rise to the so-called "placebo effect."[1] In general, this refers to a change in the patient's condition that is attributable to the symbolic aspects of the overall care, rather than the medicinal qualities of the substance prescribed by the physician.[1,2] Although there is some debate as to the origins of the placebo effect,[3,4] much has been learned in recent years regarding its anatomical and physiological foundations.[5]

ETHICALLY APPROPRIATE PLACEBO USE

Physicians administer placebos because they might relieve symptoms causing distress to their patients.[6] Historically, physicians used placebos without patients' knowledge, at a time when they had great latitude in providing treatment without a patient's consent if they believed the intervention to be medically indicated.[7] Accordingly, placebos often were used to relieve pain or other complaints that appeared to have no objective medical explanation.[6,8] Such use of placebos could convey benefits derived from the placebo effect or from the symbolic affirmation of physicians' willingness to help their patients.[9]

The deception associated with placebo use, however, is now widely viewed as problematic because it directly conflicts with contemporary notions of patient autonomy and the practice of shared

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* Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

decision-making.[7,10] Today, if physicians attempt to deceive patients by representing placebos as pharmacologically active medications, they risk undermining their patients' trust.[7,10] Loss of trust is a serious consequence because it is a foundational component of the patient-physician relationship.[10] If trust is undermined, patients may be less satisfied with their physicians, and therefore less likely to consult them when making health-related decisions.[11] Moreover, patients may not adhere to treatment recommendations when trust in their physician has been compromised, thereby adversely affecting patients' overall health outcomes.[12,13,14]

Deceptive use of placebos poses other potential harms to patients, as well. For example, this use of placebos may mask and potentially delay the treatment of medical conditions.[15] Furthermore, some patients may encounter adverse side effects resulting from placebo use, an occurrence known as the "nocebo phenomenon."[16]

Ultimately, the deceptive use of placebos is not ethically acceptable because it may harm patients to a greater degree than it helps them. This is particularly true in cases where placebos are utilized to serve the convenience of the physician rather than to promote patient welfare. Perhaps the most pernicious use of placebos is for mollifying a patient who is demanding, displays a difficult personality, or has a complex problem that has become frustrating to the physician. Placebos should never be used in this way because it is fundamentally inconsistent with physicians' professional obligations to promote patients' welfare and respect patient autonomy.

In some instances, it may be most appropriate to forego the use of placebos altogether. Several studies have described placebo-like effects that lead to better health outcomes when physicians are able to comfort and reassure patients presenting with symptoms that do not appear to have a clear medical basis.[6,17] This seems to work best when physicians establish partnerships with patients that are built on respect and trust, and encourage adherence to treatment plans.[2,18]

In other instances, physicians may utilize placebos within their clinical practice without relying on the act of deception. In these cases, physicians should make decisions regarding the use of placebos in partnership with their patients.[19,20] For example, a physician could explain to a patient that a more certain diagnosis or better understanding of his or her condition could be achieved by evaluating the effects of different types of medication, including one that is not pharmacologically active, namely, a placebo.[21] By obtaining the patient's cooperation in this manner, the physician need neither identify which medication is the placebo nor seek specific consent immediately before its administration.[22] This example of shared decision-making demonstrates an approach that respects patient autonomy and fosters trust within the patient-physician relationship. Moreover, the authorized use of placebos is not expected to significantly diminish their clinical effectiveness as research suggests that little variation in clinical outcomes is observed between patients who are informed that they are to be treated with placebos and patients who where administered placebos in a deceptive manner.[23,24,25]

When physicians are faced with significant clinical or diagnostic uncertainty, the authorized use of placebos may prove particularly valuable for conducting single-patient controlled studies, known as a "N-of-1" trials.[26] In these trials, a disease-specific intervention and a placebo are alternated through several treatment cycles; the duration of each cycle depending on the nature of the disease.[27] Such studies can be single-blinded, in which only the patient is unaware of which drug is being administered, or they can be double-blinded, in which the assignment of treatment is managed by a third person, such as a pharmacist, so neither patient nor physician knows which medication is in use. In either case, the patient keeps a detailed journal of the waxing and waning of symptoms. At the study's conclusion, the physician can differentiate between benefits attributable to the pharmacologically active drug and to the placebo.[28] Throughout this process, the patient's progress should be monitored and the placebo discontinued if the active agent is found clearly to be more effective.[8]

CONCLUSION

Placebos are substances that the physician believes have no specific pharmacological activity against the condition being treated. They may be used in clinical practice to determine a diagnosis or appropriate treatment in the face of clinical uncertainty. Physicians must avoid deception when administering placebos by informing the patient that a placebo may be used.

RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

A placebo is a substance provided to a patient that the physician believes has no specific pharmacological effect upon the condition being treated. In the clinical setting, the use of a placebo without the patient's knowledge may undermine trust, compromise the patient-physician relationship, and result in medical harm to the patient.

Physicians may use placebos for diagnosis or treatment only if the patient is informed of and agrees to its use. A placebo may still be effective if the patient knows it will be used but cannot identify it and does not know the precise timing of its use. A physician should enlist the patient's cooperation by explaining that a better understanding of the medical condition could be achieved by evaluating the effects of different medications, including the placebo. The physician need neither identify the placebo nor seek specific consent before its administration. In this way, the physician respects the patient's autonomy and fosters a trusting relationship, while the patient still may benefit from the placebo effect.

A placebo must not be given merely to mollify a difficult patient, because doing so serves the convenience of the physician more than it promotes the patient's welfare. Physicians can avoid using a placebo, yet produce a placebo-like effect through the skillful use of reassurance

and encouragement. In this way, the physician builds respect and trust, promotes the patient-physician relationship, and improves health outcomes.

(New HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

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