



Position Statement

Use of Placebos in Pain Management

Paul Arnstein, Ph.D., RN, FAAN
Kathleen Broglio, ANP-BC, ACHPN, CPE
Elsa Wuhrman, MS, FNP, BC
Mary Beth Kean DNP, ACNS-BC
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Candace Coggins, MS, MA, CARN, NP
Paul Arnstein, Ph.D., RN
Sarah Leahy BA, RN, RSCN

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Position Statement Abstract:

The American Society for Pain Management Nursing (ASPMN) holds the position that a placebo should not be used by any method to assess and/or manage an individual's pain regardless of their age or diagnosis. The only justifiable use of placebos is for participants enrolled in a blinded clinical trial. These clinical trials must be Institutional Review Board (or equivalent) approved with participants clearly informed they may receive a placebo before they consent to participate and actually have the sham treatment administered.

Background and History:

Pain is a complex, multidimensional phenomenon with physical, emotional, social, and spiritual aspects (Arnstein, 2010). It is universal in prevalence but a uniquely subjective experience. Health professionals and family members are consistently unable to precisely determine the intensity of a patient's pain. For these reasons, assessments of pain should be based, when possible, on the patient's self-report. Behavioral and observational indices are reserved for use in non-verbal or non-communicative patients who are unable to convey their perception of pain (Herr et al., 2006). One of the ways that pain is erroneously assessed and improperly treated is by administering placebos outside the context of an IRB-approved clinical trial. Placebos administered in this manner are often intended to discredit the patient's report of pain or discomfort and cast doubt on its validity. In these cases, it is actually the professional's deception that defies the precept of truth-telling.

Position statements and clinical guidelines calling for a stop to using placebos as a method to assess and manage pain have been published and widely disseminated for over twenty years. The federal Agency for Health Care Policy and Research (1992), the Oncology Nursing Society, (1996), the American Society of Pain Management Nurses (1998), the American Pain Society (1999), and other reputable medical, nursing, and interdisciplinary organizations consistently denounce the practice of placebos outside the context of clinical trials. Fässler and colleagues

(2010) recently revealed an astounding pervasiveness, with the vast majority of doctors, nurses and even some caregivers treating pain and other health problems with placebos. Even more alarming is that some medical students are being taught that prescribing and administering placebos is clinically appropriate (Sherman & Hickner, 2008).

Definitions:

The *placebo* is any sham medication or procedure designed to be void of any known therapeutic value. Placebos often take the form of sugar pills, saline injections, or minuscule doses of drugs expected to have no beneficial effect based on their physical or chemical properties (Hrobjartsson & Gotzsche, 2001).

The *placebo effect* is the positive response some patients/participants experience after receiving a placebo. When present, this response has a perceptible and measurable beneficial effect that may be subjective (e.g. pain reduction) or objective (e.g. improved blood pressure). These effects are believed to be related to intrinsic factors (e.g. personal expectations or learned responses) and/or extrinsic (e.g. provider, environment, technology, and contextual) factors (McCaffery & Arnstein, 2006).

The *nocebo effect* is the negative response some patients/participants experience after receiving a placebo. These effects range from minor discomforts (e.g. headache, nausea) to life-threatening complications (e.g. cardiac arrest) (Barsky, Saintfort, Rogers and Borus, 2002).

The *Institutional Review Board (IRB) - approved clinical trial* is a research study that protects human subjects from having their rights violated. Most countries, including the United States, have laws requiring an IRB (or similar decision-making authority) to approve all research before it is conducted. These boards are comprised of a diverse group of at least five specially trained members who are qualified to safeguard the welfare of human subjects (National Institute of Health, 2005). The IRB may be within the researcher's institution, or part of an external group that monitors research activities and has the authority to permit, prohibit, or stop any investigation at any time.

Informed consent is the voluntary process by which a fully informed individual (or a surrogate decision maker) participates in making choices about health care. Casarett and colleagues (2001) delineated the IRB elements of informed consent as research study participants who 1) are told of the study's design, potential benefits and risks or burdens 2) fully understand the information provided, including alternatives and 3) agree to participate in the study voluntarily without coercion. The participant retains the right to refuse to participate or withdraw participation at any time without adversely affecting the quality of care provided. This requirement includes "n-of-1" trials (McCaffery & Arnstein, 2006).

Elaborated Position Statement:

In response to concerns raised by nurses in clinical practice, ASPMN convened a group of professionals to examine the literature, reflect on the realities of clinical practice and create a document to support the nurse who is ordered to administer a placebo. The morally distraught nurse who brought the issue forward was put in a position of deciding between violating her own commitment to providing the best possible treatment, and the possibility of being reprimanded or fired for not carrying out a medical order. She is not alone as more than half of nurses sampled from 22 research studies have been asked to administer a placebo at some point during their career (Fassler, et al. (2010).

The use of ineffective treatments violates the Pain Management Nursing Scope and Standards of Practice (ASPMN & ANA, 2005) which calls for all nurses to promote the high quality of pain relief through collaboration, facilitation of access to quality care and intervention by using methods known to control pain. Nurses on this workgroup report firsthand knowledge that concealed placebos are sometimes used diagnostically to determine who will and will not get access to interventions known to relieve pain. Thus, it is the ASPMN position that a placebo should not be used by any method to assess and/or manage an individual's pain regardless of their age or diagnosis. The only justifiable use of placebos is for participants enrolled in an Institutional Review Board (or equivalent) approved study. These participants, then, will have been clearly informed they may receive a placebo before they consent to participate in the study and before actually having the sham treatment administered.

Legal and Ethical Considerations

Regulatory bodies consistently affirm that patients have basic rights when seeking healthcare. These include the right to receive appropriate pain assessment and treatment. The evaluation and treatment of pain must be commensurate with the nature of pain and the resources available in the setting. In places where required pain treatments are not available, patients can be referred to other settings where pain control needs can be met (The Joint Commission, 2010).

Professional nursing standards uphold the patient's right to receive respectful care regardless of race, gender, age, or other medical / non-medically relevant factors. As part of their duty, nurses must protect patients from incompetent or unethical practices (American Nurses Association, 2001). The use of placebos to assess and manage pain represents a failure to demonstrate the skilled use of available methods described in standards and guidelines related to pain (Agency for Health Care Policy and Research, 1992; American Nurses Association, 2001; American Pain Society, 2008; American Society for Pain Management Nursing and American Nurses Association, 2005; The Joint Commission, 2010).

Ethical arguments could be made for using placebos, however, those are hard to justify. The most common ethical argument examines the conflict between beneficence (benefiting the patient by relieving pain) and non-maleficence (avoiding the potential harm of treatment). This is often referred to as the principle of the "double effect." This same principle could be used to argue against placebo use, because:

- deceptive placebo administration is morally wrong;
- an innocuous, sham (placebo) treatment is not the safest, most effective available treatment;
- tenuous benefits do not outweigh foreseeable harm, including nocebo effects, uncontrolled pain and the loss of trust which is the foundation of therapeutic relationships.

The deceptive use of placebos is morally wrong. It violates the ethical principles of honesty (veracity), trustworthiness (fidelity) and fairness (justice) (Grace, 2006). The nurse may experience moral distress when these values are violated by a prescriber who orders a placebo to be administered, or asks the nurse to assist with a sham procedure; while telling the patient it will relieve pain. This concealed use of placebos violates the nurses' duty to respect the autonomy and dignity of patients, while protecting their right to self-determination (American Nurses Association, 2001). Nurses are uniquely situated to coordinate and initiate crucial conversations to address the conflict of values when ethical dilemmas exist. Getting involved parties together to engage in meaningful dialogue, while difficult, often has a positive long-term impact.

The concealed use of placebos carries the risk of liability for fraud, malpractice, breach of contract, and the violation of informed consent requirements. As health care consumers become

more sophisticated, they reject the notion that pain should be endured and are less reluctant than previous generations to use the civil court system when their rights to pain management are violated (Vaglianti & Grinberg, 2004). Although there have been cases brought against physicians for improper placebo use, medical boards have acknowledged poor judgment, but declined to take action against doctors.

Nurses, on the other hand, have been held legally accountable when they administered placebos. Multimillion dollar damages have been awarded in claims of nursing negligence; and disciplinary actions resulting in the loss of nurses' license to practice have resulted from the deceptive use of placebos (Rich, 2003; Tucker & Pasero, 2001). These cases illustrate that "following doctors' orders" does not absolve nurses from their professional duties. In essence, the nurse who administers a placebo deceptively is more directly involved in harming the patient than the doctor who wrote the order.

Recommendations for Practice:

Nursing Practice:

Nurses are often faced with conflicting expectations from patients, families, other healthcare team members and employers (American Nurses Association, 2001). Nurses may find it difficult to act in a way that is consistent with their values and knowledge. Nurses may experience moral distress when they are expected to act in a manner inconsistent with personal and professional values. Even when the nurse knows the correct course of action, he or she may feel reluctant to take that action, due to a perceived lack of authority in the organization's hierarchy. The resultant moral distress can lead to emotional suffering, burn out and loss of nurses from the workforce (Corley, Elswick, Gorman and Clor, 2001).

Actively addressing the unethical use of placebo analgesia in clinical practice advocates for the patient and preserves the professional integrity of the nurse, nursing colleagues and other healthcare team members (Grace, 2006). Nurses faced with the use of placebos outside of the context of an IRB study should consider taking the following steps:

- Identify the clinical, ethical and moral issues in the case
 - Clinical facts regarding pain and its effect on the patient
 - Placebo use is not the best choice among therapeutic alternatives
 - Placebo use violates the duty to alleviate pain
 - How placebo use conflicts with the values of honesty, and providing respectful care aligned with best practices and the patient's wishes
- Identify the resources that can support your position
 - Trusted colleagues, supervisors, clinical specialists, etc.
 - Patient advocates and ethics committee members in your setting
 - Policies, mission, and patient rights statements in your setting
 - Relevant position papers, clinical and ethics literature
- Assertively communicate concerns to the prescriber and your supervisor
 - Focus on patient's need for effective pain relief
 - Discuss potential harm to patient, professional integrity and institution
 - Offer reasonable clinically appropriate alternatives
- Refuse to administer placebos in the absence of informed consent as part of an IRB-approved research study.

Prescriber Practice:

ASPMN urges prescribers to not prescribe placebos outside the context of an IRB-approved clinical trial. Doing so undermines the trust needed to develop and maintain a therapeutic

relationship with the patient. Prescribing treatments that are not believed to be effective not only reinforces unhealthy notions that drugs or medical interventions are the only way to treat discomforts, but it wastes valuable healthcare resources, while exposing the patient to potentially harmful placebo effects.

Institutional Recommendations:

Establish policies to ensure that no patient will receive a placebo unless it is in the context of an IRB-approved clinical trial. For example the policy could state: *It is the policy of [name of organization] to prohibit the administration of placebos unless it is done within the context of an IRB-approved clinical trial.* The policy should include at least the following elements:

- Mechanisms of reporting policy violations by a prescriber or clinician, including notification of the appropriate supervisor/managers.
- Delineate the appropriate venue(s) where violations of the policy will be discussed (e.g. Ethics Committee, Risk Management, Quality Assurance, Utilization Management, Credentialing Departments, HR-Performance Evaluations etc.).
- Define actions taken to censure those who prescribe and/or administer placebos, including penalties for repeated violations
- Delineate in these policies the rationale for withholding placebos based on current literature, position papers, policies, and codes of professional behavior, regulations, and evidence-based clinical practice guidelines.
- Protect the rights of professionals who refuse to permit the administration of placebos.
- Protect the anonymity of those who report the use of placebos outside the context of an IRB-approved clinical trial.
- Train members of the IRB about the need for more transparency in the informed consent procedures to ensure the patient understands what a placebo is and whether they will possibly, probably or certainly receive a placebo. This is necessary to protect pain patients from the physical and mental harm of unrelieved pain or placebo effects.

To establish these policies and procedures, involve key stakeholders such as:

- Pharmacy and Therapeutics Committee
- Ethics Committee
- Risk Management/Legal Department
- Quality Assurance and Utilization Management professionals
- Credentialing Departments
- Clinical Practice Committees (or equivalent committees addressing the clinical practice of nurses, pharmacists and physicians).

Summary:

Placebo use for the clinical assessment and/or treatment of pain represents substandard care and constitutes fraud or deceptive practices. The American Society for Pain Management Nursing adamantly opposes the use of placebos outside the context of an IRB-approved clinical trial. Professionals are urged to refuse to administer placebos. Institutions are advised to establish policies that prohibit their use outside of a blinded IRB-approved clinical trial where informed consent is obtained and that support the health care professionals who upholds these policies.

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