Reviewer’s report

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

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Reviewer: Mary Faith Marshall

Reviewer’s report:

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.

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. Here are some concerns and recommendations:

1. 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).

2. 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.
3. 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?).

4. 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.

5. 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.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
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Unable to assess

Are the conclusions drawn adequately supported by the data shown?
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No

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