

## The ethics of using placebos for diagnosis and treatment in clinical practice

### CASE

The patient (Mr. K) presented to the clinic for treatment of his allergies and allergy-induced asthma. He had had problems related to these conditions for many years and had tried various treatments, none of which provided adequate relief. The clinic started him on immunotherapy, and shortly after he received his first dose, he reported “shortness of breath” and “chest discomfort.” The dose was reduced to almost undetectable levels of allergen, but after his next three injections, the patient continued to report shortness of breath (SOB) and chest discomfort.

During these symptoms, Mr. K’s vital signs remained stable except for mild tachycardia. Pulmonary function and oxygen saturation remained within normal limits. Accordingly, the PA, with the concurrence and encouragement of the supervising physician, injected the patient with normal saline to determine if his symptoms were a physiologic response to immunotherapy or psychosomatic. Shortly after the saline injection, Mr. K again reported SOB and chest discomfort. The PA and physician discontinued immunotherapy and prescribed an oral antihistamine with nasal, inhaled, and oral corticosteroids. The patient’s response to these new medications was minimal.

### THE ETHICAL QUANDARY

The PA now wonders if it was ethical to give a placebo (the saline solution) to the patient without his knowledge. Whether to disclose the placebo use to

the patient after the fact is also a question. Should the PA explain to the patient that he still had symptoms even after receiving the saline solution, or should he tell the patient only that he is having enough of a reaction to warrant discontinuation of immunotherapy?

### DISCUSSION

This case raises questions regarding the ethics of using a placebo, truth-telling to patients, the PA-patient relationship, trust, and the medical goals consistent with prescribing a placebo.

**How often are placebos used in clinical practice?** A number of studies have tried to answer this question. In 2008, Sherman and colleagues reported that 45% of 231 physicians at three medical schools in Chicago utilized placebos.<sup>1</sup> In 2004, Nitzin and colleagues reported that 60% of 90 Israeli physicians and nurses in tertiary and primary care used placebos;<sup>2</sup> and in 2003, Hrobjartsson and colleagues reported that of 500 physicians surveyed in Denmark, 54% of hospital physicians, 86% of general practice physicians, and 45% of specialists used placebos in their practices.<sup>3</sup>

**Is it defensible to use placebos in clinical practice?** Placebos are used regular-

ly in clinical trials—where they often have a therapeutic effect, even though this effect is not intended. In a clinical setting, however, the placebo is intended to provide a therapeutic benefit. Despite their obviously widespread use, the use of placebos continues to be debated.

In 2000, the National Institutes of Health held a conference, “The Science of the Placebo: Toward an Interdisciplinary Research Agenda,” to discuss the use of placebo in clinical trials and clinical medicine (<http://placebo.nih.gov/>). The conference included a session on the ethics of using a placebo as treatment. Straus and colleagues observed, “The fruits of . . . basic research are needed to help engender new strategies to exploit placebo mechanisms as therapeutic allies. . . . As clinicians and researchers, we eagerly await the fruits of the interdisciplinary research efforts we at the NIH are now soliciting in pursuit of the science of the placebo.”<sup>4</sup> In April 2003, “Placebo: Its Action and Place in Health Research Today,” a conference, was held in Warsaw, Poland (<http://www.iitd.pan.wroc.pl/events/Placebo.html>). This conference considered the use of placebos as an essential tool in clinical research and supported their use while upholding the highest ethical principles.

Both conferences noted that the goal of research is to advance medical knowledge and that in achieving that goal, the best interests of the patient may be compromised. The goal of clinical care, however, is to provide the patient with best current treatment.

Shortly after the NIH conference, Hrobjartsson and colleagues published a meta-analysis of 114 studies. They concluded, “We found little evidence that placebos had powerful clinical effects. . . .”<sup>5</sup> In 2008, Hrobjartsson wrote in opposition to the American Medical Association’s Council on Judicial Af-

### CONTACT US

#### Do you have an ethical quandary?

This department addresses the real-world ethics concerns and problems of PAs. These might include problems in practice that may be inconspicuous, problems related to systems of care, problems related to the process of care, and preventive ethics.

Please e-mail your ethics question to [jaapa@haymarketmedia.com](mailto:jaapa@haymarketmedia.com). We will consider it for discussion in a future installment of PA Quandaries

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fairs support of placebos that “Clinical placebo interventions are unethical, unnecessary and unprofessional.”<sup>6</sup> Another writer criticized these conclusions, however, saying that “... the uncompromising condemnation of placebos ... seems ... just a bit too sweeping.”<sup>7</sup> Yet this same author admits that “I would not want to prescribe or receive a placebo without some reason that was far more specific than the weak evidence of some general ‘placebo’ effect.”<sup>7</sup>

**If a placebo is given to identify malingerers, is this a just use? If it is given to treat and alleviate symptoms, is this use principled?** The placebo response begs the question of truth-telling and deception if the patient is not told that a placebo is being used. Markus contends, “... It is whether the patient gets better that matters, not the treatment used.”<sup>8</sup> Do we ever prescribe antibiotics for viral or other nonbacterial illnesses, subtherapeutic doses of

referred to the placebo as “a substance that may help and will not hurt,” and 33% added, “This may help you, but I am not sure how it works.”<sup>1</sup>

In a randomized, double-blind, placebo-controlled study of 1,295 male veterans with moderate hypertension, more than 20% of the subjects treated with the placebo achieved a normal BP.<sup>12</sup> Brown commented that as a result, some patients may want the placebo.<sup>13</sup> Brown adds that the clinician could say to the patient, “You have several options. One is to take the diuretic. It will probably bring your blood pressure down, but it does have some side effects. There are also other treatments that are less expensive and less likely to cause side effects and that help many people in your condition. Some find herbal tea twice a day helpful; others find taking these pills twice a day helpful. These pills do not contain any drug. We do not know how the herbal tea or these pills work.

gest that the way the placebo is introduced is important. Honesty and efficacy may be conveyed as follows: “I would like to offer you a pill which I believe can help lessen your suffering. I do not know exactly how it works. I have other pills to offer whose mechanism is clearer, but I am not sure they will work better for you, and they may also entail more serious side effects.”<sup>15</sup>

To return to our patient Mr. K, one way to approach using a placebo is to explain to the patient, “There are a number of preparations we could use to help us better understand your condition, including one that appears to have no pharmacological activity. It is sometimes called a placebo. We have used this in the past with some success.” As with many issues in medicine, the context of the issue is core to prescribing a successful treatment. A placebo—used honestly, openly, and with respect for patient autonomy—may be one of our therapeutic tools. **JAAPA**

## “Can a placebo—if it is used honestly, openly, and with respect for the patient’s autonomy—be an ethical therapeutic tool?”

medications, herbal supplements, or saline infusions? In one study, 51% of physicians reported the use of at least one of such placebo treatments.<sup>1</sup>

*Disease* is commonly described as a state of impaired normal function that is manifested by distinctive signs and symptoms. *Illness* is a subjective feeling of being unwell, and the cause is frequently unknown. We care for the patient by curing the disease or by treating symptoms of the illness. Thomas has observed that between 40% and 60% of patients seen in general practice have an illness with no abnormal physical signs and that no firm diagnosis can be made.<sup>9-11</sup> If so, a placebo is an effective treatment modality.

**If a placebo is used with “informed consent,” how do we tell the patient we are prescribing a placebo?** Of the physicians in Sherman’s study, 34%

They may trigger or stimulate your body’s own healing process. We do know that about 20% of people with your type of high blood pressure get their blood pressure into the normal range using this approach. If you decide to try one of these treatments, I will check your progress every two weeks. If after six weeks your blood pressure is still high, we should consider the diuretic.”<sup>13</sup>

In November 2006, the AMA House of Delegates adopted the recommendation of their Council on Ethical and Judicial Affairs on the use of placebos in clinical practice: “In the clinical setting, the use of a placebo without the patient’s knowledge may undermine trust.... Physicians may use placebos for diagnosis or treatment only if the patient is informed and agrees to its use.”<sup>14</sup> Lichtenberg and colleagues sug-

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