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How defensive medicine is defined and understood in European medical literature: Protocol for a systematic review

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4 ADMINISTRATIVE INFORMATION
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9 **Title:**

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13 systematic review.
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18 **Registration:**

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20 This review will be registered in PROSPERO, International prospective register of systematic
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NBP	Conceptualisation, protocol design, development of search strategy, study inclusion, data extraction, quality assessment, data analysis/synthesis, drafting and writing of protocol and manuscript.
PSJJ	Conceptualisation, development of search strategy, study inclusion, data extraction, quality assessment, data analysis/synthesis, drafting and writing of manuscript.
EAH	Conceptualisation, protocol design, writing of protocol and manuscript.
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MKA	Conceptualisation, protocol design, writing of manuscript.
JL	Conceptualisation, protocol design, study inclusion, writing of protocol and manuscript.

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ABSTRACT

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Introduction: The term defensive medicine originates from the United States and is used in medical research literature since the late 1960s. Differences in medical legal systems between the US and most European countries raise the question whether the US definition of defensive medicine, as actions motivated primarily by litigious concerns, holds true in Europe where in most countries there is no tort legislation.

Aim: To present the protocol of a systematic review of variations in the definition and understandings of the term “defensive medicine” in European research articles.

Methods and Analysis: In accordance with the PRISMA guidelines, a systematic review of all medical research literature that investigates defensive medicine will be performed by two independent reviewers. The databases PubMed, Embase and Cochrane will be systematically searched on the basis of predetermined criteria. Data from all included European studies will systematically be extracted including the studies’ definitions and understandings of defensive medicine, especially the types of motives for medical actions that each study regards as defensive.

Ethics and Dissemination: No ethics clearance is required as no primary data will be collected. The results of the systematic review will be published in a peer-review journal.

Strengths and limitations of this study

- The systematic review will be based on a systematic and thorough search of literature independently performed by two reviewers following the PRISMA guidelines hereby increasing the generalisability and reliability of the findings.
- The review will identify variations in the definitions of defensive medicine employed in the European research literature and analyse essential elements herein.
- Only publications of original research studies are reviewed.

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INTRODUCTION

Background

Defensive medicine (DM) is a term used in the medical research literature since the late 1960s (2). The term originates from the US (3) and has since then taken on various connotations (4). The most commonly used definition describes DM as physicians' deviations from sound medical practice due to fear of liability claims and lawsuits (5-9). DM can additionally be subdivided into two main forms of behaviour: 1. positive DM (also named either active DM or assurance behaviour), which involves physicians ordering extra diagnostic tests, procedures or visits and 2. negative DM (also named passive DM or avoidance behaviour) which is the avoidance of high-risk patients or procedures. Both forms aim to reduce physicians' exposure to malpractice liability (5-8). The above definition of DM consists of two components: A medical action and an underlying motive for acting defensively.

DM has been associated with rising health care costs (8). Furthermore, it has been associated with overtreatment, -prescription and -diagnosing of patients and decreased trust in the physician-patient relationship, leading physicians to regard patients as potential plaintiffs (8, 10-13). Moreover, physicians report patient disrespect for their professionalism, personal frustration among physicians, and inequality in healthcare as possible consequences of defensive medicine (14, 15).

In the US, DM is reported to be frequent (16). The number of lawsuits for medical malpractice has risen significantly in the US (10), and DM has been shown to be directly related to this growth (13). US physicians are forced to hold expensive malpractice insurances in order to cover the cost from malpractice suits (17). Hence, with inadequate legislation protecting physicians from tort, concerns about malpractice liability is likely to be the predominant reason to act defensively (8). Indeed, negative associations have been found between physicians' use of medical resources and risk of malpractice claims (18).

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4 In several European countries malpractice litigation is reported to happen less frequently than in
5 the US, e.g. in The Netherlands (3, 19) Denmark (14), Switzerland (20), and the UK (21).
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7 Furthermore, in some European countries, the medico-legal system protects the physicians who are
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9 not held financially liable for malpractice or other treatment related adverse events. In addition, the
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11 patients are instead compensated by the government (known as a no-fault system) (22-24).
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13 Nevertheless, DM seems also to be prevalent in Europe, e.g. Denmark (14), the UK (25), Italy (13),
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15 Belgium (26), The Netherlands (3), Germany (27) and Switzerland (21), and a substantial part of
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17 research on DM seems to originate from Europe.
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23 Variations in medico-legal systems between the US and most European countries raise the question
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25 whether the definition of DM, as actions motivated primarily by litigious concerns, holds true in
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27 European countries where physicians are not subjected to tort legislation (21) and if other motives for
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29 performing defensive medical actions are documented in the European literature on DM (28).
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33 **Rationale**

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35 To our knowledge no systematic review exists of how DM is defined and understood in the European
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37 medical literature. A systematic review of the term “defensive medicine” in the European context
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39 will provide a more nuanced understanding of this complex and non-beneficial phenomenon, hereby
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41 increasing the possibilities to reduce the practice of DM in future health care.
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46 **Objectives**

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48 The aim of this study is to present a protocol paper for a systematic review with the following
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50 objective: To analyse variations in the definition and understandings of the term “defensive medicine”
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52 in European research articles.
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56 METHODS

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Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination of our research.

Protocol

This protocol for a systematic review is conducted in accordance with the PRISMA-P (Preferred Reporting Items for Systematic Reviews – Protocol) (29).

Eligibility criteria

Publications will be included in the review based on the following criteria:

Inclusion criteria:

1. The terms “defensive medicine” or “defensive practice” are stated in title or abstract.
2. The study is available in full-text and written in English language.
3. DM is performed by physicians.
4. The study is an original research study or systematic review published in a medical journal.
5. DM is stated as part of the study’s aim/objective in at least one of the following ways:
 - a. DM is included in the publication’s aim/objective.
 - b. DM is implicitly a significant part of the aim/objective.

Further

6. The study’s research data includes data from Europe.

Information sources

Eligible studies will be searched in three databases: PubMed, Embase and Cochrane.

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7 **Search strategy**

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9 The preparation of search strategy is based on the term “defensive medicine”. In accordance with the
10 database PubMed, the MeSH term “defensive medicine” is combined with the entry terms “defensive
11 practice”, “defensive practices” and “medicine, defensive”. On the basis of this, the following search
12 strategy will be used: “defensive medicine OR defensive practice OR defensive practices OR
13 medicine, defensive”, see appendix. All references in the papers fulfilling the inclusion criteria will
14 be examined in order to identify potentially neglected studies. The literature search will be updated
15 before the final analysis. See appendix for detailed search strategy.
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27 **Study records**

28 *Data management*

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30 Publications found by the search strategy will be exported into the reference management software
31 (EndNote) (30) and the software Covidence (31), where the systematic screening and data extraction
32 will be performed, including the removing of duplicates. Number of citations for each study will be
33 assessed with Web of Science (32) in accordance with the PRISMA guidelines (29).
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44 *Selection process*

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46 Two independent reviewers (NBP and PSJJ) will screen all potentially relevant studies in a two-phase
47 screening process to ensure compliance with the inclusion criteria and eligibility by use of Covidence
48 (31). NBA and PSJJ will discuss and resolve any disagreements to reach consensus. If consensus is
49 not achievable, a third reviewer (JL) will be involved in the discussion and finally decide whether the
50 study in question is to be included or not.
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Data collection process

The primary authors (NBP and PSJJ) will extract data from the included studies, including publication details (author(s), name of journal, year of publication), study characteristics (design, country of origin, sample size, medical speciality investigated, and number of citations), study objective, stated definition of DM and understandings of DM.

Quality assessment

The two reviewers (NBP and PSJJ) will independently assess the quality of each study. The qualitative studies will be reviewed using the Critical Appraisal Skills Programme (CASP) (33), recommended by the Centre for Clinical Guidelines (CFKR) (34), to ensure a critical and standardized assessment of the quality and analysis of the study. The quantitative studies will be reviewed using a cross-sectional appraisal tool with questions adapted from Guyatt GH et al. JAMA 1993 and 1994 (35, 36). The systematic reviews and meta-analysis will be reviewed using Assessing the Methodological Quality of Systematic Reviews (AMSTAR) (37) recommended by the Centre for Clinical Guidelines (CFKR) (34). Disagreements will be discussed until consensus is reached.

Data items

Data items are as stated above under “methods”. The design of the review is based on the hypothesis that a definition of DM reflects the medico-legal context in which it is used. Therefore, we expect the definitions stated and understandings of DM in the European research literature to be different than those stated in the literature deriving from the US.

Data synthesis

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For each paper, the stated definition and understanding of DM will be extracted by the first author (NBP). The definition of DM will be identified as: “DM is...”, “DM is defined as...”, “DM refers to...”, or “DM is characterized by...”. If no definition of DM is stated, the way in which DM is introduced will be identified. A paper’s understanding of DM is assessed from its use in the study and may differ from the stated definition. Quotes identifying how DM is understood will be extracted and analysed according to a thematic analysis approach aiming to categorize the findings. Based on the above definitions of DM, it is expected that the vast majority of papers will define DM as healthcare actions conducted by healthcare professionals during their work, but that the motives making the actions defensive may differ between papers showing a broader understanding of DM in some European studies than according to the US definition. Thus, for each paper, the motives regarded as defensive will be identified in the texts, tables, figures, as well as in the data collection methods. The identified categories of DM definitions and understandings will be scrutinized by the author group.

Outcomes and prioritization

The review’s main outcomes will be 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 and a graphical display of the historical trend in the annual number of published European original research papers regarding DM divided on the identified categories of DM definitions.

Risk of bias in individual studies

Since the objective of this study differs from most reviews by not taking interest in the results found by the reviewed studies, the quality assessment of the identified papers serves a different purpose.

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The quality of the papers is used to show whether high quality papers use a different definition of DM than other papers. See the above described quality assessment procedure.

Conclusion

This systematic review will address the variations in the definition and understandings of the term “defensive medicine” in European research articles. This review will provide a more nuanced understanding of this complex and non-beneficial phenomenon, hereby increasing the possibilities to reduce the practice of DM in future health care.

Potential amendments

We do not envisage any amendments to the present protocol. However, should an amendment be necessary, it will be notified, registered and reported.

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34 **Conflict of interests** 35

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38 The authors declare that they have no competing interests.
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5 article about therapy or prevention. A. Are the results of the study valid? Evidence-Based
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Appendix

Search strategy from PubMed search string:

defensive medicine OR defensive practice OR defensive practices OR medicine, defensive

("defensive medicine"[MeSH Terms] OR ("defensive"[All Fields] AND "medicine"[All Fields]) OR "defensive medicine"[All Fields]) OR ("defensive medicine"[MeSH Terms] OR ("defensive"[All Fields] AND "medicine"[All Fields]) OR "defensive medicine"[All Fields] OR ("defensive"[All Fields] AND "practice"[All Fields]) OR "defensive practice"[All Fields]) OR ("defensive medicine"[MeSH Terms] OR ("defensive"[All Fields] AND "medicine"[All Fields]) OR "defensive medicine"[All Fields] OR ("defensive"[All Fields] AND "practices"[All Fields]) OR "defensive practices"[All Fields]) OR ("defensive medicine"[MeSH Terms] OR ("defensive"[All Fields] AND "medicine"[All Fields]) OR "defensive medicine"[All Fields] OR "defensive medicine"[All Fields] OR ("defensive"[All Fields] AND "practices"[All Fields]) OR "defensive practices"[All Fields]) OR ("defensive medicine"[MeSH Terms] OR ("defensive"[All Fields] AND "medicine"[All Fields]) OR "defensive medicine"[All Fields] OR ("medicine"[All Fields] AND "defensive"[All Fields]))

PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 4:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	x		1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such		x	
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	x		2
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	x		2-3
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	x		3
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments		x	
Support					
Sources	5a	Indicate sources of financial or other support for the review	x		3
Sponsor	5b	Provide name for the review funder and/or sponsor	x		11
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	x		3
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	x		6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	x		6
METHODS					

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	x		7
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	x		7
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	x		8
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	x		8
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	x		8
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	x		9
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	x		9
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	x		10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	x		10-11
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	x		9-10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2 , Kendall's tau)		x	
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)		x	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	x		9-10
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)		x	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)		x	

BMJ Open

How defensive medicine is defined and understood in European medical literature: Protocol for a systematic review

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-034300.R1
Article Type:	Protocol
Date Submitted by the Author:	18-Dec-2019
Complete List of Authors:	<p>Baungaard Pedersen, Nathalie; University of Southern Denmark Faculty of Health Sciences, Department of Public Health, Research Unit of General Practice.</p> <p>Skovvang Juul Jespersen, Pia; University of Southern Denmark Faculty of Health Sciences, Department of Public Health, Research Unit of General Practice.</p> <p>Assing Hvidt, Elisabeth; University of Southern Denmark Faculty of Health Sciences, Department of Public Health, Research Unit of General Practice.; University of Southern Denmark, Department for the Study of Culture</p> <p>Gerbild, Helle; Aalborg Universitet, Center for Sexology Research, Department of Clinical Medicine; University College Lillebaelt - Campus Odense, Health Sciences Research Centre University College</p> <p>Kirstine Andersen, Merethe; University of Southern Denmark Faculty of Health Sciences, Department of Public Health, Research Unit of General Practice</p> <p>Lykkegaard, Jesper; University of Southern Denmark Faculty of Health Sciences, Department of Public Health, Research Unit of General Practice</p>
Primary Subject Heading:	Qualitative research
Secondary Subject Heading:	Communication, Patient-centred medicine, Health economics
Keywords:	Defensive medicine, Systematic review, Definition

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16 European medical literature: Protocol for a systematic
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Word count: 2532

1 December 2019
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4 ADMINISTRATIVE INFORMATION
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8
9 **Title:**

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11 How defensive medicine is defined and understood in European medical literature: Protocol for a
12 systematic review.
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18 **Registration:**

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20 This review will be registered in PROSPERO, International prospective register of systematic
21 reviews.
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27 **Authors:**

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Authors' contributions

NBP	Conceptualisation, protocol design, development of search strategy, study inclusion, data extraction, quality assessment, data analysis/synthesis, drafting and writing of protocol and manuscript.
PSJJ	Conceptualisation, development of search strategy, study inclusion, data extraction, quality assessment, data analysis/synthesis, drafting and writing of manuscript.
EAH	Conceptualisation, protocol design, writing of protocol and manuscript.
HG	Conceptualisation, protocol design, writing of manuscript.
MKA	Conceptualisation, protocol design, writing of manuscript.
JL	Conceptualisation, protocol design, study inclusion, writing of protocol and manuscript.

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ABSTRACT

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4 **Introduction:** The term defensive medicine, referring to actions motivated primarily by litigious
5 concerns, originates from the United States and has been used in medical research literature since the
6
7 late 1960s. Differences in medical legal systems between the US and most European countries with
8
9 no tort legislation raise the question whether the US definition of defensive medicine holds true in
10
11 Europe.
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15 **Aim:** To present the protocol of a systematic review investigating variations in definitions and
16 understandings of the term “defensive medicine” in European research articles.
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19 **Methods and Analysis:** In concordance with the PRISMA guidelines, a systematic review of all
20 medical research literature that investigate defensive medicine will be performed by two independent
21 reviewers. The databases PubMed, Embase and Cochrane will be systematically searched on the basis
22 of predetermined criteria. Data from all included European studies will systematically be extracted
23 including the studies’ definitions and understandings of defensive medicine, especially the motives
24 for doing medical actions that the study regards as “defensive”.
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34 **Ethics and Dissemination:** No ethics clearance is required as no primary data will be collected. The
35 results of the systematic review will be published in a peer-reviewed, international journal.
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41 **Strengths and limitations of this study**

42 **Strengths:**

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45 • The present systematic review will be based on a systematic and thorough search of literature
46 independently performed by two reviewers concordant with the PRISMA guidelines, hereby
47 increasing the generalisability and reliability of the findings.
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50 • The scientific quality of each reviewed study will be assessed by use of standardised quality
51 assessment tools and only the content of peer-reviewed original research papers will be
52 included in the analysis.
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Limitations:

- Only English language studies will be included in the systematic review.

INTRODUCTION

Background

Defensive medicine (DM) is a term that has been used in the medical research literature since the late 1960s (1). The term originates from the US (2) and has since then taken on various connotations (3). The most commonly used definition describes DM as “physicians’ deviations from sound medical practice due to fear of liability claims and lawsuits” (4-8). DM can additionally be subdivided into two main forms of behaviour: 1. positive DM (also labelled active DM or assurance behaviour), which involves physicians ordering extra diagnostic tests, procedures or visits and 2. negative DM (also labelled passive DM or avoidance behaviour) which is the avoidance of high-risk patients or procedures. Both forms aim to reduce physicians’ exposure to malpractice liability (4-7). The above definition of DM consists of two components: A medical action and an underlying motive for acting defensively.

DM has been associated with rising health care costs (7). Furthermore, it has been associated with overtreatment, -prescription and -diagnosing of patients and decreased trust in the physician-patient relationship, leading patients to mistrust physicians’ motivations and physicians to regard patients as potential plaintiffs (7, 9-12). Moreover, physicians report patient disrespect for their professionalism, personal frustration, and inequality in healthcare as possible consequences of defensive medicine (13, 14).

In the US, DM is reported to be frequent (15). The number of lawsuits for medical malpractice has risen significantly (9), and DM has been shown to be directly related to this growth (12). US physicians are forced to hold expensive malpractice insurances in order to cover the cost from

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4 malpractice suits (16). Hence, with inadequate legislation protecting physicians from tort, concerns
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6 about malpractice liability is likely to be the predominant reason to act defensively (7). Indeed,
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8 negative associations have been found between physicians' use of medical resources and risk of
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10 malpractice claims (17).
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14 In several European countries malpractice litigation is reported to happen less frequently than in
15
16 the US, e.g. in the Netherlands (2, 18) Denmark (13), Switzerland (19), and the UK (20). In these
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18 countries, the medico-legal system does not hold physicians financially liable for malpractice or other
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20 treatment related adverse events. The patients are instead compensated by the government (known as
21
22 a no-fault system) (21-23). Nevertheless, DM seems also to be prevalent in Europe, e.g. Denmark
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24 (13), the UK (24), Italy (12), Belgium (25), The Netherlands (2), Germany (26) and Switzerland (20).
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26 Furthermore, a substantial part of research on DM seems to originate from Europe.
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30 Variations in medico-legal systems between the US and most European countries raise the question
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32 whether the definition of DM, as actions motivated primarily by litigious concerns, holds true in
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34 European countries where physicians are not subjected to tort legislation (20) and if other motives for
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36 performing defensive medical actions are documented in the European literature on DM (27).
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40 41 **Rationale**

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43 Science needs definitions. To our knowledge no systematic review exists of how DM is defined and
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45 understood in the European scientific, medical literature. A systematic review of the term “defensive
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47 medicine” in the European context will provide a more nuanced understanding of this complex and
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49 non-beneficial phenomenon, hereby supporting the quality of future research on the topic.
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53 54 **Objectives**

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The aim of this study is to present a protocol paper for a systematic review with the following objective: To analyse variations in the definitions and understandings of the term “defensive medicine” in European research articles.

METHODS

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination of our research.

Protocol

This protocol for a systematic review is conducted in concordance with the PRISMA-P (Preferred Reporting Items for Systematic Reviews – Protocol) (28).

Eligibility criteria

Publications will be included in the review based on the following criteria:

Inclusion criteria:

1. One or both of the terms “defensive medicine” and “defensive practice” are stated in title or abstract.
2. The study is available in full-text and written in English language.
3. DM is performed by physicians, including general practitioners, as well as physicians from medical, surgical and paraclinical specialities.
4. The study is an original research study (quantitative or qualitative primary research) or systematic review published in a peer-reviewed, medical journal.

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5. DM is stated as part of the study's aim/objective in at least one of the following ways:
 - a. DM is included in the publication's aim/objective.
 - b. DM is implicitly a significant part of the aim/objective.

Further

6. The study's research data includes data from Europe.

Information sources

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

Search strategy

The preparation of search strategy is based on the original American term "defensive medicine". In accordance with the database PubMed, the MeSH term "defensive medicine" is combined with the entry terms "defensive practice", "defensive practices" and "medicine, defensive". On the basis of this, the following search strategy will be used: "defensive medicine OR defensive practice OR defensive practices OR medicine, defensive". All references in the papers fulfilling the inclusion criteria will be examined in order to identify potentially neglected studies. The literature search will be updated before the final analysis. See appendix for detailed search strategy.

Study records

Data management

Publications found by the search strategy will be exported into the reference management software (EndNote) (29) and the software Covidence (30), where the systematic screening and data extraction

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4 will be performed, including the removing of duplicates. Number of citations for each study will be
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6 assessed with Web of Science (31) in concordance with the PRISMA guidelines (28).
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10 11 *Selection process*

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13 Two independent reviewers (NBP and PSJJ) will screen all potentially relevant studies in a two-phase
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15 screening process to ensure interrater reliability, compliance with the inclusion criteria and eligibility
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17 by use of Covidence (30). NBA and PSJJ will discuss and resolve any disagreements to reach
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19 consensus. If consensus is not achievable, a third reviewer (JL) will be involved in the discussion and
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21 finally decide whether the study in question is to be included or not.
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26 27 *Data collection process*

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29 The primary authors (NBP and PSJJ) will extract data from the included studies, including publication
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31 details (author(s), name of journal, year of publication), study characteristics (design, country of
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33 origin, sample size, medical speciality investigated, and number of citations), study objective, stated
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35 definitions of DM and understandings of DM.
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41 **Quality assessment**

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43 The two reviewers (NBP and PSJJ) will independently assess the quality of each study. The
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45 qualitative studies will be reviewed using the Critical Appraisal Skills Programme (CASP) (32),
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47 recommended by the Centre for Clinical Guidelines (CFKR) (33), to ensure a critical and
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49 standardized assessment of the quality and analysis of the study. The quantitative studies will be
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51 reviewed using a cross-sectional appraisal tool with questions adapted from Guyatt GH et al. JAMA
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53 1993 and 1994 (34, 35). The systematic reviews will be reviewed using Assessing the Methodological
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4 Quality of Systematic Reviews (AMSTAR) (36) recommended by the Centre for Clinical Guidelines
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6 (CFKR) (33). Disagreements will be discussed until consensus is reached.
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10 11 **Data items**

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13 Data items are as stated above under “methods”. The design of the review is based on the hypothesis
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15 that a definition of DM reflects the medico-legal system in which it is used. Therefore, we expect the
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17 definitions and understandings of DM stated in the European research literature to be different than
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19 those stated in the literature deriving from the US.
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25 **Data synthesis**

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27 For each paper, the stated definition and understanding of DM will be extracted by the first author
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29 (NBP). The definition of DM will be identified as: “DM is...”, “DM is defined as...”, “DM refers
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31 to...”, or “DM is characterized by...”. If no definition of DM is stated, the way in which DM is
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33 introduced will be identified. A paper’s understanding of DM is assessed from its use in the study
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35 and may differ from the stated definition. Quotes identifying how DM is understood will be extracted
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37 and analysed according to a thematic analysis approach aiming to categorize the different
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39 understandings. Based on the above definitions of DM, it is expected that the vast majority of papers
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41 will define DM as healthcare actions conducted by healthcare professionals during their work, but
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43 that the motives making the actions defensive may differ between papers showing a broader
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45 understanding of DM in some European studies than according to the US definition. Thus, for each
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47 paper, the motives regarded as defensive will be identified in the texts, tables, figures, as well as in
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49 the data collection methods. The identified categories of DM definitions and understandings will be
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51 scrutinized by the author group.
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Outcomes and prioritization

The review's main outcomes will be 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 and a graphical display of the historical trend in the annual number of published European original research papers regarding DM divided on the identified categories of DM definitions. The review will report if any differences in the definitions and understandings of DM between countries and between high- and low-quality papers exist.

Risk of bias in individual studies

Since the objective of this study differs from most systematic reviews by not taking interest in the results found by the reviewed studies, the quality assessment of the identified papers serves a different purpose. The assessment of the quality of the papers is used to show whether high quality papers use a different definition of DM than other papers (see the above described quality assessment procedure). 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.

Conclusion

This systematic review will address the variations in the definitions and understandings of the term "defensive medicine" in European research articles. 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.

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4 **Potential amendments**
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6 We do not envisage any amendments to the present protocol. However, should an amendment be
7 necessary, it will be notified, registered and reported.
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13 **Funding**
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15 This work was supported by “General practitioners’ education- and development fund”
16 (Praktiserende Lægers Uddannelses- og Udviklingsfond) grant number 27.810,00 DKK.
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Conflict of interests

The authors declare that they have no competing interests.

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Appendix

Search strategy from PubMed search string:

defensive medicine OR defensive practice OR defensive practices OR medicine, defensive

("defensive medicine"[MeSH Terms] OR ("defensive"[All Fields] AND "medicine"[All Fields]) OR "defensive medicine"[All Fields]) OR ("defensive medicine"[MeSH Terms] OR ("defensive"[All Fields] AND "medicine"[All Fields]) OR "defensive medicine"[All Fields] OR ("defensive"[All Fields] AND "practice"[All Fields]) OR "defensive practice"[All Fields]) OR ("defensive medicine"[MeSH Terms] OR ("defensive"[All Fields] AND "medicine"[All Fields]) OR "defensive medicine"[All Fields] OR ("defensive"[All Fields] AND "practices"[All Fields]) OR "defensive practices"[All Fields]) OR ("defensive medicine"[MeSH Terms] OR ("defensive"[All Fields] AND "medicine"[All Fields]) OR "defensive medicine"[All Fields] OR ("defensive medicine"[All Fields] OR ("medicine"[All Fields] AND "defensive"[All Fields]))

PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 4:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	x		1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such		x	
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	x		2
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	x		2-3
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	x		3
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments		x	
Support					
Sources	5a	Indicate sources of financial or other support for the review	x		3
Sponsor	5b	Provide name for the review funder and/or sponsor	x		12
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	x		3
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	x		6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	x		6-7
METHODS					

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	x		7-8
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	x		8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	x		8
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	x		8-9
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	x		9
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	x		9
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	x		10
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	x		11
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	x		11
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	x		10
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2 , Kendall's tau)		x	
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)		x	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	x		10
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)		x	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)		x	