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How does communication affect patient safety? Protocol for a systematic review and logic model

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ABSTRACT

Introduction One in 10 patients are harmed in healthcare, more than three million deaths occur annually worldwide due to patient safety incidents, and the economic burden of patient safety incidents accounts for 15% of hospital expenditure. Poor communication between patients and practitioners is a significant contributor to patient safety incidents. This study aims to evaluate the extent to which patient safety is affected by communication and to provide a logic model that illustrates how communication impacts patient safety.

Methods and analysis We will conduct a systematic review of randomised and non-randomised studies, reported in any language, that quantify the effects of practitioner and patient communication on patient safety. We will search MEDLINE, CINAHL, APA PsychINfo, CENTRAL, Scopus and ProQuest theses and dissertations from 2013 to 7 February 2024. We will also hand-search references of included studies. Screening, data extraction and risk of bias assessment will be conducted by two independent reviewers. Risk of bias will be assessed using the Cochrane Risk of Bias in Non-Randomised Studies of Interventions (ROBINS-I) for non-randomised studies, and the Cochrane Risk of Bias V.2 (RoB2) for randomised controlled trials. If appropriate, results will be pooled with summary estimates and 95% confidence intervals (CIs); otherwise, we will conduct a narrative synthesis. We will organise our findings by healthcare discipline, type of communication and type of patient safety incident. We will produce a logic model to illustrate how communication impacts patient safety.

Ethics and dissemination This systematic review does not require formal ethics approval. Findings will be disseminated through international conferences, news and peer-reviewed journals.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This planned systematic review will provide an up-to-date estimate of the effect of poor communication (both practitioner–patient and practitioner–practitioner communication) on patient safety.
⇒ This study may further our understanding of the relationship between different types of communication and patient safety incidents.
⇒ We will provide a logic model that illustrates how communication affects patient safety.

INTRODUCTION

Rationale

One in 10 patients are harmed in healthcare, and more than three million deaths occur annually worldwide due to patient safety incidents.[1] In the UK, over 1700 lives are lost per year because of medication errors alone,[2] and between April 2022 and June 2022 alone, 652 246 patient safety incidents were reported in England.[3] In the US in 1999, the Institute of Medicine[4] reported that between 44 000 and 98 000 people in the US die annually from preventable errors. The situation is getting worse and now over 160 000 avoidable deaths occur yearly in the US due to preventable errors.[5] Internationally, over 50% of patient harm is preventable[6] and is attributed largely to medication errors.[7] Notably, the *actual* number of patient safety incidents is expected to be greater than those *reported*,[8] because a culture of blame within healthcare systems makes practitioners fear reporting patient safety incidents.[9 10]

Patient safety incidents also impose an economic burden.[1] In high-income countries, up to 15% of hospital expenditure is attributed to resource wastage following lapses in patient safety.[1] For example, the National Health Service (NHS) lost £1.63 billion to litigation costs because of patient safety incidents between 2017 and 2018.[11] Moreover, medication errors cost the NHS upwards of £98 million per year.[2] Things are similar in the US, where the cost of medication errors exceeds $17 billion per year[12] and in Europe, where medication errors cost up to €2 billion per year.[13]

Although the causes of patient safety incidents are multifaceted,[1] research shows that ineffective communication contributes to unexpected care events and adverse care outcomes.[14–16] The Joint Commission, a non-profit organisation responsible for objectively

evaluating US healthcare organisations, reported that poor communication is a contributing factor in over 60% of all hospital adverse events in the USA.[17] Both poor communication between healthcare practitioners, and between practitioners and patients can result in misunderstandings that lead to medical errors through misdiagnosis or suboptimal treatments.[18] In some cases, the poor communication between practitioners and patients can lead to life-threatening complications.[18] Relatedly, poor communication between healthcare practitioners during patient hand-offs can cause critical information to be lost,[19] resulting in subsequent harm to patients. Both the Francis Report[20] and the Ockenden Report[21] in the UK cited a lack of effective communication as a cause of unnecessary deaths at the Mid-Staffordshire NHS Foundation Trust and the Shrewsbury and Telford Hospital NHS Trust respectively, and the UK health ombudsman cited poor communication as a cause of 48 000 avoidable sepsis deaths each year.[22]

Several reviews have explored the effects of poor communication on patient safety, showing that ineffective communication leads to adverse events, delays in treatment, medication errors and wrong-site surgery.[23–26] However, these reviews have been limited to specific dimensions of patient safety (such as medication errors),[25] particular healthcare disciplines (such as pharmacy or medicine)[23 26] or particular forms of communication (such as practitioner to practitioner).[26] Moreover, several studies have been published[27–29] since the most recent review was completed in 2018, but these new studies have not yet been synthesised.

This study aims to provide an up-to-date synthesis of the extent to which patient safety is affected by communication and to provide a logic model that illustrates how communication affects patient safety.

Definition of patient safety

Patient safety is defined by the WHO as 'A framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make errors less likely and reduce the impact of harm when it does occur'.[1] The Institute of Medicine[4] defined safety as 'freedom from accidental injury' and NHS described patient safety as 'the avoidance of unintended or unexpected harm to people during the provision of healthcare'.[30] The European Commission also considered patient safety as 'the absence of preventable harm to a patient during the healthcare process'.[31] We acknowledge the heterogeneity of definitions of patient safety, and will extract and report definitions of patient safety from the primary studies included in our proposed review.

Types of patient safety incidents

There are three main categories of patient safety incidents: (1) adverse events (injuries related to medical management such as death, life-threatening illness or disability),[4] (2) medical errors (including failure to carry out a planned action as intended or application of an incorrect plan that may or may not lead to an adverse event)[4] and (3) near misses or close calls (errors that have the potential to cause adverse events but do not reach the patient due to chance, corrective action and/or timely intervention).[4] There are several subcategories within these categories. From the first category (adverse events), a never event is considered the most egregious of patient safety incidents. Never events are adverse events that are wholly preventable, such as wrong-site surgery.[32] A sentinel event is a type of adverse event that was defined by the Joint Commission as an unexpected, potentially avoidable occurrence that resulted in death or serious physical or psychological injury to a patient. Despite being distinct, the terms 'never event' and 'sentinel event' are often used interchangeably.[33] The second category (medical errors), typically includes surgical, diagnostic and medication errors, and are broadly categorised as either errors of commission (taking the wrong action) or errors of omission (not taking the correct action).[4 34] The third category (near misses) can be divided into incidents that do not reach the patient because of formal and planned interventions, and incidents that do not reach the patient because of chance or unplanned intervention.[35] We consider all type of patient safety that provided in this section in this review. Figure 1 summarises the different categories of patient safety incidents and their subcategories.

Measuring patient safety incidents

Patient safety incidents are measured in a number of different ways, including patient reports, voluntary error reporting systems, automated surveillance, and chart reviews.[36] We anticipate that patient safety incidents will be measured in these standard ways but will also include studies that measure patient safety incidents using other measures. We will extract details about the measures used and describe them.

Types of communication (and definition of poor or ineffective communication)

There are several types of communication related to patient safety. The main type is communication between the patient (or carer) and practitioner.[23] However, communication between practitioners (both interprofessional and intraprofessional) can also affect patient safety.[26] Within each type of communication, there are different modes of communication, including verbal and written (including letters, emails, notes and text messages),[23] all of which could have an effect on patient safety. Figure 2 summarises different types of communication.

Poor communication is often contrasted with *effective* communication, which has been defined as verbal speech or other methods of relaying information to get a point across.[37] Ineffective or poor communication, therefore, involves lack of precise, accurate, meaningful and relevant information having been exchanged and

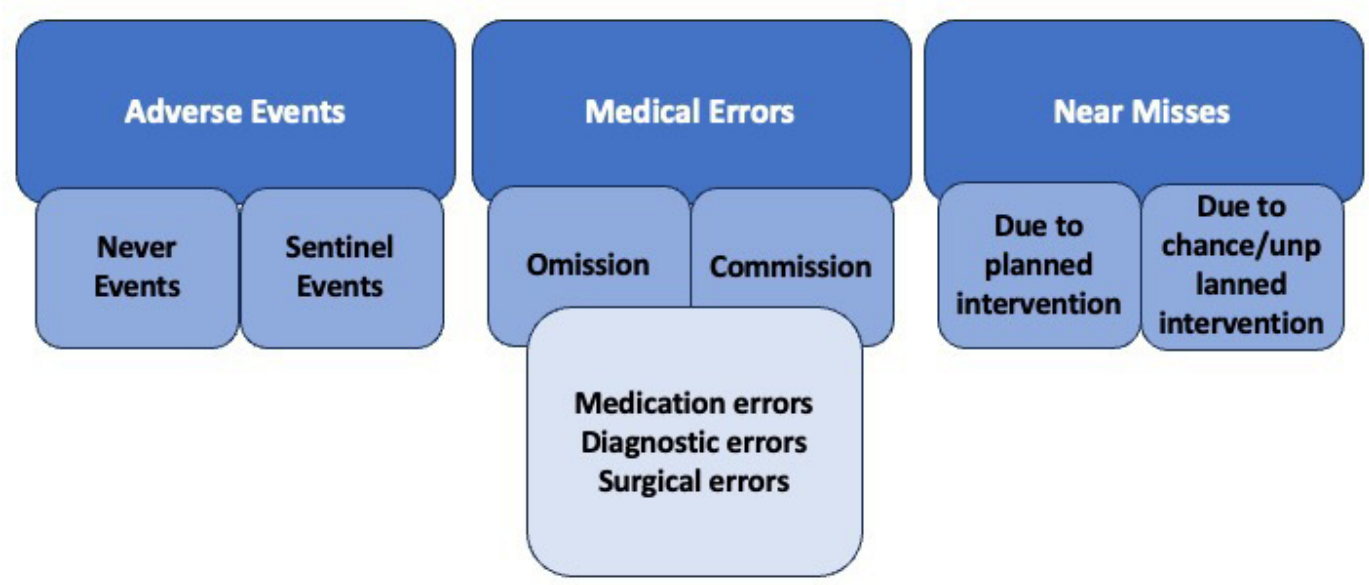

Figure 1 Categories and subcategories of patient safety incidents.

understood. Examples of poor communication between healthcare practitioners and patients include failure to adequately explain medical procedures, test results or treatment plans in a way that patients can understand. An example of poor communication between healthcare practitioners is when handoffs between healthcare practitioners omit essential information. Of note, definitions of ineffective or poor communication are often not provided in primary studies.[38] To address this problem with the primary studies in this area, we will extract and report on the definitions of poor or ineffective communication from the primary studies, and, if feasible, conduct a subgroup analysis.

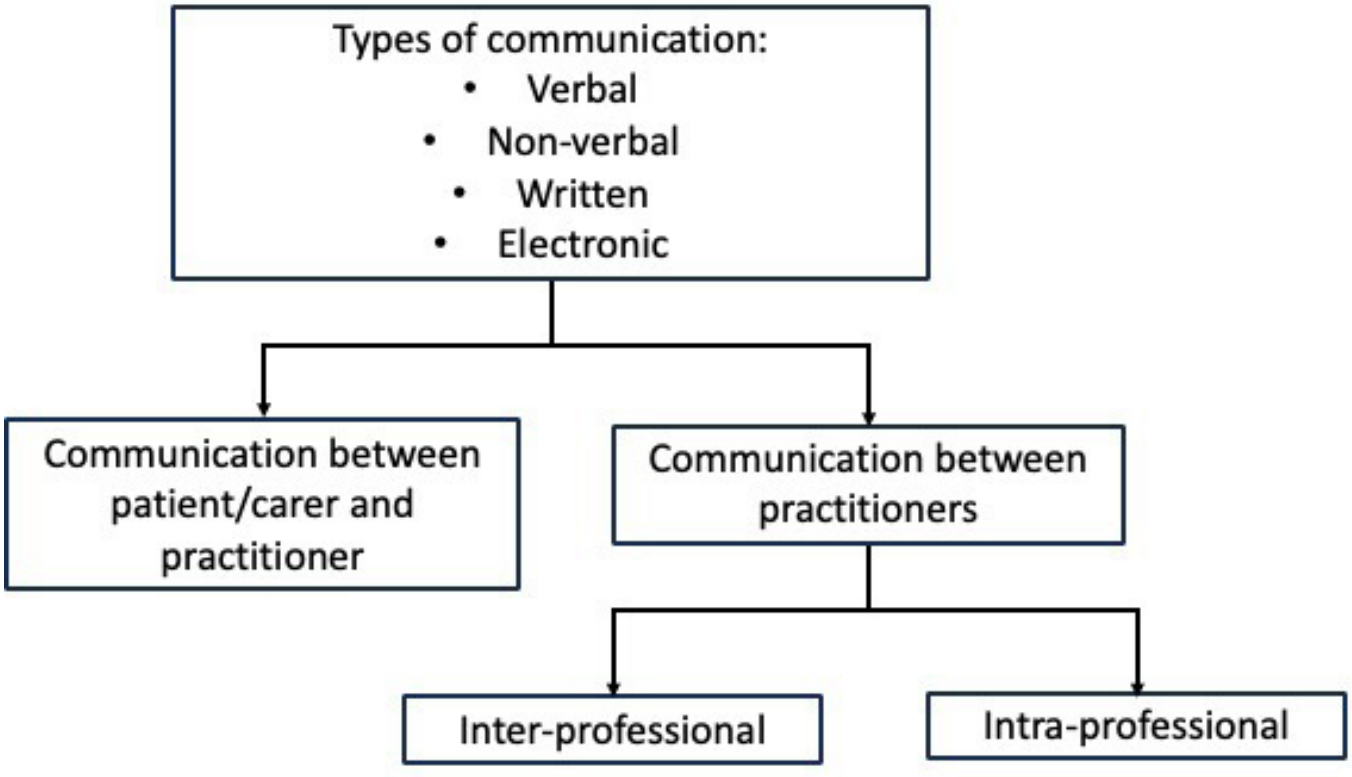

Figure 2 Different types of communication.

Table 1 Inclusion and exclusion criteria using PICO and other relevant criteria

Element	Inclusion	Exclusion
Population-participants	Patients.	Healthy volunteers, participants outside of a healthcare setting.
Population-practitioners	Healthcare practitioners (any).	–
Intervention	Written, verbal or non-verbal communication between (1) healthcare practitioner and patient, (2) between healthcare practitioners, (3) non-clinical staff to clinical staff, (4) non-clinical staff to patients and (5) non-clinical staff to non-clinical staff (including lack of communication, poor communication or effective communication).	–
Comparison	For studies that compare different more or less adequate: less adequate communication. For studies that do not have a control group: n/a.	–
Outcomes	Patient safety incidents (including adverse events, medical errors and near misses).	Studies that do not include and measure patient safety incidents as an outcome.
Study design	Any study that quantitatively reported patient safety incidents.	Systematic reviews Narrative reviews
Language	Any	–
Timing of intervention	Any	–

n/a, not applicable.

METHODS AND ANALYSIS

This protocol has been described using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P).[39]

Eligibility criteria

Studies will be selected according to the criteria outlined in Table 1 and described below.

Participants

We will include studies with any clinical patients of any age treated by any healthcare practitioner, and healthcare practitioners of any age from any discipline (e.g., medicine, nursing and midwifery). We will exclude studies conducted in a non-clinical setting (e.g., with simulated patients or healthy volunteers). We will include studies with non-human practitioners (such as care-bots or chatbots), but analyse these in a separate sub-group.

Intervention

The intervention is communication (including a lack of communication, poor communication and effective communication) between healthcare practitioners and patients/carers, or between healthcare practitioners (including both intraprofessional and interprofessional communication). Studies of written, verbal, electronic and non-verbal communication will all be included.

Comparator

For studies comparing more or less adequate communication, the comparator is less adequate communication. For studies that do not have a control group, there is no comparator.

Outcome

The main outcome will be patient safety incidents, including adverse events, medical errors (including errors of commission and errors of omission), and near misses.

Study design

We will include any study that quantitatively classifies patient safety incidents.

Language

We will include articles reported in any language. For the articles that were not published in English, we will use translator software and/or reviewers who are fluent in that language.

Timing of intervention

We will include studies which considered the relationships between communication and patient safety for any time lag between the communication and the patient safety incident.

Information sources

We will search the following databases: MEDLINE, CINAHL, APA PsychINfo, CENTRAL, Scopus and ProQuest theses and dissertations from 2013 to 7 February 2024. We will also manually search the reference lists of the included studies to identify additional relevant studies. The cut-off date was chosen to ensure relevance to current practice. The Francis report into the quality and safety failings at the Mid Staffordshire NHS Foundation Trust was published in 2013 and made 290 recommendations to enhance the safety of healthcare, including improving communication with and about

patients.[20] Following the report, the UK Government, the Care Quality Commission (CQC), and several other regulatory bodies (including the National Institute for Health and Care Excellence, National Quality Board, General Medical Council and The Royal College of Physicians) implemented new quality guidelines and strategies for improving the quality and safety of NHS care.[40] Moreover, the size of the inquiry and its importance in patient safety meant that its impact was felt beyond the UK.[41]

Search strategy

The search will consist of a combination of controlled vocabulary terms and natural language keywords, combined using appropriate Boolean operators. The search strategy will be developed by an information specialist (KN). A PRISMA[42] flow diagram will be completed (see online supplemental file 1 for the proposed search strategy for all databases). The search strategy was peer-reviewed, and the results of the review will be reported according to using the Peer Review of Electronic Search Strategies (PRESS) checklist (see online supplemental file 2).[43] A PRESS peer review involves the person requesting the peer review (requestor) and the person completing the peer review (reviewer). The requestor first fills out the pertinent information in the PRESS guideline form for the primary search strategy (MEDLINE for our review). The form is then sent to an independent reviewer who appraises the search in accordance with the PRESS.[43]

Study records: selection process

All references will be imported into Covidence.[44] All titles and abstracts will be screened for eligibility by two independent reviewers. Any discrepancies will be resolved in discussion and by a third reviewer if necessary. Full-texts will also be screened independently by two reviewers. Disagreement between reviewers regarding item eligibility at either stage will be resolved by reaching a consensus with a senior reviewer (JH). Studies that are excluded will be recorded in a table with reasons for exclusion. The study selection process will be presented in a complete PRISMA flowchart, showing the number of studies excluded at each stage of screening.

Study records: data management

Search results for initial and supplemental searches will be recorded in EndNote. Results will be exported to Covidence for screening. This software package will be used to manage the screening process including the title and abstract screening and full-text screening. Papers meeting the eligibility criteria will be forwarded to the data extraction stage of the review process.

Study records: data extraction

Data will be extracted by two independent reviewers into a bespoke extraction sheet, tailored to the individual study design, in Covidence. Two reviewers will independently extract data for each included study. Then, we will summarise the main findings and apply GRADE (Grading of Recommendations, Assessment, Development and Evaluations)[45] to each of these outcomes.

Data items

Patient safety incidents, as defined above, are the primary outcome of this study. The following data will be also extracted:

- Administrative information: study ID, name/ID of person extracting data, reference citation, study author contact details, publication type.
- General demographics: first author, date published, study's country.
- Study eligibility: type of study, participants, types of intervention, types of outcome measures, reasons for exclusion.
- Characteristics of included studies: the aim of study, design, start date, end date, duration of participation and ethical approval needed/ obtained for study.
- Participants: population description, setting, inclusion criteria, exclusion criteria, method of recruitment of participants (e.g., phone), (if relevant) informed consent obtained.
- Interventions: description of the intervention.
- Outcomes: the value of the main measure of association between communication and patient safety.
- Risk of bias.
- Type of patient safety incident (eg, adverse event, never event, medical error (of commission or omission), medication error or near miss).
- Type of communication (eg, practitioner–patient, practitioner–practitioner (including intraprofessional and interprofessional communication) written, verbal and non-verbal).
- Contextual information (eg, the context in which communication/patient safety incidents took place, which healthcare professions were involved, and the content of the communication).
- Definition of ineffective or poor communication.
- Type of patient safety incident measurement.
- The time between communication and safety incidents.
- (Including from introduction or discussion) how the authors believe communication impacts on patient safety.
- Where reported, mediator or moderator variables.

Quality assessment

Study risk of bias assessment

We will assess the risk of bias of included studies using the Cochrane Risk of Bias in Non-randomised Studies of Interventions (ROBINS-I)[46] tool for non-randomised studies, and the Cochrane Risk of Bias tool V.2 (RoB 2)[47] for randomised controlled trials. The ROBINS-I tool assesses domains of bias preintervention, at intervention and postintervention.[46] Signalling questions support the assessment of the risk of bias in each domain. The categories for risk of bias judgements are 'low risk', 'moderate risk', 'serious risk' and 'critical risk' of bias.[46] RoB 2

involves the clear reporting of individual elements of an RCT including random sequence generation, allocation sequence concealment, blinding (participants and personnel), blinding (outcome assessment), completeness of data and selective outcome reporting.[47] Two authors will independently assess the risk of bias and disagreements will be resolved in discussion with a third author.

Certainty assessment

We will use the GRADE to evaluate the overall quality of evidence.[45] The quality of evidence will take into account the risk of bias, inconsistency, indirectness, imprecision and publication bias. Additional domains may be considered where appropriate. Quality will be refereed as high (further research is very unlikely to change our confidence in the estimate of effect), moderate (further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate), low (further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate), or very low (very uncertain about the estimate of effect). The GRADEpro software[48] will be used to prepare the summary of the findings table.

Synthesis methods

If there are at least three sufficiently similar studies, we will pool the studies using a random effects model. If so, we will use aggregate (not use individual patients) data. We will use RevMan[49] for meta-analysis. Results for all main outcomes will be provided, with an indication of the number of included studies and participants for each. If meta-analysis is completed, a report of the summary estimate and confidence interval will be provided. If comparing groups, the direction of the effect (i.e., which group is favoured) will be indicated.

Where statistical synthesis is not possible (due to insufficient similarity), we will conduct a systematic narrative synthesis. Information will be provided in the text and in tables to summarise and explain the results of the included studies. We will follow narrative synthesis guidelines[50] to ensure rigour. Our narrative synthesis will be organised by the type of patient safety incident and the type of communication. If a narrative synthesis is conducted, we will follow the 'synthesis without meta-analysis' (SWiM) reporting guidelines.[51]

Effect measures

If data are pooled, dichotomous outcomes will be analysed by considering the risk ratio with a 95% confidence interval. Continuous outcomes will be analysed using weighted mean differences (with 95% confidence interval) or standardised mean differences with 95% confidence intervals if different measurement scales are used. Skewed data and non-quantitative data will be presented descriptively.

Analysis of subgroups or subsets

If sufficient data are available, we will conduct subgroup analyses based on the factors listed below:

- Type of communication (practitioner to practitioner or practitioner to patient/carer).
- Mode of communication (written, verbal and non-verbal).
- Definition of poor or ineffective communication.
- Type of patient safety incident (adverse event, medical error, or near miss).
- Geographic location (continent).
- Studies with human versus non-human practitioners.
- Type of patient safety incident measurement.
- Different healthcare settings (e.g., primary and secondary)

We will also perform a sensitivity analysis excluding studies that are rated to be at a greater risk of bias or exceptionally large effect size.

Logic model

Logic models are diagrams that map out intervention(s), outcome(s) and the mediating and moderating factors between the intervention(s) and outcome(s).[52] Logic models adopt a left to right flow of 'if … then' propositions, to outline how an intervention leads to short and/or long-term outcome(s).[53] Using extracted data from the included studies, we will develop a logic model to illustrate why and how communication affects patient safety. Underpinned by the evidence, the model will include the type(s) of intervention, the moderating and mediating factor(s) and the long-term outcome(s) and impact.[53] Each section of the model will be developed systematically based on the data extracted from the included studies.

Project timeline

The timeframe to complete this project is 12 February 2024 to 31 May 2024.

Patient and public involvement

One patient representative (JB) is a coauthor of the study. JB is the patient and public involvement colead for the quality safety and outcomes policy research unit, which is charged in part with providing research evidence of patient safety within health and social care. JB contributed to the review of this protocol, made specific suggestions for improving the protocol and edited the main messages of the protocol to make sure they were understandable and relevant to a non-specialist audience.

ETHICS AND DISSEMINATION

This systematic review will not collect any primary data and does not require formal ethics approval. Findings will be disseminated through international conferences, news and peer-reviewed journals.

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Contributors JH drafted the first version of the protocol, AB-W, LK and JS further developed it. JB reviewed, suggested improvements and edited the protocol. All authors edited and contributed to the protocol. KN developed the search strategy.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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