

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	How defensive medicine is defined and understood in European medical literature: Protocol for a systematic review
<b>AUTHORS</b>	Baungaard Pedersen, Nathalie; Skovvang Juul Jespersen, Pia; Assing Hvidt, Elisabeth; Gerbild, Helle; Kirstine Andersen, Merethe; Lykkegaard, Jesper

### VERSION 1 – REVIEW

<b>REVIEWER</b>	José Joaquín Mira Universidad Miguel Hernández, Spain
<b>REVIEW RETURNED</b>	01-Nov-2019

<b>GENERAL COMMENTS</b>	<p>This is a future systematic review study for the purpose of analyzing how defensive medicine is defined and understood in the European medical literature. It is planned to follow the PRISMA recommendations. The study describes correctly how this systematic review is planned. In this sense, what is expected to be done to adequately conduct a study of these characteristics is fulfilled.</p> <p>However, I have some doubts about the opportunity of publishing a study with this approach.</p> <ol style="list-style-type: none"><li>1. The introduction justifies this research because the different implications that defensive medicine may have in the USA and Europe due to differences in legislation and, in particular, by the no-fault-policy. However, the objective of the study is limited to how defensive medicine has been defined in different studies. In my opinion, the former is much more relevant than the latter.</li><li>2. It is not clear to me that there is sufficient interest in publishing a study protocol with this approach and scope.</li><li>3. Although the study is intended to cover studies conducted in Europe, it will only include studies published in English. A study of this type should consider a broader set of languages. It is quite possible that studies on this subject have been published in national journals and therefore the purpose of the study may not be achieved if it is limited to English.</li></ol> <p>Minor</p> <ol style="list-style-type: none"><li>4. The method includes meta-analysis term but does not seem to make sense here. This study does not focus on reviewing any results from any study.</li><li>5. The dates of the review are deducted but not defined.</li></ol>
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<b>REVIEWER</b>	Claudio Bilato Division of Cardiology, Department of Medicine, West Vicenza General Hospitals, Arzignano-Vicenza, Italy
<b>REVIEW RETURNED</b>	05-Nov-2019

<b>GENERAL COMMENTS</b>	Since this is a protocol paper, the dates of the study should be included in the manuscript.
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<b>REVIEWER</b>	Andrew Papanikitas University of Oxford, UK I have written and taught on the subject of defensive medicine and the ethical aspects of this
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<b>REVIEW RETURNED</b>	18-Nov-2019
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<b>GENERAL COMMENTS</b>	<p>This is a welcome and useful study. I have some minor points that the authors may have already considered and might improve the clarity and usefulness. The key outcome, "a categorisation of the identified definitions of DM in the European medical research literature focusing on the motives for medical acting that the studies regard as defensive" could be clearer throughout the protocol. For example when discussing physicians do the authors include studies family practitioners and surgeons (a large part of the literature I am aware of refers to the latter) or include medical students?</p> <p>I was unsure what kinds of original research would be considered - quantitative studies, systematic reviews of educational initiatives, qualitative research, systematic reviews of non-research literature etc.</p> <p>Also, are the authors sure that they wish to restrict their review to original research and not include editorials and education where much 'definition-work' is concentrated? This is potentially a study limitation or indeed a strength (see below). I was unsure from the list which were limitations and which were strengths.</p> <p>if so then perhaps a reason for this would be useful - for example that they aim to build a conceptualisation of defensive medicine out of the behaviours identified in original research that are identified as defensive. Also more could be made of the assessment of what original research has contributed to the understanding of defensive medicine and any limitations of empirical research studies.</p>
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## VERSION 1 – AUTHOR RESPONSE

\Reviewer 1:

1. The introduction justifies this research because the different implications that defensive medicine may have in the USA and Europe due to differences in legislation and, in particular, by the no-fault-policy. However, the objective of the study is limited to how defensive medicine has been defined in different studies. In my opinion, the former is much more relevant than the latter.

Reply to reviewer:

Thank you for review and for directing our attention to the point regarding the relevance of investigating the implications of different understandings of defensive medicine. We agree that this is indeed a very relevant subject to investigate. However, we believe that before this can be done a thorough and systematic investigation of differences in understanding of the term is necessary. This being a large and complex field and having only limited time resources at our disposal, we have chosen to focus entirely on this question of variations in understandings and definitions of defensive medicine. Hopefully, other researchers might use our systematic review as a point of departure to address and investigate the question of implications.

The following change has been made to the manuscript:

Page 6, Rationale: Science needs definitions. To our knowledge no systematic review exists of how DM is defined and understood in the European scientific, medical literature. A systematic review of the term “defensive medicine” in the European context will provide a more nuanced understanding of this complex and non-beneficial phenomenon, hereby supporting the quality of future research on the topic.

Page 11, Conclusion, line 2-4: This review seeks to provide a more nuanced understanding of the complex and non-beneficial phenomenon of defensive medicine, hereby supporting the quality of future research on the topic.

2. It is not clear to me that there is sufficient interest in publishing a study protocol with this approach and scope.

Reply to reviewer:

We are delighted to inform you that during our research on defensive medicine, we have been met with several inquiries and suggestions regarding variation in understandings and definitions of the phenomenon of defensive medicine. Meeting this interest from clinicians and researchers alike, motivated us to investigate the question further by conducting a systematic review.

The following change has been made to the manuscript:

Page 6, Rationale: Science needs definitions. To our knowledge no systematic review exists of how DM is defined and understood in the European scientific, medical literature. A systematic review of the term “defensive medicine” in the European context will provide a more nuanced understanding of this complex and non-beneficial phenomenon, hereby supporting the quality of future research on the topic.

Page 11, Conclusion, line 2-4: This review seeks to provide a more nuanced understanding of the complex and non-beneficial phenomenon of defensive medicine, hereby supporting the quality of future research on the topic.

3. Although the study is intended to cover studies conducted in Europe, it will only include studies published in English. A study of this type should consider a broader set of languages. It is quite possible that studies on this subject have been published in national journals and therefore the purpose of the study may not be achieved if it is limited to English.

Reply to reviewer:

We kindly acknowledge your consideration about the advantage of including non-English studies. The review’s outcome will be formulations identified in the European studies which require thorough language proficiency. Since we are not an international team of authors, we do not have the language resources, as well as funding and time resources in order to include non-English studies. Therefore, we have made a bullet point in “Strengths and limitations”, in order to address this limitation. Furthermore, we have added arguments for regarding a review of only English language scientific literature as sufficient for answering the research question.

The following change has been made to the manuscript:

Page 4, Strengths and limitations of this study, Limitations, bullet point number 1: Only English language studies will be included in the systematic review.

Page 8, Search strategy, line 1: The preparation of search strategy is based on the original American term “defensive medicine”.

Page 11, Risk of bias in individual studies, line 5-8: Although there are multiple languages used in Europe, the review only includes English scientific literature. However, most high-ranking scientific journals reporting on DM is written in English and we specifically aim to support future research on DM. Furthermore, DM was originally conceptualized in English.

4. The method includes meta-analysis term but does not seem to make sense here. This study does not focus on reviewing any results from any study.

Reply to reviewer:

The term “meta-analysis” does not apply to our study, which will not generate numerical data. We have therefore omitted the term in the manuscript.

The following change has been made to the manuscript:

We have omitted the term “meta-analysis” from the manuscript.

5. The dates of the review are deducted but not defined.

The following change has been made to the manuscript:

Page 8, Information sources: Eligible studies will be searched in three databases: PubMed, Embase and Cochrane, 3rd of February 2020.

Reviewer 2:

1. Since this is a protocol paper, the dates of the study should be included in the manuscript.

The following change has been made to the manuscript:

Page 8, Information sources: Eligible studies will be searched in three databases: PubMed, Embase and Cochrane, 3rd of February 2020.

Reviewer 3:

1. The key outcome, "a categorisation of the identified definitions of DM in the European medical research literature focusing on the motives for medical acting that the studies regard as defensive" could be clearer throughout the protocol. For example when discussing physicians do the authors include studies family practitioners and surgeons (a large part of the literature I am aware of refers to the latter) or include medical students?

The following change has been made to the manuscript:

Page 6, Rationale: Science needs definitions. To our knowledge no systematic review exists of how DM is defined and understood in the European scientific, medical literature. A systematic review of the term “defensive medicine” in the European context will provide a more nuanced understanding of this complex and non-beneficial phenomenon, hereby supporting the quality of future research on the topic.

Page 7, Eligibility criteria, Inclusion criteria, bullet point number 3: DM is performed by physicians, including general practitioners, as well as physicians from medical, surgical and paraclinical specialities.

Page 11, Outcomes and prioritization, line 5-6: The review will report if any differences in the definitions and understandings of DM between countries and between high- and low-quality papers exist.

2. I was unsure what kinds of original research would be considered - quantitative studies, systematic reviews of educational initiatives, qualitative research, systematic reviews of non-research literature etc.

The following change has been made to the manuscript:

Page 7, Eligibility criteria, Inclusion criteria, bullet point number 4: The study is an original research study (quantitative or qualitative primary research) or systematic review published in a peer-reviewed, medical journal.

3. Also, are the authors sure that they wish to restrict their review to original research and not include editorials and education where much 'definition-work' is concentrated? This is potentially a study limitation or indeed a strength (see below). I was unsure from the list which were limitations and which were strengths. If so then perhaps a reason for this would be useful - for example that they aim to build a conceptualisation of defensive medicine out of the behaviours identified in original research that are identified as defensive. Also more could be made of the assessment of what original research has contributed to the understanding of defensive medicine and any limitations of empirical research studies.

The following change has been made to the manuscript:

Page 4, Strengths and limitations of this study, Strengths, bullet point number 2: The scientific quality of each reviewed study will be assessed by use of standardised quality assessment tools and only the content of peer-reviewed original research papers will be included in the analysis.

Page 6, Rationale: Science needs definitions. To our knowledge no systematic review exists of how DM is defined and understood in the European scientific, medical literature. A systematic review of the term “defensive medicine” in the European context will provide a more nuanced understanding of this complex and non-beneficial phenomenon, hereby supporting the quality of future research on the topic.

Page 11, Outcomes and prioritization, line 5-6: The review will report if any differences in the definitions and understandings of DM between countries and between high- and low-quality papers exist.

Page 11, Risk of bias in individual studies, line 6-7: However, most high-ranking scientific journals reporting on DM is written in English and we specifically aim to support future research on DM.

Page 11, Conclusion, line 2-4: This review seeks to provide a more nuanced understanding of the complex and non-beneficial phenomenon of defensive medicine, hereby supporting the quality of future research on the topic.

#### **VERSION 2 – REVIEW**

<b>REVIEWER</b>	José Joaquín Mira Universidad Miguel Hernández, Spain
<b>REVIEW RETURNED</b>	20-Dec-2019
<b>GENERAL COMMENTS</b>	Authors have replied point-by-point all comments and suggestions made by reviewers. In my opinion changes introduced have enhanced the manuscript understanding.