

Rancho Los Amigos National Rehabilitation Center

ADMINISTRATIVE POLICY AND PROCEDURE

SUBJECT: PLACEBO USAGE Policy No.: B844

Supersedes: October 24, 2018 Revision Date: May 13, 2022

Page: 1 of 2

PURPOSE:

To provide guidelines for use of placebos in patient management.

POLICY:

Placebo is any substance given to a patient with the knowledge that it has no specific clinical effect, yet with the suggestion to the patient that it may provide some benefit. This must be distinguished from the placebo effect which is defined as "the psychological, physiological, or psychophysiological effect of any medication or procedure given with therapeutic intent, which is independent of or minimally related to the pharmacological effects of the medication or to the specific effects of the procedure, and which operates through a psychological mechanism" (Shapiro, 1959). The placebo effect occurs for many different reasons: (I) patient's faith in the physician delivering the medication, (ii) administration of a medication that the physician believes will be pharmacologically effective and tells the patient so, but is not, (iii) the condition to be treated is one known to have a high response rate to placebos (e.g., mild mental depression or postoperative pain), or (iv) the alternative to placebo use is either continued illness or use of a drug with known toxicity. Importantly, the placebo effect must take place without deliberate deception.

Placebos are commonly used in controlled clinical trials, whereby policy statements which have been reviewed and approved by institutional review boards are paramount. At Rancho, drug study designs through the Food and Drug Administration and IRB policies are available for physician review. In all of these actions, there is no pretense involved and the practice is ethical.

When a placebo is given, it needs to be part of a careful clinical plan moving actively in the direction of health; it is accepted as moral when it enhances physician-patient communication and is accompanied by active efforts to achieve health. Conversely, placebo therapy is viewed as immoral if it diminishes or replaces patient-physician communication and there is no genuine pursuit of health. A patient could be advised that what is being given has no active ingredient but has been known to help others in similar circumstances; patients' right to informed consent has been respected. At times, justifiable placebo use may necessitate some form of deception, but should never involve outright lying. The problem of deception arises when the physician knows that a medication will not have specific characteristics necessary for efficacy and when the patient is kept ignorant of this fact (e.g., weekly shots of vitamin B for fatigue but without a diagnosis of pernicious anemia). In some of these cases, the deception may be a deliberate outright moral offense (e.g., desire to keep the patient's fees) and is clearly not ethically acceptable. Similarly, the deceptive use of placebos and the misinterpretation of

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SUBJECT:

PLACEBO USAGE Policy No.:

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Page: 2 of 2

the placebo response to discredit the patient's report of acute or chronic pain are also unethical and should be avoided.

PROCEDURE:

1. It is unethical to use placebos for any purposes except the following:

- (a) with informed consent in experimental trials;
- (b) in instances where the condition to be treated has a known high response rate to placebos, and the patient is informed of its use; and
- (c) when placebos are alternatives to toxic medications, and the patient is informed of its use.
- 2. Placebo is definitely not to be given to patients who say they do not want it.
- 3. Placebo should be given for a very limited time only; intervention should be underway to find a more definitive treatment.
- 4. The patient should undergo a thorough physical and psychological workup before placebo is given, to rule out pathological conditions; in addition, the reason for administration of placebo therapy should be clear to the patient and care giver.
- 5. The patient should be informed in appropriate instances that a substance is being used in place of their regular medication which contains no active ingredient but that has been proven to be effective in many cases.
- 6. Any nurse who feels that the administration of a placebo violates his/her ethical beliefs may refuse to administer the placebo without disciplinary action by the institution by which she is employed.

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