

## PEER REVIEW HISTORY

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## ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Euthanasia and Assisted Suicide Not Meeting Due Care Criteria in the Netherlands: A Qualitative Review of Review Committee Judgments
<b>AUTHORS</b>	Miller, D. Gibbes; Kim, Scott

## VERSION 1 – REVIEW

<b>REVIEWER</b>	Bernard Lo The Greenwall Foundation USA
<b>REVIEW RETURNED</b>	27-May-2017

<b>GENERAL COMMENTS</b>	<p>This is a carefully designed, thoughtful study that provides an important empirical description of cases of physician-assisted suicide and active euthanasia that the Dutch Regional Euthanasia Review Committees determined did not meet criteria for due care. The findings of this study provide important empirical information on how the Dutch legal framework for euthanasia and assisted suicide is working in practice.</p> <p>Major comments: My main concern is the distinction the authors make between procedural and substantive criteria. This distinction is not explicitly defined. Are these categories defined in Dutch law or RTE procedures, or did the authors generate them? During the coding or analysis, what criteria did the investigators use to sort cases into procedural or substantive violations? Cases in which a neuromuscular blocker was administered without first inducing coma were classified as “procedural” violations, but arguably could also be classified as substantive violations of a medical standard of care (in U.S. terms).</p> <p>The authors let the RTE reviews speak for themselves. Yet some of the cases seem to cry out for more commentary and interpretation, particularly the cases in which neuromuscular blocking drugs were administered without adequate induction of coma or the case in which a patient was restrained to prevent withdrawing from insertion of a needle. One could well argue that the procedure of active euthanasia, even if morally justified (and it apparently was not in 2016-85), might well have caused the patient avoidable suffering. Even if the RTE did not comment on this, the authors should raise this possibility, rather than leaving it up to the reader to draw this inference from the Tables. This would be an important issue to raise, because it suggests a possible significant shortcoming the design or</p>
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	<p>implementation of the RTE reviews. If the authors are concerned about being criticized from reading too much into the RTE reports, I think that they could raise issues in a hypothesis-generating way, making it clear that others may disagree with their interpretation and perhaps suggesting how or why they might do so. Offering alternative interpretations is a well-established technique in empirical research, and I encourage the authors to use it.</p> <p>The discussion section, while concise and modest, could suggest what the lessons might be learned from the RTE review. Does the RTE provide suggest how care in the individual cases might have been improved? If not, this seems to be an important missed opportunity for improving the implementation of the national policy on EAS.</p> <p>Other comments: The investigators should explain why a few cases were excluded.</p> <p>Please provide more background on the organization SCEN than is contained in Box 1: Are they a pro-euthanasia organization, or are their members supposed to be neutral with regard to euthanasia? Are they recognized as experts by the government or Dutch medical associations? What is their training, and was it designed in conjunction with physicians who are not advocates for euthanasia? This additional information is important to help the reader interpret some of the project's findings.</p>
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<b>REVIEWER</b>	<p>Brian L. Mishara Centre for Research and Intervention on Suicide and Euthanasia, Université du Québec à Montréal Canada</p>
<b>REVIEW RETURNED</b>	02-Jun-2017

<b>GENERAL COMMENTS</b>	<p>This paper clearly describes a qualitative analysis of reports which are available to the public on instances where physician reports were deemed to not meet criteria. The methodology and results are clearly presented, and the discussion is appropriate and consistent with the results. This is an excellent article, and it is important to publish it so that those considering new legislation, and countries examining changes in existing legislation (as is the case now in Canada), could profit from this research to aid their considerations. There are wider considerations which require an ethical, rather than empirical analysis, which is beyond the scope of this paper: How much "error" or "abuse" may be tolerated in a society. Some would believe that when death is the outcome of a medical act, zero tolerance should be the rule. However, humans (including physicians) are not perfect. I do not request revisions since the article is very clear and presents data to help inspire the development of ethical debates, which others can undertake.</p>
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## VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

We thank the reviewer for these positive comments.

1. The distinction between substantive and procedural criteria is an accepted convention used in official Dutch documents and academic literature, and we now cite the official reports and an article for reference. Due care criteria a through d pertain to physician judgments about patient eligibility, while criteria e and f regard due medical process. We added a sentence in Methods and a footnote in Box 2 to clarify this.

2. We have added a sentence at page 15 indicating that the RTE in fact seems very sensitive to the incompetent administration of medication issue as it would cause unnecessary suffering.

We did consider discussions of individual cases. But we found that every case could have deserved extensive analysis—but there is no good way to do this without making the paper very long. However, we now have made another addition that partially addresses the reviewer's concern. Specifically, rather than individually discussing cases, we now point out at several places in the Discussion (along with a change at page 7) more explicitly that most of the substantive cases involve controversial features (such as EAS for psychiatric disorders or for 'tired of living,' or involve incapable patients, or involve doctors from advocacy organizations), and then draw some lessons regarding adequacy of current oversight process given these developments that were not as common when the current review system was put in place.

3. In retrospect, we believe that the reviewer is correct that the discussion section could suggest what lessons might be learned from the RTE review. As he and the other reviewer have noted, we have tried as much as possible to let the cases speak for themselves. However, it does seem necessary to at least comment on what lessons the review might have for interpreting why there are so few DCNM cases and whether the Dutch system has a 'strict' approach, and also whether there might be lessons for other jurisdictions and for the current Dutch system.

We now better explain that the Dutch system is largely based on trust and this likely explains the low number of DCNM. Other jurisdictions will need to appreciate this feature, if they are to implement a system consistent with their goals.

One significant addition we have made is to point out that almost all (9 of 10) cases of substantive criteria DCNM cases were non-cancer, non-terminal, and most of them involve what might be called controversial elements—incapacitated patients, psychiatric patients, 'tired of living' as basis for EAS, or EAS physicians from advocacy organizations. By pointing this out, we do raise the question of whether a system that was largely developed early on when these issues were non-existent or rare can adequately address these new developments in the Dutch EAS practice.

We also made slight adjustments in the Abstract to accommodate this new discussion point.

We thank the reviewer for forcing us to think more deeply about how this review might suggest ways to perhaps improve the system.

4. No cases that were available on the RTE website were excluded. There were no cases from prior to 2012 that were available on the website, and there was one case since 2012 that the RTE did not publish. Thus, we have 32/33 cases from 2012 to our study's cutoff date, January 31, 2017. Since the

cutoff date, additional cases may have been added for 2017 but they are not included in this study. No cases available online at the cutoff date were excluded from the study.

5. We have added more information on the SCEN organization. SCEN is not necessarily a “pro-euthanasia” organization, but it was created in tandem with the Dutch euthanasia system to professionalize the process of EAS. SCEN was created by the Royal Dutch Medical Association, and it receives funding from the Dutch government. We have added additional information about SCEN in Box 1.

Reviewer 2

We thank the reviewer for the positive comments.

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Bernard Lo The Greenwall Foundation USA
<b>REVIEW RETURNED</b>	16-Aug-2017

<b>GENERAL COMMENTS</b>	Excellent article and important contribution to the literature.
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