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Placebos, Full Disclosure, and Trust: The Risks and Benefits of Disclosing Risks and Benefits

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Consider the following patient: a 40 year old man who has had back pain that radiates down his left leg, on and off for two months. He performs his normal activities and does not have any “red flag” symptoms like fever or weakness. He’s using two commonly prescribed pain medications (ibuprofen and acetaminophen) as needed, and they help somewhat. The pain is slightly better than when it started but not much. He is frustrated and wants to feel better.

What can the doctor do for him? First, she can reassure him that the duration of his symptoms is not uncommon for sciatica, a pinched nerve in the back, and there is no reason to believe that something more dangerous is going on. Second, she can advise against invasive steps, such as surgery, which research shows to be useless and potentially dangerous.

Third, she can offer a medication that might help, such as a muscle relaxer, tricyclic antidepressant (TCA), or anticonvulsant. Each of these can reduce sciatic pain, though only in a minority of patients and usually by only a moderate amount. Each medication has risks, most commonly symptoms such as drowsiness, dry mouth, constipation, or dizziness, which resolve when the medication is stopped. These medications also have rare severe side effects, such as allergic reactions that could be life threatening.

Let’s say that the doctor is considering prescribing amitriptyline, a TCA. Should she utilize the techniques that Alfano suggests to improve the patient’s chance of benefit and reduce the risk of side effects?

As Alfano (2015) describes, research shows that mentioning a side effect, such as dry mouth, can increase the chance of its occurring, due to the “expectation-confirmation” mechanism. Recognizing this, the doctor could use the authorized concealment approach that Alfano describes, which builds on an earlier suggestion by Miller and Colloca (2011).

Is this approach ethical? A critic might complain that authorized concealment blocks informed consent by eliminating discussion of an important issue. In fact, demonstration of the expectation-confirmation mechanism simply proves what doctors have long suspected and used to justify nondisclosure, as discussed and seminally critiqued by Jay Katz (1984).

One can defend authorized concealment by arguing that the side effect has in fact been disclosed, just vaguely, and the doctor and patient are discussing what sort of discussion to have. The process that Alfano describes is a far cry from the complete lack of disclosure that Katz and others have fought against, where doctors don’t even mention the possibility of

side effects or of alternative treatments for the patient to consider. In authorized concealment, the patient decides for himself whether hearing about the risk is worth the cost of increasing its chance of occurring.

In addition, Alfano's defense of authorized concealment is strictly circumscribed, to apply only to symptomatic side effects, not to more dangerous or irreversible ones. Amitriptyline has such potential side effects, including blood abnormalities and heart attacks. Even if describing these could increase the chance of their occurring, Alfano's position does not justify authorized concealment of them, since they are presumably too important to the patient's making an informed decision about whether to take the medication.

Katz (1984) would certainly approve of this limit to authorized concealment, but Carl Schneider (1998) might not. Imagine that some blood abnormality occurs in 1 in 1000 patients taking amitriptyline and causes severe problems for one month when it occurs. Schneider's (1998) reviews research showing that many patients may have trouble understanding this danger or the probability of its occurring and may react irrationally to information about it. Patients may thus rationally defer to the doctor to decide whether the benefit of the medication is worth the risk. Note that from this perspective a physician may also ethically conceal purely symptomatic side effects as well, without asking for authorization.

Deciding whether to utilize authorized concealment, or other techniques, depends in part on questions about the magnitude of the effect. If the chance of dry mouth is 20% in an uninformed patient, and this goes up to 23% if that side effect is mentioned, then authorized concealment may simply not be worth it. Even asking the patient for authorized concealment may confuse or concern individuals, causing anxiety or even raising the chance of developing other symptoms. As Alfano says, such questions could be empirically studied. But there are also more global impacts that may be hard to empirically measure: just bringing up the possibility of authorized concealment or deception may reduce the patient's trust in the truthfulness and completeness of what his physician says. One patient asked to authorize concealment may feel valued and respected, but another who is asked may simply not know what to think, or may start to question other times the doctor seemed less than completely forthcoming.

Another technique that Alfano describes is "priming" to increase the chance that the medication will work, taking advantage of the attentional-somatic feedback loop. The doctor may increase the chance of amitriptyline's reducing the patient's pain by failing to mention that it works in only a minority of patients, and by projecting a strong conviction that it will work for this patient.

Priming raises more ethical questions than authorized concealment since it does not involve the patient's agreement. In fact, the doctor cannot ask the patient to agree: If the doctor tells the patient that knowing the true probability of the medication working may reduce the chance, then many patients will figure out that the probability must not be very good.

Perhaps a discussion could have happened earlier, before this specific problem arose, where the doctor asked the patient for consent to utilize "fake optimism" in the future. The main

problem with this approach is that the patient is being asked to make a choice about situations where the medical problem, prognosis, potential therapies, magnitude of benefit and risk, etc., are all undefined. The doctor could ask the patient to trust her to decide when to utilize fake optimism, but this asks for a lot. A patient who agreed would be putting a good deal of trust in the doctor's judgment, both about the situation and about what the patient would want to know.

Schneider (1998) argues that this is exactly the sort of trust that we put in our doctors, and he argues that we should. And, again, if Schneider is right, then it looks like we might also trust our doctors to decide when to conceal symptomatic side effects, without asking for our authorization. Now the concerns of Katz (1984) and others come to the fore, since we have traveled so far from shared evaluation of risks and benefits. We are back to medicine's old habit, of doctors deciding when it is good for the patient to consider risks and benefits.

The fact that amitriptyline has a low chance of reducing risk may convince a patient that it's not worth the risks it carries, both the common, symptomatic ones, but also the unlikely but serious ones. This suggests that amitriptyline's low efficacy would be material to a reasonable patient, and, according to the Reasonable Person Standard (Beauchamp & Childress, 2009, pp. 122–23) the low efficacy should be disclosed. On the other hand, one might argue that a fully informed and reflective reasonable person, recognizing the dangers of knowing this piece of information, would feel that the information is not that important. As is often the case, the devil is in the details of applying the standard.

Once again, the magnitude of the effect may be particularly relevant. If the effect is small, leaving out a key fact about the medication's probability of working may simply not be worth it. Or, to put it another way, a doctor who justifies her reticence based on the priming effect may be giving an inadequate defense for this failure of communication. The doctor could truthfully say to the patient that the medication works in only a minority of people, but could also put this in the most positive light, saying that it may work and that she has seen it work before. In this way, the doctor is being encouraging without being deceptive.

Early in the paper, Alfano convincingly argues that "placebo" is not a natural kind term. His point is somewhat unsurprising, since the concepts of medicine and psychology are rarely (if ever) natural kinds. His example of congestive heart failure is apt, since that category encompasses a range of conditions of with extremely variable physiology, causes, treatments, and prognosis. We group conditions together as "congestive heart failure" due to their common characteristics and practical management, but their differences are also crucially important.

Similarly, although the expectation-confirmation mechanism and attention-somatic feedback loops differ, utilizing either to improve outcomes raises similar ethical issues. Placebo may be an ethical category as much as a biological and psychological one.

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