

PERSPECTIVE

The Placebo Phenomenon: Implications for the Ethics of Shared Decision-Making

Howard Brody, MD, PhD¹, Luana Colloca, MD, PhD², and Franklin G. Miller, PhD³

¹Institute for the Medical Humanities and Department of Family Medicine, University of Texas Medical Branch, Galveston, TX, USA; ²National Center for Complementary and Alternative Medicine, National Institutes of Health, Bethesda, USA; ³Department of Bioethics, Clinical Center, National Institutes of Health, Bethesda, USA.

Recent research into the placebo effect has implications for the ethics of shared decision-making (SDM). The older biomedical model views SDM as affecting which therapy is chosen, but not the nature or likelihood of any health outcomes produced by the therapy. Research indicates, however, that both the content and manner in which information is shared with the patient, and the patient's experience of being involved in the decision, can directly alter therapeutic outcomes via placebo responses. An ethical tension is thereby created between SDM aimed strictly and solely at conveying accurate information, and "outcome engineering" in which SDM is adapted toward therapeutic goals. Several practical strategies mitigate this tension and promote respect for autonomous decision-making while still utilizing the therapeutic potential of SDM.

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INTRODUCTION

Peabody's classic 1927 paper, "The Care of the Patient," argued ahead of its time that science shows an association between psychosocial factors and disease.^{1–3} The placebo and nocebo effects exemplify this association.^{4,5} Despite homage to Peabody's eloquence, 20th century American medicine largely ignored or derided the placebo effect. Recently, the science of the placebo has achieved greater (if still grudging) acceptance.^{4,6} Patients' expectations can alter the course of illness, and surveys indicate that physicians often prescribe medications to promote placebo effects.^{7–9} It is time to apply these findings to the ethics of shared decision-making (SDM), especially given SDM's inclusion in the Affordable Care Act of 2010.¹⁰

The term SDM is often used inconsistently.^{11,12} The following elements characterize our understanding of SDM^{13–18}:

- Physician and patient both actively share information
- The physician actively explores the patient's values and preferences
- The physician assists the patient in selecting the best option through supportive conversation
- The physician is guided by the patient's preferences both in how much information to share, and how much to involve the patient in the decision process
- The physician ultimately respects the patient's right to make the decision

SDM may (and should) be employed in life-threatening disease, where biomedical factors far outweigh placebo effects in determining the outcome. Nevertheless, physicians frequently encounter treatment decisions involving chronic and self-limited illnesses. In these latter cases, SDM's role in promoting therapeutic placebo effects assumes greater importance.

Two Models of SDM's Impact on Patient Outcomes

SDM is generally interpreted according to a biomedical model. The SDM process starts with the scientific data on the nature and likelihood of the benefits and harms associated with each treatment. The physician explains these facts and then assists the patient in choosing the option that seems most in accord with her values. SDM helps the patient choose one treatment or another, which then acts on the patient's body by a purely materialistic mechanism, independent of the SDM process.

Consider a patient with chronic low back pain. SDM requires that the physician explain the many treatment options, including perhaps surgery, medications, physical therapy, massage, and acupuncture. The patient, guided by the physician to the extent that the patient wishes, then chooses a treatment option (e.g., acupuncture). Any relief the patient receives from acupuncture is attributed either to its physiological properties or to placebo effects. The SDM process itself is presumed to have no role in determining the outcome.

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This biomedical model neglects recent findings about placebo effects. Consider for example a study by Kalauokalani et al. comparing acupuncture to massage for back pain.¹⁹ After eliciting subjects' expectancies regarding the efficacy of both modalities, investigators randomly assigned the subjects to one of these two treatments. Overall, there was no difference in outcomes between the acupuncture and massage groups. But there was a significant and clinically important difference between the high- and low-expectancy groups—subjects administered the *treatment they believed was best* for back pain, whether massage or acupuncture, had outcomes superior to those given the opposite treatment (Fig. 1).

In an expanded model of SDM (Fig. 2), the SDM process can powerfully shape the patient's emotions and beliefs, which in turn can influence the therapeutic outcome. Consider a physician about to recommend massage, but SDM elicits the patient's belief that acupuncture would be better. The physician might then alter the recommendation, arguing that the patient is more likely to respond well to acupuncture. Alternatively, the physician could explain in more detail why she is recommending massage. The discussion might change the patient's belief, shifting from uninformed to better informed preferences, and thus contribute to an improved outcome from massage.

The Scientific Base for the Expanded Model

Extensive research, which we only briefly summarize here, supports the expanded model of SDM.²⁰ Patient participation in treatment decisions as part of a "sustained partnership" with the physician improves health outcomes to a degree not fully explained merely by better adherence to treatment.^{21–24} Outcomes affected range from emotional well-being and improved function to symptom relief and altered physiological measures.^{25,26}

Percentage of Subjects Reporting Low Back Pain Symptom Improvement after Randomization to Acupuncture or Massage (n=135)

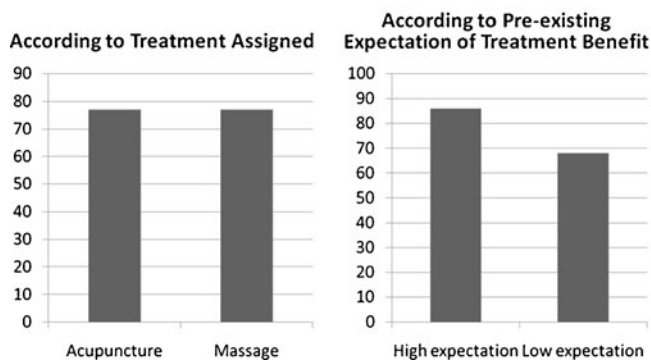


Figure 1. Data summarized from Kalauokalani et al.¹⁹ matched vs. mismatched expectancies and therapeutic response to massage or acupuncture in low back pain.

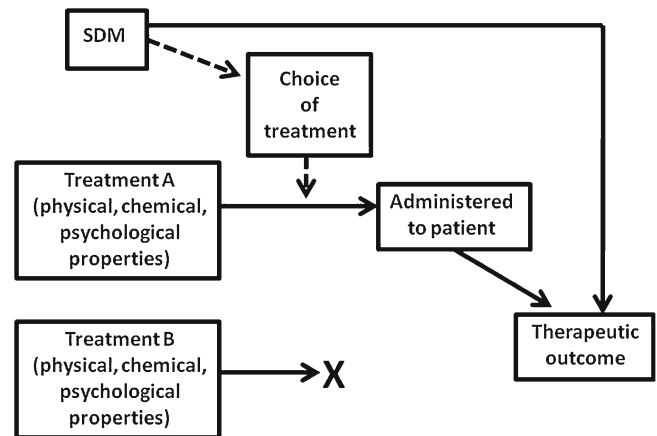


Figure 2. Expanded model of SDM. Solid arrows denote presumed causal connections.

Placebo effects operate on different diseases and organ systems by activating different neurochemical pathways.^{4,7} Both cognitive and affective brain areas participate in these neurochemical processes in an overlapping and interactive manner. One area of research that illuminates the clinical significance of placebo effects is hidden vs. open administration of medication. Experiments involving medications for pain, anxiety, and Parkinson's disease reliably demonstrate approximately twice the symptomatic relief when patients see medication injected intravenously, compared with administration of the same medication by a concealed, pre-programmed infusion pump.²⁷ The patient's knowledge of and psychological reaction to the medication appear to be as important as its chemical properties in producing the desired outcome. Supportive, empathic communication with the physician further enhances therapeutic results.²⁸

While we have focused on positive placebo effects, the nocebo effect—undesired outcomes resulting from the patient's negative expectations—also has important implications for SDM.^{4,5} Communications about adverse effects of treatments may affect the likelihood of these reactions.

Ethical Implications for SDM

The expanded model of SDM raises several ethical questions:

- How much of the scientific evidence must be discussed with patients? Should patients be told, for example, that a treatment recommendation is based only on level B evidence rather than level A?
- Should we tell patients that their mental states could account for treatment outcomes, when the "bare" treatment (in pharmacological or physiological terms) may have little or no efficacy?
- Is it legitimate to manipulate the SDM process to maximize placebo reactions, stretching or even abandoning truthful disclosure? How much and what kind of "spin" is permissible in describing treatment options to stimulate healing?²⁹

Negotiation and transparency in SDM help to address these ethical concerns to promote both autonomy and therapeutic benefit.

Negotiation and Transparency

Ideally, patients are involved in making decisions on two levels.³⁰ The decision we generally focus on is a specific choice among alternative treatments. But these decisions are lower-level exercises of SDM that ideally should reflect a prior higher-level decision. Higher-level SDM is a negotiation over the patient–physician relationship—to what degree the patient wishes to be informed, how much the patient desires the physician to interject her own values into the discussion, and so on. In short, the patient decides where to locate this relationship on a spectrum between physician as neutral information purveyor and physician as trusted counselor.³¹

Higher-level negotiation could address the ethical question of “spin.” The patient, for example, might agree that the physician add optimistic spin to later therapeutic discussions but not conceal critical evidence or deceive the patient. The patient could later ask for additional details if she suspected that spin was interfering with her rational choice among treatments.

Transparency—the physician’s thinking out loud about therapeutic choices—is another tool that may enhance the ethical use of SDM. Transparency is generally a helpful strategy for incorporating SDM smoothly into the flow of the typical patient encounter.^{32,33} Exactly how transparent a discussion ought to be to achieve placebo-related “boost” in treatment is a matter for research and careful judgment. But the following statement seems ethically justified as well as likely to be therapeutically effective:

Science shows that we have built-in chemical responses that help make medicines and other treatments work better. My job is to work with you to turn on those powerful inner forces. How can we apply this to your back pain? One thing that turns on those powerful inner chemicals is your belief that a treatment will work, and your picking the treatment in which you have the greatest confidence. I sense that you have a lot of faith in acupuncture. So acupuncture could give you the best of both worlds, the potential benefits from the needles plus that extra boost from your own confidence.

By being transparent about promoting placebo effects, the physician invites more questions from skeptical patients, and avoids using deception to secure benefit. Many assume that honest disclosure would negate placebos’ therapeutic potential. However, irritable bowel syndrome patients randomized to receive open-label placebo pills and told that

such pills often relieve symptoms through a “mind-body self-healing process” experienced more relief than no-treatment controls.³⁴ Thus disclosure of the physician’s goal of enhancing the placebo response may be perceived by the patient as a positive “pep talk” and actually augment the placebo reaction by reinforcing positive expectations.

Transparency and negotiation both help determine how much scientific evidence to share with each patient. Even if the difference between level A and B evidence seems purely technical, physicians can give patients a general sense of whether a recommendation is strongly or weakly supported. Moreover, the physician as health educator should convey some rudiments of evidence-based medicine to patients as part of routine care. That understanding will help patients to be realistic about the uncertainties of medical interventions. Negotiation may reveal which patients wish to know more about the evidence, and physicians limited in either time or knowledge may refer patients to resources such as internet sites. The further development of interactive decision aids will assist interested patients in understanding the evidence.

Further Ethical Recommendations

Negotiation and transparency illustrate how some degree of *outcome engineering* is both permissible and desirable on the expanded SDM model. As with acupuncture for back pain, physicians will generally be most justified in recommending a treatment primarily for its placebo properties when evidence shows the modality is associated with a pronounced placebo response and when the risk of adverse reactions is low. Nevertheless, considerable judgment is needed, partly because such evidence exists for very few modalities today. As Kalauokalani et al. show, the likelihood of a placebo response may depend on individual expectancies which cannot be discerned from population averages.¹⁹

Outcomes engineering may help prevent nocebo effects.^{5,35} In a study of influenza immunization, those told that 5% of patients suffered reactions ended up reporting more side effects than those told that 95% would suffer no such reactions.³⁶ Since both disclosures were logically equivalent, it seems reasonable to encourage the framing that produces the better therapeutic outcome.³⁷

Outcomes engineering risks indirectly leading to false patient beliefs. Since many patients are firmly wedded to the traditional biomedical model, they may conclude incorrectly that a treatment that works must have done so due to its pharmacological or physiological properties rather than via placebo effects. Whether such false beliefs would arise, when physicians practice transparency to avoid this result, requires further research. We suggest that the physician who has exercised due care to frame information in a positive but truthful way should not be held responsible for any false beliefs that occur.

Information disclosure is always selective, and different physicians convey the same information differently. Thus outcome engineering is unavoidable. Physicians should become self-conscious about the engineering process and promote optimal outcomes while respecting patient autonomy. Further research is needed to guide physicians in achieving these goals.

CONCLUSION

Placebo and nocebo effects can result from any aspect of the medical encounter and are not exclusively tied to SDM. We have focused on SDM because of its ethical importance and because its role in eliciting these effects has commonly been ignored.

As Peabody understood in 1927, unless the science of medicine is fully deployed to elucidate and contribute to the art of medicine, medicine suffers as both a science and an art.^{1,3} Incorporating placebo and nocebo effects, the expanded model of SDM allows us to reintegrate the art and science of medicine for the ultimate benefit of patients.

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Corresponding Author: Howard Brody, MD, PhD; Institute for the Medical Humanities and Department of Family Medicine, University of Texas Medical Branch, Galveston, TX, USA (e-mail: habrody@utmb.edu).

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