

# BMJ Open Public and patient involvement (PPI) in health policy decisionmaking on the health system-level: protocol for a systematic scoping review

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## ABSTRACT

**Introduction** Public and patient involvement (PPI) in healthcare decisions at the health system-level (macro-level) has become increasingly important during recent years. Existing evidence indicates that PPI increase patient centredness and the democracy of healthcare decisions as well as patients' trust and acceptance of these decisions. However, different methods for PPI exist, and an overview of the outcomes and influential contextual factors has not yet been conducted. Therefore, this scoping review aims to provide an overview of the different methods used for PPI in health system decisionmaking and the reported outcomes and contextual factors for these methods.

**Methods and analysis** The structure of this protocol is guided by the advanced scoping studies framework of Arksey and O' Malley, developed by Levac, Colquhoun and O'Brien, and the PRISMA-ScR Statement. We will systematically search electronic databases (MEDLINE, Cochrane Library, Scopus, CINAHL, PDQ-Evidence, Web of Science and PsycINFO) for peer-reviewed literature and screen the reference lists of included studies. Additionally, we will search for relevant grey literature and consult experts from the field to identify further information. Studies focusing on PPI in the context of health policy decision-making at the macro-level will be eligible for full-text screening. Studies focusing on decisions at the individual treatment-level (micro-level) and the organisational-level (mesolevel) as well as those dealing with PPI in health research will be excluded. A qualitative analysis will dissect how the included studies define PPI and its desirable outcomes, the achieved outcomes and reported contextual factors.

**Ethics and dissemination** We will present the results at relevant conferences and in an open-access journal. Additionally, we will share them with the experts involved in the research process and consider ways in which to transfer the findings into practice. As only secondary and previously published information will be used, ethical approval is not necessary.

## INTRODUCTION

Healthcare systems aim to promote, restore or maintain the health of a population. Therefore, they should be responsive to the needs and expectations of the public.<sup>1 2</sup> As a consequence, there has been a growing

## Strengths and limitations of this study

- A comprehensive literature search strategy, including a search for peer reviewed and grey literature, will be implemented to identify relevant information.
- Experts in the field of public and patient involvement (PPI) in health system decision-making will be consulted to identify additional sources of information and to develop a strategy by which to transfer the research findings into practice.
- The charting and interpretation of the research findings builds on the existing frameworks of PPI in health system decisionmaking.
- Due to limited resources, title and abstract screening will be conducted by two independent reviewers only for a random sample comprising 10% of the identified documents. After the inclusion and exclusion of the screened documents has been discussed and a consensus has been reached, the first author (LAB) will screen the remaining documents alone. The same procedure will be used for the full-text analysis.
- Despite the comprehensive search strategy, it is possible that some relevant articles may not be identified.

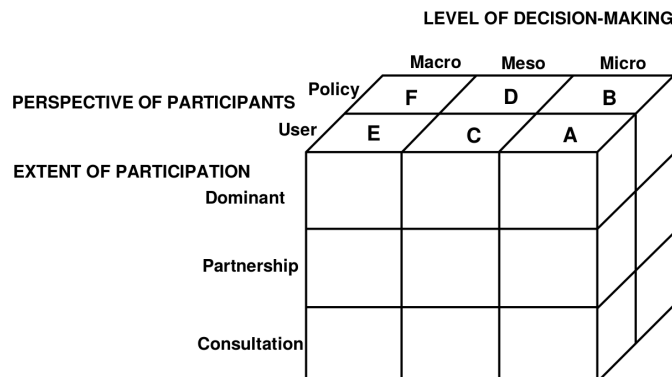
debate during past decades about involving patients and the public in the process of making system-level health policy decisions (macro-level) such as health services planning, resource allocation and priority setting.<sup>1 3-7</sup> Different methods are used to achieve this involvement, including citizen juries, advisory committees, public hearings or consensus conferences.<sup>8</sup>

The definition of public and patient involvement (PPI) in health system decision-making is not uniformly established.<sup>1 3 7 9</sup> In addition to the term 'involvement', a variety of other terms such as 'participation' and 'engagement' are used in the literature to describe a process of decisionmaking carried out in cooperation with patients and the public.<sup>3</sup> Regarding the individuals involved

in these decision-making processes, some authors distinguish between patient involvement and citizen involvement,<sup>4 10 11</sup> whereas others view patients and citizens as one group.<sup>1 6 12–14</sup> The distinction between these terms is mainly due to an assumption that these two groups have different interests. Citizens are thought to have a more general and societal interest in healthcare, whereas patients are thought to have individual interests based on their diseases.<sup>1 4 10 11</sup> In addition to varying definitions of terms, the extent of public and patient participation also varies, as well as the level at which the participatory action takes place.<sup>1 3 15</sup>

To enable a better conceptual clarity of PPI in healthcare decision-making, several frameworks exist.<sup>16</sup> A frequently mentioned generic framework is the participation ladder of Arnstein,<sup>17</sup> where eight steps represent citizen's level of power in decision-making. The framework considers only one dimension: the extent of participation. The level of participatory action (eg, in individual treatment decisions or health system decisions) as well as the group of participants (eg, patients or citizens) is missing.<sup>16 18</sup> Further rather specific frameworks exist.<sup>19 20</sup> The somewhat more general framework of Carman *et al*<sup>21</sup> considers the level of participatory action (micro-, meso- and macro-level) and the extent of participation (ranging from consultation to shared leadership). Due to its focus on patient participation, the group of participants is still missing.<sup>16</sup> Another framework, which considers all three dimensions, is the one of Charles and DeMaio.<sup>12</sup> Regarding the group of participants, this framework does not differentiate between patients and citizens; rather, it differentiates between the perspectives that people adopt during the decision-making process (single-service user or member of the society, described with policy in the framework). The extent of participation is divided in three levels, ranging from consultation, where the final decision-making power still lies with the traditional decision-makers (eg, politicians and health service providers), over partnership-based decision-making processes to citizen control, where the citizens have full decision-making power (described with dominant). The level of participatory action is classified into treatment-, service- and macro-domain: the domain of treatment addresses the involvement of patients in their individual treatment, the service-domain concerns specified service regions or healthcare organisations and the macro-domain involves the whole healthcare system- on a national-, state- or province-level (eg, financing and organisation of service provision). An example for PPI at the service-domain would be the involvement of community members in planning and setting up a public healthcare intervention in their service region. In contrast, an PPI intervention at the macro-domain could be the involvement of citizens in decisions regarding the allocation of financial resources to different healthcare services at national level.

As the three-dimensional framework of Charles and DeMaio is easy to apply and support a comparative analysis



**Figure 1** Dimensions of PPI in healthcare decisionmaking adapted from the framework of Charles and DeMaio.<sup>12</sup>

between PPI methods, we decided to use this one for the purpose of our scoping review. We have made some minor linguistic adjustments according to Carman *et al*, as these terms are used more frequently in the current literature of PPI in healthcare decisions. We differentiate therefore between decisions at the micro-level (treatment), meso-level (service) and macrolevel with regard to the domain of participatory action. Additionally, we use the term extent to describe the level of participation in order to avoid using the same term for different dimensions (figure 1).

As PPI gets more and more attention, the question arises, why it is currently necessary to increase PPI in health system decision-making? The relevant literature provides several theoretical arguments. The first argument concerns fairness within the decision-making process. The public funds the healthcare system (either through taxes, employer contributions or out-of-pocket payments) and is mainly impacted by decisions about funding or the organisation of healthcare. Therefore, they should be involved in such decisions.<sup>22</sup> Second, members of the public are users of health services and can provide valuable information about what works in practice and what does not.<sup>13 22–24</sup> Thus, it is possible for example to gain insights into negative treatment results, medical errors or difficulties accessing healthcare services. Therefore, service quality and patient orientation can be enhanced by taking patients' perspectives into account. Third, considering the viewpoint of citizens and patients could represent a means by which to protect patients' interests and increase patients' safety. Information asymmetries among health service providers and patients can lead to supply-induced demand,<sup>24–26</sup> and the economic interests of health service providers and financiers increase the risk of incorrect treatment (eg, overuse, underuse or misuse).<sup>24 27</sup> These issues negatively impact the well-being of patients.<sup>27</sup> Including the perspective of the public and of patients alongside those of health service providers and health insurance companies in health system decisions could help to prevent biased decisions.<sup>24</sup> Fourth, an increased level of public trust in the healthcare system and a greater acceptance of political decisions are mentioned as further arguments supporting

PPI in health system decisionmaking.<sup>11 23 28</sup> Finally, the proponents of PPI see the participation process as a desirable outcome itself, because it is an expression of a democratic society and increases transparency.<sup>1 29</sup>

The outcomes that are or that can be expected in practice from increased PPI in health system decision-making are not sufficiently agreed on; clear definitions of the aims and, therefore, of the desired outcomes of PPI in health system decisionmaking are missing.<sup>3 7 30</sup> Due to the large number of outcome parameters used in the literature, the aims of PPI vary. Several studies assume that macro-level PPI produces positive outcomes in organisation and provision of healthcare. According to these studies, PPI leads to an improved quality of care and better access to provided healthcare services<sup>30–33</sup> and increases user responsiveness and satisfaction.<sup>15 30 33 34</sup> New services have been developed, and healthcare priorities have been changed through the involvement of the public.<sup>15 34 35</sup> In addition, political decisions regarding resource allocation made in cooperation with the public are more widely accepted and better meet the expectations of citizens.<sup>36</sup> The exact outcomes that can be considered successful or efficient are not yet consistently established, making a comparison of the different PPI interventions difficult.

However, there is consensus about the importance of the context in which PPI occurs and that the outcomes of specific methods are not necessarily the same when applied to different situations.<sup>6 29 31 37 38</sup> Abelson *et al*<sup>38</sup> and Pagatpatan *et al*<sup>7</sup> identified some key areas of important contextual factors that should be considered when evaluating PPI in health system decision-making. One area relates to the political environment; this includes the political system, legislation and opportunities for participation, the commitment of leadership and the historical relationship between the public and the government. The subject or health problem that is addressed during a participation process is also important, as different subjects may have differing levels of relevance to the public. Furthermore, the attributes of the participants (eg, the diversity and characteristics of these participants and their participation preferences) represent a relevant contextual factor. Abelson *et al*<sup>38</sup> additionally viewed the relationship between researchers and decision-makers as an additional contextual factor when studying the effects of PPI because this relationship can make a difference if there is an ongoing research partnership or if decisionmakers have earlier experiences with participatory processes.

The previous reviews that have addressed the issue of PPI in health system decisionmaking have been limited to specific types of health system decisions (eg, priority setting<sup>6</sup>), methods of participation,<sup>39</sup> countries (eg, UK<sup>40–42</sup>), care settings (eg, disabled people,<sup>32 43</sup> hospitals,<sup>44</sup> mental health,<sup>33</sup> family planning<sup>45</sup> or rural health<sup>35</sup>) or study designs (eg, randomised controlled trials<sup>34</sup> or systematic reviews<sup>46</sup>). Additionally, some of these reviews mainly focus on meso-level decisions<sup>33 40 42 44 47–49</sup> rather than on macro-level service design and policy making.

Some of the reviews that considered macro-level decisions concentrated on patient participation rather than on broader public participation<sup>15</sup> or mostly focused on outcomes rather than on specific contextual factors that lead to these outcomes.<sup>30 31 50</sup> Pagatpatan and Ward<sup>7</sup> performed a realist synthesis of the underlying contextual factors of PPI on a theoretical level. However, the influence of contextual circumstances on the outcomes of different PPI methods is still unclear.<sup>7 14 29–31 34 37 51</sup>

## STUDY RATIONALE

The existing reviews on this subject are limited in terms of their focus and concentrate more heavily on the outcomes of PPI than on the contextual factors affecting it and the performance of different methods. Because of this, to our knowledge, there is no scoping review to date that gives an overview of the PPI methods used in health policy decision-making at the macrolevel, their desired and practically achieved outcomes and which contextual factors were reported to impacted the overall performance.

## STUDY OBJECTIVES

This scoping review focuses on giving an overview of the evidence for PPI methods used in health policy decision-making at the macrolevel. The main objectives of this review are as follows:

- To examine how PPI and its effectiveness in macro-level health policy decisionmaking are defined in the literature and to assess the outcomes that are used to measure the effectiveness of PPI in this context.
- To provide an overview of the methods used to implement PPI in macro-level health policy decisionmaking, which outcomes were desired and achieved by different methods as well as the contextual factors that were reported.

## METHODS

### Protocol design

The structure and content of this review protocol is guided by the scoping studies framework developed by Arksey and O'Malley's,<sup>52 53</sup> which was refined by Levac, Colquhoun and O'Brien's,<sup>52 53</sup> the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) Statement and the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) Statement.<sup>54</sup> Because the aim and extent of a scoping review is different than that of a systematic review, three of the elements of PRISMA-P will be excluded (assessing the risk of bias assessment and meta-biases as well as assessing evidence strength).<sup>55</sup> Therefore, this review protocol provides an overview of the following steps: identifying the research question (step 1); identifying the relevant studies (step 2); selecting the relevant studies (step 3); charting the

**Table 1** Elements of the PCC framework used for the development of the research questions and the related search terms

PCC element	Operationalisation	Search terms
Population	Patients and the public	citizen OR public OR patient OR lay OR user OR community OR consumer
Concept	Involvement (eg, methods, outcomes and context)	participation OR involvement OR engagement OR PPI
Context	Health policy decision-making on the macrolevel	health policy OR policymaking OR health planning OR priority setting OR health system

data (step 4); collecting, summarising and reporting the results (step 5); and conducting the stakeholder consultations (step 6).

### Step 1: identifying the research question

The main research question was defined in accordance with the PCC framework (population, concept and context) (table 1).<sup>55</sup>

According to the three elements of the above-mentioned framework, the main research question is: ‘Which methods of PPI are used in macro-level health policy decision-making, which outcomes were measured and which contextual factors are reported?’.

We further define the elements as follows: we use the term public in our scoping review, including patients in this definition because patients are also members of the public; thus, a clear distinction between the interests of the public and those of patients is not possible.<sup>1 13</sup> We further include persons who are not currently involved in health policy as central decision makers in our definition of the public. Involvement will be used as an umbrella term that includes all the terms describing decision-making processes carried out in cooperation with the public (as described in the Introduction).<sup>3</sup> Macro-level decisions are defined in accordance with the theoretical framework established by Charles and DeMaio;<sup>12</sup> this framework has already been described in the introduction section.

Therefore, we will be searching for studies that focus on PPI in the context of decisions that have interinstitutional and system-wide impacts rather than decisions that only impact a few institutions or a specific community involved in healthcare programmes.

### Step 2: identifying the relevant studies

Because the aim of a scoping review is to provide an overview of the existing evidence, a broad search strategy incorporating different sources is needed.<sup>55</sup> Primary peer-reviewed literature will be included as well as empirical grey literature without date restriction. Grey literature is not uniformly defined and varies based on search topic.<sup>56 57</sup> Because of the topic of our scoping review and the resources available to us, we will include journal articles, institutional reports, conference proceedings and academic dissertations that are available online in our search for grey literature. The reference lists of the included studies will be screened to identify additional eligible studies. Relevant systematic reviews that are

identified will be used as sources of additional primary research.

Systematic electronic literature searches will be conducted in January 2021 within the following databases: MEDLINE (via PubMed), Cochrane Library, Scopus, CINAHL, PDQ-Evidence, Web of Science and PsycINFO. Additionally, certain databases of grey literature (Grey Literature Report and Open Grey), web search engines (Google Scholar) and websites of relevant organisations (eg, WHO, NHS, IAP2 and Canadian Foundation for Healthcare Improvement) will be searched for empirical grey literature. The search terms will be piloted against some relevant articles to ensure that the relevant literature will be identified by the search strategy.

The search terms that will be used are based on the PCC framework and are summarised in table 1. The comprehensive search strategy to be used for searching the MEDLINE database via PubMed is listed in box 1. In databases, where a search with a combination of direct phrases and truncation is possible, we will use truncation as well for concept terms. This search is restricted to the English and German languages. When searching for grey literature, the search terms will be simplified or reduced when it is not possible to use the entire search strategy.

### Step 3: study selection

The studies identified during the literature search will be imported into the reference management software Citavi.<sup>58</sup> Any duplicates will be removed. The study selection process will consist of two phases: (A) title and abstract screening and (B) full-text analysis.

Inclusion and exclusion criteria were developed after an exploratory literature search was conducted on the topic of PPI in health policy decisions. According to these criteria, studies and documents will be considered eligible if:

- ▶ They are empirical work.
- ▶ They deal with a macro-level PPI intervention in the context of health policy decisions.
- ▶ They state how and which form of PPI was implemented.

All study designs are eligible for inclusion. Peer-reviewed research studies as well as grey literature will be considered.

Studies and documents will be excluded if:

- ▶ They were written in a language other than English or German.

### Box 1 Search strategy for MEDLINE

(((“PPI”(Text Word) OR “patient participation”(Text Word) OR “public participation”(Text Word) OR “user participation”(Text Word) OR “lay participation”(Text Word) OR “citizen participation”(Text Word) OR “community participation”(Text Word) OR “consumer participation”(Text Word) OR “patient engagement”(Text Word) OR “public engagement”(Text Word) OR “user engagement”(Text Word) OR “lay engagement”(Text Word) OR “citizen engagement”(Text Word) OR “community engagement”(-Text Word) OR “consumer engagement”(Text Word) OR “patient involvement”(Text Word) OR “public involvement”(Text Word) OR “user involvement”(Text Word) OR “lay involvement”(Text Word) OR “citizen involvement”(Text Word) OR “community involvement”(Text Word) OR “consumer involvement”(Text Word))) AND (“health policy”(Text Word) OR “policymaking”(Text Word) OR “health planning”(Text Word) OR “priority setting”(Text Word) OR “health system”(Text Word))) AND humans(MeSH Terms)

- ▶ They deal with PPI in areas other than the healthcare sector.
- ▶ They deal with decisions at the micro-level or mesolevel.
- ▶ They deal with PPI in the context of healthcare research, health technology assessments (HTAs) or guideline development.

We decided to exclude studies that focus on PPI in the context of HTAs or guideline development because both of these topics are more closely related to the field of health research. Even when guidelines affect practical healthcare decisions, they are more of a recommendation than a commitment.<sup>59</sup> Therefore, PPI in the context of guideline development is at best indirect participation in health system decisionmaking; thus, the effects of this type of PPI cannot be measured differentially.

Two reviewers will independently screen the titles and abstracts of a random sample consisting of 10% of the papers that fit the inclusion and exclusion criteria. If a paper does not have an abstract (eg, grey literature), the full text of that paper will be screened. After screening the studies, the reviewers will discuss their results to ensure that they both understood and applied the criteria equally. The two reviewers will compare their results and discuss any differences between their assessments. After

reaching a consensus regarding the studies that are eligible for full-text analysis, the first author (LAB) will screen the remaining studies alone. The same procedure will be used for full-text analysis. The reviewers will independently screen a 10% random sample, discuss their results and make a joint decision about which studies to include in the final analyses; after this is complete, the lead researcher will continue the study selection process alone. The selection process will be documented and visualised in a Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart. This chart includes the number of papers found, the reasons for excluding the papers that were not selected and the final number of included studies.<sup>60</sup>

#### Step 4: data collection

A data extraction form was predeveloped and will be pilot tested on five randomly selected studies; if necessary, this form will be adapted before the overall data extraction process starts.<sup>53</sup> Therefore, the two reviewers will independently apply the data extraction form to the five selected studies and will compare their results. Any differences between these results will be discussed. The data will be extracted in accordance with the main research objectives. The elements that are to be extracted are summarised in [table 2](#).

#### Step 5: data summary and synthesis of results

The findings will be synthesised according to the information provided by the extraction sheet. The publication types, years and countries of the papers as well as their study objectives, methods of participation and measured outcomes will be described descriptively (via frequencies) in a tabular form to provide an overview of the scope of the existing literature.

The content of the studies will be qualitatively analysed. A deductive approach will be used, and a predefined and pilot-tested code system will be applied to the documents. MAXQDA software will be used.<sup>61</sup> The content will be classified into several main categories, namely, the forms of participation implemented, the contextual factors examined, the definitions of public participation and desired outcomes included, the extent

**Table 2** Data extraction elements

Element	Included information
Publication details	Author, year of publication, journal, country and study design.
General study details	Study objective, study sample and recruitment, healthcare setting, PPI method used, extent of the involvement (eg, consultation, partnership or dominant) and the perspective of participants (eg, user or policy) according to the framework of Charles and DeMaio. <sup>12</sup>
Definitions	Definitions of PPI and its desired outcome/effects.
Outcome	Reported outcome of PPI.
Context	This will be categorised in accordance with the framework of Abelson <i>et al</i> <sup>38</sup> as follows: political, community, decisionmaking, organisational and researcher/decision maker relationship contexts.

PPI, public and patient involvement.

of participation applied and the outcomes obtained. Similar topics will be summarised and reported under key themes.

A critical appraisal of the included studies will not be performed, as it is contradictory to the objective of a scoping review to give a comprehensive overview of the existing evidence independent of the study type and design.<sup>53 60</sup> The results will be reported and discussed in accordance with the PRISMA-ScR Statement.<sup>60</sup> We will also discuss the limitations of our study and provide overall conclusions and implications that can be derived from our findings.

### Step 6: stakeholder consultation

The involvement of stakeholders can improve the quality and relevance of research, therefore increasing its impact.<sup>53 62</sup> When stakeholders are involved in research, the stage of the research process at which they should be involved and the ways in which they should be involved must be determined. Pollock *et al.*<sup>63</sup> conducted a scoping review and found that stakeholders have been commonly involved either during the interpretation of the results of a study or during the whole process. Furthermore, these involved individuals have often been personally contacted, and face-to-face meetings or electronic delphi rounds have been held to discuss the research methods and findings of these studies. The number of stakeholders involved in previous studies has varied depending on the method used for their involvement.<sup>63</sup> We will involve experts from the Federal Joint Committee's (G-BA) coordination committee of patient representatives in Germany.

After providing of information on our study project to the main contact person for patient representatives in the G-BA, we agreed on the following involvement strategy: stakeholders will be involved at the stage of literature search and interpretation and dissemination of results. The exchange on the search strategy has already be undertaken by email. Results will be discussed with stakeholders in group meetings (either via telephone or face to face). Short questions will also be clarified via email contact. Especially for the search of grey literature, the experts are able to provide important suggestions of further sources that do not appear in systematic literature searches.<sup>52</sup> When interpreting the results and considering the best way to disseminate our findings, the members of the coordination committee of patient representatives will be asked for their feedback and recommendations. This should help to ensure that the results will be transferable to practice and understandable to the public. We will try to keep the time required for the patient representatives involved as low as possible since most of them work voluntarily and receive a large number of inquiries. For the meeting to discuss and interpret the results, a time frame of one up to 2 hours is planned. The results will be sent to the experts in advance for preparation.

### Patient and public involvement

Patient representatives of the G-BA were recruited for an advisory board for the study. During the design of this protocol and the development of the research strategy, they were consulted. Additional recommended sources for grey literature were implemented in the search strategy and the above-mentioned strategy for further involvement in the research project was developed and agreed on.

### ETHICS AND DISSEMINATION

Search results will be presented at relevant conferences and published in a peer-reviewed open-access journal. The transfer of these results into practice will be discussed in consultation with the above-mentioned stakeholders. In a group meeting, different options for the transfers (eg, policy brief or presentation of results to policy makers) as well as key persons for transfer will be discussed and identified. Afterwards, a step by step plan for the transfer will be developed. The findings of this review can inform health policy decisionmakers about the different ways in which to involve the public in their decisions. As PPI in healthcare decisionmaking is related to improved health systems and patient orientated care, it is important to implement opportunities for participation and, in doing so, also address issues of fairness and access of different groups in the decision-making process.

As a scoping review only uses secondary and previously published information, ethical approval is not necessary. However, even when formal ethical approval is not necessary, some ethical issues must be considered. One concerns the inclusion of unethical research or research without information on ethics in our work. We decided to not exclude these papers as this would be contradictory to the aim of a broad overview of existing evidence.

We also discussed the potential influence of poorly conducted research on the acting of policy makers. Because quality approval of included studies will not be conducted in a scoping review, final conclusions from our findings are not possible, and we do not aim to give any advice for political action. In the discussion and conclusion part of our scoping review, we will discuss this issue and make clear which conclusions can be derived from our research and which are inadmissible.

Furthermore, as we involve patient representatives in our research, we provided information on study aims and methods and informed consent was sought.

The amendments to this protocol will be reported in its final publication.

**Contributors** LAB contributed to the development of the study concept and wrote and edited the manuscript. ALB contributed to the development of the study concept, supervised the process of manuscript preparation and edited the manuscript. Both authors approved the final version of the protocol.

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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 required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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