Reviewer's report

Title: The Principle of Respect for Autonomy - Concordant with the Experience of Physicians and Molecular Biologists in their Daily Work?

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Reviewer: rudolf H ter Meulen

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I have severe problems with this article particularly with 1) the methodology of the research, 2) the outcomes of the research and 3) the theoretical claims of the authors. I have only major compulsory revisions.

Major compulsory revisions

1) In the background section of the abstract, the authors tell the reader that they present Ã¢Â#Â#the results from a qualitative empirical research as an investigation how Danish physicians (in fact only oncology physicians, RtM) and molecular biologists experience the principle of respect for autonomy in their daily practiceÃ¢Â#Â#. This is an acceptable research question which can indeed be researched by way of qualitative research. However, in the section on the background of the study, the authors say immediately after this introduction that they want to test empirically Ã¢Â#Â#whether the principles of respect for autonomy of the American bioethicists Tom L. Beauchamp & James Childress and the Danish bioethicists Jakob Rendtorff & Peter Kemp are applicable to these groupsÃ¢Â#Â#. This means that the researchers were in fact trying to test or verify theoretical models and that they were structuring their approach to the field on the basis of the two theoretical frameworks. This becomes clear in the interview guide which includes a long question under 11 where the interviewees were asked their opinion about the two (Ã¢Â#Â#testedÃ¢Â#Â#) frameworks. Such a design has little to do with qualitative research: One may have presuppositions in qualitative research (as the authors acknowledge, and others contest), as you will always have some theoretical framework for your empirical approach. However, this does not mean that you ask the interviewees (in my view highly probing) questions about your own theoretical framework. In that case you are leaving the qualitative approach, and particularly a phenomenological approach, and you are testing theories (instead of building theories on the basis of your qualitative data.

It is of course interesting and absolutely acceptable to explore moral views and attitudes of researchers and practitioners on the principle of respect for autonomy, and to compare these views with theories in bioethics. But that does not mean that you are testing a theory by empirical means, in order to judge which theoretical model works the best. I will come back on this issue under 3. You would in fact need a completely different (hypothetical deductive) design to do so.

There are more questions about the methodology, and particularly with the interview guide and how it is used in the research. Items 9 and 10 contain two cases which do not come back in the article. First of all I question the relevance of the case 10 for both researchers and oncologists. Secondly, what where the responses to the cases? Did they raise interesting answers that were relevant for the theoretical discussion? Why were these two cases included anyway?

The authors should clarify the choice for the qualitative design, should tell more about the case analysis, should explain the limits of the study, meaning should be more modest in their claims about the theoretical value (see below) and particularly should leave out the idea of 'testing a theory of respect for autonomy'.

2) The authors conclude that the Beauchamp & Childress (B&C) principles approach is superior to the Rendtorff & Kemp (R&K) concepts of ethical principles (including autonomy, dignity, integrity & vulnerability) as B&C allow a Ã¢Â#Â#positiveÃ¢Â#Â# approach to autonomy (as complementary to a Ã¢Â#Â#negativeÃ¢Â#Â# approach) while R&K define autonomy in a negative way only (according to the authors). The evidence for this superiority is found in the fact that physicians Ã¢Â#Â#stress the principle of respect for autonomy as a positive obligationÃ¢Â#Â#. However, apparently the researchers are not bothering about a positive approach: is their view not relevant? If so, why include them in the research? Moreover, the physicians appear to stress various elements of R&KÃ¢Â#Â#s theoretical model of autonomy, like Ã¢Â#Â#the importance of the capacity of the patient for the creation of ideas and goals for lifeÃ¢Â#Â#, as well as the concepts of dignity and integrity. As both approaches to autonomy (B&C and R&K) seem to be shared by the physicians (and not to that extent by the researchers), I do not see any evidence for a claim to superiority of the B&C approach to autonomy.

The authors need to be less biased in their conclusions which should be more consistent with the results of the study. The model of Rendtorff and Kemp does not get a fair deal, which gives the impression that the study has been led inappropriately by moral presuppositions.

3) The authors are making very contestable theoretical claims at the end of their conclusion. They argue (p.18), that Ã¢Â#Â#the principle of autonomy of Rendtorff & Kemp is too narrow to be used in the Danish biomedical setting by focusing on the negative obligation. They do not come closer to the positive obligation of health care professionals by supplementing their principle of respect for autonomy by the principles of vulnerability, dignity and integrity. To conclude, this study indicates that the principle of respect for autonomy is concordant with the experience of Danish physicians and molecular biologists in their daily workÃ¢Â#Â#. (italics RtM) I wonder how the authors can draw such a conclusion. First of all, the molecular biologists do not share the positive approach to respect for autonomy as put forward (according to the authors) by Beauchamp & Childress. Secondly, the approach by Rendtorff & Kemp is certainly shared to some extent by the physicians and can definitely not be seen as Ã¢Â#Â#too

narrowÃ¢Â#Â#.

Moreover, the fact that a small group of oncology physicians have a preference for a Ã¢Â#Â#positiveÃ¢Â#Â# approach to the principle of respect for autonomy does not give in itself sufficient support for such a theoretical claim. As stated in the beginning of the article, the authors want to present empirical data to Ã¢Â#Â#investigate ethical reasoning in biomedicineÃ¢Â#Â#, particularly Ã¢Â#Â#to support the claim of efficacy of the four principles approach of B&CÃ¢Â#Â#. However, the fact how we think, or how oncologists think, does not say automatically how we (or the oncologists, or the molecular biologists, should think. The authors discuss this issue in the Introduction where they mention the reflective equilibrium as a method to combine descriptive and normative approaches to ethical thinking and decision-making. Empirical studies may help to provide researchers and practitioners with normative principles, as they repeat again at the end. But how and to which extent empirical research can or may do so stays unclear. The conclusion that Ã¢Â#Â#this study might provide health care professionals and biomedical researchers with normative principles that are concordant with their biomedical practice and which have normative implicationsÃ¢Â#Â# is overstretched and is from a meta-ethical viewpoint unjustified: Ã¢Â#Â#Das Sein bestimmt nicht das SollenÃ¢Â#Â# as Kant would say.

Moreover, I would like to know that when the researchers have a negative approach to autonomy, on which basis are we then allowed to say that that is not the Ã¢Â#Â#rightÃ¢Â#Â# approach to the respect of autonomy of patients or research subjects? Because the oncologists have a different view to respect for autonomy? Why is their approach Ã¢Â#Â#betterÃ¢Â#Â# and more justifiedÃ¢Â#Â# than the approach of the researchers? Are there not some moral presuppositions at work to make such a claim (and to say that the oncologists have more adequate views)? The authors seem to have already a presupposition (bias?) in favour of a positive approach to the principle of respect for autonomy and with it, for the principles approach of Beauchamp & Childress. The problem is that the authors do not make a thorough meta-ethical analysis of their approach and of the results of their study. This is a shame as empirical studies in bioethics, like the one they have conducted, are important. However, such studies 1) need to be conducted with the right methodological design (and without bias), 2) need to come to valid and reliable results, and 3) need to incorporate its results in a meta-ethical view of the relation between empirical data and normative claims.

The authors need to make a stronger theoretical and meta-ethical analysis of the results, should use the theortical models as mentioned in the introducion to clarify the relation between empirical data and normative principles,like for exampe the use of the reflective equilibrium.

One final question: has the research been approved by a research ethics committee? Or is this not required in the Danish context? It would need approval in the United Kingdom, as health care practitioners have been involved in the study.

Bristol, 12th of December 2007

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

No competing interests