Author’s response to reviews

Title: Influence of response shift and disposition on patient-reported outcomes may lead to suboptimal medical decisions: A medical ethics perspective

Authors:

Iris Hartog (hartog.iris@gmail.com)
Dick Willems (d.l.willems@amc.uva.nl)
Wilbert van den Hout (W.B.van_den_Hout@lumc.nl)
Michael Scherer-Rath (m.scherer-rath@ftr.ru.nl)
Tom Oreel (t.h.oreel@amc.uva.nl)
José Henriques (j.p.henriques@amc.uva.nl)
Pythia Nieuwkerk (p.t.nieuwkerk@amc.uva.nl)
Hanneke van Laarhoven (h.vanlaarhoven@amc.uva.nl)
Mirjam Sprangers (m.a.sprangers@amc.uva.nl)

Version: 1 Date: 19 Jul 2019

Author’s response to reviews:

Rebuttal “Influence of response shift and disposition on patient-reported outcomes may lead to suboptimal medical decisions: A medical ethics perspective”. In the manuscript, changed and added text is highlighted.

Reviewer: 1, Ognjen Arandjelovic:

Comment:

It is seldom that I am happy with the first version of a submitted manuscript but in this case that indeed is so. The question addressed by the authors is relevant, the identification of problems with the current methodology is well argued and convincing, and the authors' arguments are sound and logical. The quality of writing is also very good. In short, I am happy to recommend acceptance of the submission as it stands, as trying to fish for objections would be dishonest. No doubt as in any paper on ethics there are many points where a reader can disagree with the authors but this is not a valid reason for objecting to the manuscript's acceptance given that the
authors are clear about their assumptions and ethical starting points, the soundness of these, and the logic of the argument thereafter.

Response: We are grateful for these generous comments.

Reviewer 2, Mary Faith Marshall, PhD:

Comment:

This article speaks to an important issue. The call to include the effects of response shifts and dispositional differences in any information that contains patient-reported quality of life statistics is worthwhile both within the patient/clinician encounter and at the professional guidance/policy level. The definitions/concepts of PROs and patient disposition are explained well, and the importance of clinician awareness of the effects that response shifts and patient disposition may have health care decision making is compelling.

Response: We thank the reviewer for her positive comments.

Comment:

The authors raise an important concern regarding variance in PROs and its effects on informed consent and healthcare decisions. They ambitiously approach the problem through clinical/research scenarios and the application of ethical principles and theory. However, in attempting to cast a wide net with the principlism approach, the authors fall short of producing a cohesive and critical analysis of how patient response shifts and disposition complicate shared decision making.

Response:

We agree with the reviewer on the breadth of our approach. However, in our opinion, a broad approach is necessary to do justice to the complexity of the matter. We do realize that such an approach imposes extra demands on the clarity of our argument. Below, please find the corrections we made to improve the clarity of the text.

Comment:

Here are some concerns and recommendations:

Given the comprehensive aim of the article, ‘physicians’ and ‘doctors’ should be generalized to include ‘clinicians’ or ‘healthcare practitioners’ in order to encompass the entire array of persons involved in providing patient care/human subjects research and thus participate in shared decision making and the informed consent process (e.g., nurse practitioners, physician assistants and other advanced practice clinicians).
Response:

We replaced ‘physicians’ and ‘doctors’ with ‘health care practitioners’, to emphasize the relevance for all professionals involved in shared decision-making processes. See pages 2, 7, 8, 14 and 15.

Comment:

In box 3, the ethical analysis is rather thin and attempts to shoehorn too many ethical principles into the process. Beneficence and nonmaleficence may not be violated as no benefit or harm has occurred at the point of decision making as described in the scenario.

It is unclear whether the clinician involved in the informed consent process is ignorant about or simply withholding information about the underlying mechanism of a response shift resulting in higher HRQoL. In either case, the patient is not adequately informed about the target effects explored in the article and their implications for that patient’s health care decisions. The relevant ethical principle that has been violated/compromised is respect for persons (i.e., a dignitary harm has occurred). The possibility exists for future violations of the principle of nonmaleficence (which is logically and ethically prior to beneficence) in this scenario. A proper intervention would be to educate the clinician on the effect of patient response shifts on health care decision making and the necessity of including that information in the informed consent process.

Response: In the right column of Box 3, we removed the principle of beneficence as we think that overtreatment (causing harm) mainly violates the principle of non-maleficence (see page 8). In addition, we changed the text to explicate that the harm is not done at the moment of the decision, but in the consequences of this decision (see page 9).

In the context of the theoretical framework that we use, the fact that the patient is not adequately informed is a violation of the principle of respect for autonomy (rather than respect for persons). In response to the reviewer’s comments about the clinician’s responsibility to inform patients, we elaborated on this in the right column of Box 3. We do want to stress that the information that can be provided to the patient is limited, because at the moment it is usually not known if the PRO data are influenced by response shifts and if so, what the exact influence is (see page 9).

The first lines in the right column of Box 3 now reads “The example is problematic from the perspective of nonmaleficence. At the moment of the decision, no harm is done yet. However, the overtreatment that may be the consequence, leading to a worse health state, equals ‘doing harm’.”

In the article, we already provided recommendations about educational interventions for healthcare practitioners. Please find these at the end of the Conclusions section (see page 15-16).

Comment:
The ethical principle of justice is left out of micro-analysis, the authors might consider a well-specified application of justice on the micro level (will patients with certain dispositions receive better care than patients with different dispositions?).

Response:

We agree that at the micro level, the principle of justice may be at stake. For example, in the scenario in box 4, the anxious patient is at risk of overtreatment, while other patients with the same health state but other dispositions may not. In other examples, patients who are not inclined to report symptoms, may risk undertreatment.

However, we think that the principle of justice is less relevant at this level of individual patient care, as health care providers are more concerned with the well-being of individual patients than with equal treatment. We would say that the overtreatment of the patient in box 4 is problematic because of the overtreatment as such - and not only in the case of unequal treatment (other patients not being overtreated and receiving optimal care).

Therefore, we decided not to discuss a (well-specified) principle of justice for the micro level. To explain this, we added the following sentence on page 8: “The fourth principle, i.e. justice, may also be at stake at the level of individual patient care, in the sense of equal treatment among the patient populations of individual healthcare practitioners. However, we did not include this principle as we consider it less relevant for individual patient care. For health care practitioners, over- or undertreatment of a patient is problematic as such, and not only in relation to the care provided to other patients. Neither is distributive justice considered relevant. In most Western countries at least, in the consultation room, healthcare practitioners are not concerned with the just allocation of resources in health care, but rather with providing good health care for each individual patient.”

Comment:

The macro level analysis seems to consider the principle of justice specified as distributive justice. However, the application of utilitarianism as one of the traditional theories of distributive justice seems underdeveloped and oversimplified. Health care economic theory has any number of ways to calculate expected utility. In the ethical analysis of the scenario presented in box 5, the authors claim that it is not problematic given that HRQoL scores are greater in bypass surgery. However, the increased risks and costs of bypass surgery (also discussed), would conceivably decrease collective utility and rend the scenario problematic through a utilitarian framework.

Response:

We agree that the scenario presented in Box 5 is problematic from a utilitarian point of view. This is explained in the last sentence of the second column, but not reflected in the first sentence (which states that the example is not problematic). Therefore, we changed the text of the second column, which now reads:
“Since utility should be maximized, influences of response shifts or dispositions on self-evaluations are not an issue as such. The situation is problematic because bypass surgery is more expensive than angioplasty and has more medical risks, in this case without greater health benefits. However, the higher HRQoL scores due to response shift may justify the preference for bypass surgery, despite the medical risks. Nonetheless, especially when the costs and risks of bypass surgery are substantially higher, one might question whether these ‘extra’ resources would not be better spent on other healthcare or even services other than healthcare. Indeed, this may yield a larger increase of total utility in the broad sense, i.e. the wellbeing of the population.” (see page 12)

Comment:

In showing examples where utilitarianism and fair equality of opportunity actually align, the authors may make a stronger case about the importance of considering the effects of patient response shifts and disposition. By demonstrating scenarios where the theories conflict, there is a confused policy recommendation that could be more clearly articulated.

Response:

We agree that no concrete and unambiguous policy strategies follow from our ethical analysis. However, we purposefully selected both the scenarios and ethical theories to show the complexity of the matter. We aim to illustrate that whether a practice should be seen as problematic or not depends, at least in part, on which ethical perspective and concept of health is used. Policy does not follow directly from these ethical analyses, but in the policy decision making, the different ethical perspectives should be taken into account.

To make our discussion and conclusion more balanced, we added a paragraph clarifying why also at the policy level, it would be beneficial if influences of response shift and dispositions would be considered: “Also on the level of healthcare policy, medical decision making could benefit from taking into account the influence of response shift and disposition. The ethical analysis of the scenarios presented above also show that decisions about guidelines and reimbursement of treatments may not be fully informed. Not only reflecting on the possible influences of response shift could enhance the decision making; the different ethical perspectives and conceptions of health and their differential implications for healthcare policy also need to be considered.” (See page 15).

In addition to the changes in response to the reviewer’s comments, we also made a few changes in the third column of Box 6 to make the text more clear (see page 13).