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## **Prescribing placebos ethically: the appeal of negatively informed consent**

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# **Prescribing placebos ethically: the appeal of negatively informed consent**

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## **Abstract**

Kihlbom has recently argued that a system of seeking negatively informed consent might be preferable in some cases to the ubiquitous informed consent model. Although this theory is perhaps not powerful enough to supplant informed consent in most settings, it lends strength to Evans' and Hungin's proposal that it can be ethical to prescribe placebos rather than 'active' drugs. This paper presents an argument for using negatively informed consent for the specific purpose of authorising the use of placebos in clinical contexts.

## **Introduction**

It has been shown that placebos are as effective as or more effective than expensive drugs in some situations. However, use of placebos outwith clinical trials is widely regarded as unethical given the current emphasis on informed consent (IC) and patient autonomy. Conflicts between the four principles of biomedical ethics are apparent here: if providing placebo is more clinically effective and more cost effective than an active medicine, the principles of beneficence and justice, respectively, demand that the placebo is used. But can these two principles trump the generally dominant one of autonomy?

This paper suggests that, under the recently proposed system of negatively informed consent (NIC),<sup>[1]</sup> where a patient abdicates access to information to some extent, the perfect conditions exist in which placebo use is rendered ethical in the normal healthcare context: among the information that can be legitimately withheld is that the prescribed medicine is not chemically active. (This also avoids the largely uncommented possibility that information overload might actually cause a nocebo effect in patients who obsess about potential risk.) NIC, in allowing patients to choose to circumscribe their own autonomy, allows for better clinical outcomes through use of placebo in some situations.

## **Negatively informed consent and placebo equivalence**

Kihlbom argues, contrary to the widespread view that patients should be given as much information as possible in order to maximise their autonomy, that "a relaxation of the requirement of IC would in some situations be a way to strengthen or at least to protect the autonomy of the patient".<sup>[1]</sup> He outlines a system whereby the patient is competent and capable of understanding the

treatment, but is not informed about the “method and means” or “all the significant difficulties and risks that are likely to occur.” Instead, they are told the purpose of the treatment, and that they can receive more information if they want to. Given these basic facts, the patient then “gives his/her voluntary and explicit consent to undergo the treatment and express[es] his/her voluntary and explicit wish not to have more information”.<sup>[1]</sup> Given the central relevance of Kihlbom’s argument to this paper, it is important to quote it directly. He argues that the necessary conditions are that the patient:

- a. is competent, and
- b. has the capability of understanding the information
- c. has received information of:
  - 1 Purpose of the treatment
  - 2 That it is possible to receive more information if wanted
  - 2 [sic] That the treatment is voluntary
  - 3 That the consent can be withdrawn at any time
- d. has well founded beliefs that the physician will choose the treatment that best promote his/her values
- e. has well founded beliefs that the physician will choose the treatment, the risks of which are in accordance with his/her attitudes towards different kinds of risks.
- f. on the basis of this gives his/her voluntary and explicit consent to undergo the treatment and express his/her voluntary and explicit wish not to have more information <sup>[1]</sup>

Although Kihlbom’s approach is innovative, it is unclear whether it would work as a wholesale replacement for IC. As he himself states, criteria (d) and (e) seem to require particularly skilled physicians.<sup>[1]</sup> Indeed, it might be argued that only a telepathic doctor and a very trusting patient could make negatively informed consent work in most contexts. In drafting their forthcoming new guidance on consent, the General Medical Council considered and rejected a similar model to negatively informed consent.<sup>[2]</sup> Kihlbom concedes that “long-term treatments involving close doctor-patient relationships” are most suitable for NIC.<sup>[1]</sup> But we shall see that NIC is actually appropriate for some cases involving placebos where this relationship is not close.

Evans and Hungin describe a situation where a doctor is discussing with a patient whether to prescribe him “SAS”, a fictional drug, or a placebo (itself a fictional drug in a different sense).<sup>[3]</sup> In a large trial of SAS, 35% of people found it relieved irritable bowel symptoms. However, 35% of people also experienced relief when given placebo. Of course, those people didn’t know it was a placebo, and this patient does, so that effect is lost; however, he also knows that SAS is no better than placebo, so there is a concomitant nocebo effect that might reduce the efficacy of the drug. As Evans and Hungin put it: “in prescribing either an ‘official’ placebo or SAS, Dr Jones would ordinarily expect even the limited (35%) hope of success to rest on her concealing from Smith some of the pertinent facts. Were she ethically unhappy about this concealment – and she is deeply unhappy – then she is to that extent inhibited from prescribing either.”<sup>[3]</sup> This is quite correct: if she gives him the

drug and doesn't tell him it's not better than placebo, she's withholding information; and if she gives him the placebo and doesn't tell him it's not the drug, she is doing the same.

### **Negatively informed consent to use of placebos**

This is where negatively informed consent can be very useful. Dr Jones faces this ethical problem because of the requirements of informed consent: under the current regime of respecting autonomy via full disclosure of information, she has no choice but to say whether the placebo is a placebo or whether the drug is no better than placebo. But if we adopt Kihlbom's system of NIC, we are perfectly able to obtain consent without incurring either a nocebo effect or a loss of placebo effect.

Dr Jones could simply inform her patient that she is going to give him a pill that will hopefully make him feel better. This is all that NIC requires, and works whether she prescribes the placebo or SAS (but we can assume that she goes for the placebo to save money and avoid side-effects). The patient simply doesn't need to know whether it is an 'active' drug or a placebo; he knows the purpose of the treatment and that he can withdraw consent at any time. He also believes that his doctor will choose the treatment that best promotes his values and is most appropriate to his attitudes to risk. The only possible problem is if he wants more information about the treatment, which might well negate the placebo effect; this is discussed in the next section.

What if the patient wants more information than simply knowing that the doctor is giving them a pill that will hopefully make them feel better? Lichtenberg and colleagues have offered a more specific formulation of how a doctor could phrase an offer of placebo prescription: "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 that they will work better for you, and they may also entail more serious side effects."<sup>[4]</sup> This is potentially compatible with NIC, although this phrasing avoids mentioning information at all. A more ethically rigorous approach might be to say something like: "This pill has no side-effects, but studies have shown that the more I tell you about how it works, the less effective it will be." Although this runs the risk of having the patient realise the pill in question is a placebo, it is more honest than the formulation suggested by Lichtenberg et al, and fits more closely with Kihlbom's requirements. This approach would allow patients who are not satisfied with the simpler formulation above to make a specific choice between having more information and having the greatest clinical benefit.

Although he doesn't mention placebos, Kihlbom provides a persuasive example that supports my argument here:

...suppose that I have a severe headache and take a couple of painkillers to get rid of it. To have sufficient understanding for acting autonomously, I surely need to have good grounds for believing the

pills will relieve me of my headache. It seems also reasonable that I also should have well-founded negative beliefs about [sic] that taking them will not bring with them significant risks for side-effects. However, I need no positive beliefs of how they chemically work in my brain, to have sufficient knowledge for making an autonomous decision. [1]

This passage implies that a positive belief that the pills work chemically in the brain is necessary, although Kihlbom's central account does not require this. My argument is that the patient needs no positive belief whether a particular drug will chemically work at all: that it relieves symptoms is the important point. NIC is perfect for situations such as this where normal IC would negate placebo effect or cause nocebo effect; using IC would result in a worse clinical outcome. Further support for this idea comes from Frances Kapp, who suggested a system similar to Kihlbom's: "Under the incomplete disclosure model presented here, an individual patient could contract with his or her personal physician so that the physician would be permitted to withhold from the patient some antitherapeutic information." [5] Along similar lines, Howard Spiro has suggested that "a patient has the right to waive his right to all information", although this sounds like a step too far. [6]

Of course, the case we have been looking at involves a convenient equality of efficacy between placebo and drug. But NIC would also legitimise placebo use in other circumstances. Imagine a case where the active drug relieves symptoms in 50% of patients but also has serious side-effects in 50% of those upon whom it is effective. This would mean that only 25% of patients would benefit without the side effects. Now imagine that placebo relieved symptoms in 35% of patients without side-effects. Would it not serve the patient's interests better to prescribe the placebo rather than the drug? Kihlbom's criterion (e) states that the physician will choose the treatment the risks of which are in accordance with the patient's attitudes towards risks. Prescribing the placebo in this case would completely avoid the risk of side-effects, while only slightly reducing the risk that the treatment will not work. This would very possibly be compatible with a particular patient's priorities; if asked to choose between two pills, one of which works without side effects in over a third of patients, and one of which works without side-effects in only a quarter, some patients would certainly choose the former. Using NIC solely for placebo prescription actually solves the potential ethical problem posed by withholding information about risks: if placebos are being prescribed, there won't be any side-effects, so the obligation to disclose them evaporates. Furthermore, the benefits are twofold for risk-averse patients: they can choose a treatment (placebo) with no side-effects over an active treatment whose potential side-effects might cause them to worry so much that the active effect of the drug would be diminished.

Assuming that we accept the basic ethical soundness of NIC, there would be many situations where placebos might be preferable to active drugs, and not only in the treatment of functional illnesses: "for some chronic,

distressing, fully evaluated, and relatively harmless conditions such as common colds, insomnia, phobias, most cases of premature ejaculation, and some pain or mood disorders a trial of placebo therapy may well be indicated.”[7] What if an active drug works in only 30% of patients? What if it works in 40% but with serious side effects? What if it works in 35% but costs 100 times what a placebo would? And in addition to the avoidance of side-effects, placebos are much cheaper than most active drugs, and could reduce the strain on the NHS of funding the delivery of new pharmaceutical discoveries. Furthermore, it is possible that the placebo effect obtained by prescribing via NIC would be greater in the clinical context than in drug trials: in research, “informed consent ensures that participants are aware they might receive a placebo or a drug that might not be effective. It is likely that this will reduce the placebo effect.”[7] If a patient provides NIC for a placebo pill that their doctor believes will help them, the placebo effect might well be stronger than in clinical trials.

### **Potential objections**

A first objection is that Evans’ and Hungins’ example is unrealistic inasmuch as SAS would not have been licensed for clinical use if it were no better than placebo. The first response to this is that doctors do sometimes prescribe unlicensed drugs. But more importantly, such a drug might in fact be licensed, because an active drug that is equivalent to placebo can nonetheless be ethically prescribed to patients under the current system, while placebos cannot. (There is also the separate issue of whether “no better than placebo” is really a description that merits the disdain it currently attracts.)

Another objection is that it would simply be unethical to prescribe a placebo rather than an active drug that would actually attack underlying causes of disease. However, I am limiting my argument to the treatment of functional illnesses without identifiable causes, as Evans and Hungin did in their original paper. Given that placebos “relieve some symptoms in approximately 35% of patients who suffer from conditions such as angina pectoris, cough, anxiety, depression, hypertension, headache, and the common cold”,[8] this does not circumscribe the appeal of NIC for placebos too much. As already stated, however, there may well be some situations where placebos are also preferable to pharmacologically active drugs for treatment of non-functional illnesses because of cost or side-effect considerations.

Perhaps a more serious objection to my argument is that negatively informed consent does not sufficiently respect the patient’s autonomy. But Kihlbom makes it clear that autonomy is at the centre of his account, and it is difficult to see how it would be more respectful of a patient’s autonomy to cause a nocebo or loss of placebo effect simply in order to fully inform them. Another way of putting it is that we can only assume consent to nondisclosure of such therapeutically sensitive facts: if doctors insist on always fully disclosing information on whether drugs are active to patients, they rob themselves of the best therapeutic option and might well find that the patient is annoyed at this. In fact, an insistence on fully informing the patient could itself violate a

patient's autonomy by denying them the most beneficial options. Under the current system, the patient can choose any option except to remain slightly underinformed. Of course, if a patient who has initially consented under NIC does request information, then it would have to be disclosed regardless of any therapeutic detriment, in accordance with Kihlbom's criterion c2.

Beauchamp and Childress state that "the therapeutic use of placebos typically involves intentional deception or incomplete disclosure." [8] But using NIC instead of IC avoids this deception by having the patient agree to incomplete disclosure: the doctor is saying something like "the prescriptions that are options for your condition require a certain ignorance of how they work. I could tell you more about them, but then they'd be less likely to be effective." At this point, if the patient refuses to provide NIC, the doctor would seek IC instead, and thus compromise clinical benefit only at the patient's request, rather than automatically, as is the case with IC in the particular situation we have been looking at. Thus NIC maximises therapeutic potential while continuing to respect patients' autonomy. In a sense, it maximises autonomy beyond the normal threshold by allowing access to a wider range of treatments. With Kihlbom's safeguards in place, there is no reason why NIC cannot permit ethical prescription of placebos.

A final objection is raised by Howard Brody, who argues that "unless the patient is billed for an amount commensurate with the cost of active drugs, the deception will not succeed." [9] This could indeed be a problem for my argument in some contexts, although there might be ways around it. Within the context of the NHS, however, this is not an issue: patients are charged for the prescription rather than the drug itself, so a placebo and an active drug would cost the same to them.

## **Conclusion**

The unconsented-to placebo is the classic example of utility trumping consent: if the patient is told it is a placebo, it will probably not work, negating clinical utility. Furthermore, if a 'real' drug is prescribed instead, it might cost the NHS more, meaning that utility will be compromised in this sense too. I have presented an argument that NIC can render the use of placebos ethical while respecting patients' autonomy. Using NIC to prescribe placebos increases the range of possible benefits to patients, and should not be dismissed simply because of the current dominance of IC.

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