BMJ Open

Protocol for the development of a core outcome set for studies on centralisation of healthcare services

Stefanie Pfisterer-Heise ,[1] Julia Scharfe,[1] Charlotte Mareike Kugler,[1] Eni Shehu,[1] Tobias Wolf,[1] Tim Mathes,[2] Dawid Pieper[1]

To cite: Pfisterer-Heise S, Scharfe J, Kugler CM, *et al*. Protocol for the development of a core outcome set for studies on centralisation of healthcare services. *BMJ Open* 2023;**13**:e068138. doi:10.1136/bmjopen-2022-068138

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-068138).

Received 27 September 2022
Accepted 06 March 2023

[1]Institute for Health Services and Health System Research, Center for Health Services Research Brandenburg, Brandenburg Medical School Theodor Fontane, Rüdersdorf bei Berlin, Germany
[2]Institute for Medical Statistics, University Medical Center Goettingen, Göttingen, Germany

Correspondence to
Professor Dawid Pieper;
dawid.pieper@mhb-fontane.de

ABSTRACT

Introduction Centralisation defined as the reorganisation of healthcare services into fewer specialised units serving a higher volume of patients is a potential measure for healthcare reforms aiming at reducing costs while improving quality. Research on centralisation of healthcare services is thus essential to inform decision-makers. However, so far studies on centralisation report a variability of outcomes, often neglecting outcomes at the health system level. Therefore, this study aims at developing a core outcome set (COS) for studies on centralisation of hospital procedures, which is intended for use in observational as well as in experimental studies.

Methods and analysis We propose a five-stage study design: (1) systematic review, (2) focus group, (3) interview studies, (4) online survey, (5) Delphi survey. The study will be conducted from March 2022 to November 2023. First, an initial list of outcomes will be identified through a systematic review on reported outcomes in studies on minimum volume regulations. We will search MEDLINE, EMBASE, CENTRAL, CINHAL, EconLIT, PDQ-Evidence for Informed Health Policymaking, Health Systems Evidence, Open Grey and also trial registries. This will be supplemented with relevant outcomes from published studies on centralisation of hospital procedures. Second, we will conduct a focus group with representatives of patient advocacy groups for which minimum volume regulations are currently in effect in Germany or are likely to come into effect to identify outcomes important to patients. Furthermore, two interview studies, one with representatives of the German medical societies and one with representatives of statutory health insurance funds, as well as an online survey with health services researchers will be conducted. In our analyses of the suggested outcomes, we will largely follow the categorisation scheme developed by the Cochrane EPOC group. Finally, a two-round online Delphi survey with all stakeholder groups using predefined score criteria for consensus will be employed to first prioritise outcomes and then agree on the final COS.

Ethics and dissemination This study has been approved by the Research Ethics Committee at the Brandenburg Medical School Theodor Fontane (MHB). The final COS will be disseminated to all stakeholders involved and through peer-reviewed publications and conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Core outcome set (COS) development in accordance with the COS standards for development.
⇒ Extensive stakeholder involvement including the involvement of representatives of patient advocacy groups.
⇒ Analyses of suggested outcomes largely following the categorisation scheme by the Cochrane Effective Practice and Organization of Care group.
⇒ Applicability of the COS may be limited to countries with similar healthcare systems.

INTRODUCTION

Worldwide modern healthcare faces major challenges including enormous spending on health, low quality of care especially with respect to patient safety,[1] ever more complex medical procedures as well as workforce constraints.[2] Centralisation of specialised healthcare services characterised by the 'reorganisation of healthcare services into fewer specialised units serving a higher volume of patients'[3] in this respect is regarded as a potential strategy for clinical service reconfiguration leading to better quality of care and improved patient safety.

The rationale behind centralisation is the so-called volume–outcome relationship where it is assumed that the health outcome (e.g. mortality or morbidity) is associated with hospital volume. Specifically, it is hypothesised that higher hospital volume, that is, the number of cases a hospital has performed for a given procedure in a given time span, results in better health outcomes,[4] likely explained on the basis of the 'practice makes perfect' hypothesis.

The presence of the volume–outcome relationship in surgery has been well established in the medical literature.[5 6] Yet, there are also many non-surgical examples, such as dialysis, critical care, intensive care units and care for low-birth-weight infants, as well as care for people living with HIV/AIDS, where

a volume–outcome relationship is likely to have been proven.[7–11]

While scientific evidence for the volume–outcome relationship is one driver of centralisation, it does not seem to be the most influential. Thus, a Dutch study on the centralisation of cancer care found that centralisation started on the basis of scientific evidence. It then progressed in the anticipation of the publication of norms by professional societies that is the publication of professional standards without these standards being legally determined. However, the most potential stimulus seems to have been regulations on minimum volumes,[12] i.e. cut-off thresholds in terms of a minimum number of procedures performed. This minimum volume standard is then a necessary precondition for a provider to be allowed to perform this procedure in the future. Apart from the Netherlands, these are currently in effect in Canada, England, France, Italy, the United States and Switzerland.[13] In Germany minimum volume regulations are currently in place for ten procedures, among them kidney, liver and stem cell transplantations, complex pancreatic and oesophageal surgeries, total knee replacements and care of low-birth-weight neonates.

While there seem to be three major drivers of centralisation (scientific evidence of the volume–outcome relationship, the publication of norms by professional societies as well as minimum volume regulations), there is a great variety of outcomes in studies on centralisation. Many studies report some measure of mortality such as operative mortality,[14] 30-day mortality,[15 16] crude mortality or adjusted mortality.[17] Furthermore, reported outcomes of centralisation, for example, include length of patients' hospital stay,[14 15 18] adherence or non-adherence with guidelines while delivering care,[15 19] complication rates, such as cardiac complications[16] or respiratory complications,[20] as well as indicators with respect to transportation, that is, distance travelled by patients[14] or secondary transfer between hospitals.[17] Moreover, disease-specific outcomes such as time from admission to thrombolysis for stroke care[18] or perioperative chemotherapy in cancer care[16] are reported.

Thus, first, studies on centralisation of healthcare services report a wide variability of outcomes which makes it difficult to compare or even synthesise the effects of centralisation, that is, by means of a systematic review. Second, outcomes considered are mainly at the patient level, while outcomes at the health system level are often either neglected or of poor methodological quality. In this respect, Bhattarai and colleagues[3] in a systematic review on the economic evaluations of centralisation warn that 'confounded and biased information coming from studies without standardised methods may mislead decision-makers towards making wrong decisions on centralisation'.

Accordingly, to provide a sound scientific basis for future studies on centralisation of healthcare services and thus a rationale for political decisions aiming at a higher quality and efficiency of healthcare, we set out to develop a core outcome set (COS) for studies on the centralisation of healthcare services.

METHODS AND ANALYSIS

The COS study outlined here is part of the project MIVOS—The effect of minimum volume standards in hospitals, consisting of a systematic review on the effects of minimum volume standards in hospitals as well as the development of a COS for studies on the centralisation of healthcare services, with a total project period from March 2022 until November 2023.

The COS study is designed in accordance with the Core Outcome Set-STAndards for Development (COS-STAD) recommendations[21]. The protocol follows the Core Outcome Set—STAndardised Protocol Items (COS-STAP statement)[22]; see online supplemental material 1: COS-STAndardised Protocol Items (COS-STAP) Checklist for the MIVOS study. Study findings will be reported following the COS STAndards for Reporting (COS-STAR).[23] The study is registered on the COMET database.[24]

The study will consist of five steps: (1) a systematic review on reported outcomes in studies on minimum volume standards in hospitals; (2) a focus group with representatives of patient advocacy groups for diseases with current or future minimum volume standards in Germany; (3) two interview studies, one with representatives of the German medical societies and one with representatives of German statutory health insurance funds; (4) an online survey with German health services researchers; (5) a Delphi study involving all the aforementioned stakeholder groups to prioritise the core outcomes and agree on the COS. A depiction of the development process of the COS for studies on centralisation of healthcare services is shown in figure 1.

Scope of the COS

The target population are hospital patients of any sex, age range any age, irrespective of their condition or the hospital procedure received. The intervention is the centralisation of hospital procedures. Outcomes will include (1) patient-related outcomes, for example, (hospital) mortality; (2) process-related outcomes, for example, adherence to clinical practice guidelines or clinical pathways, as well as (3) health system-related outcomes, for example, transition frequencies (i.e. number of hospitals increasing their volume to meet minimum volume standards). The COS will be applicable to observational studies, but will also inform experimental studies on the centralisation of hospital procedures in terms of outcomes to be measured. Further to this, the COS will also be relevant for governance centralisation.

Patient and public involvement

Prior research has largely neglected patients' perspectives on centralisation of hospital health services. This study aims to close this gap by examining and including patients' views and priorities. Due to the broad focus of

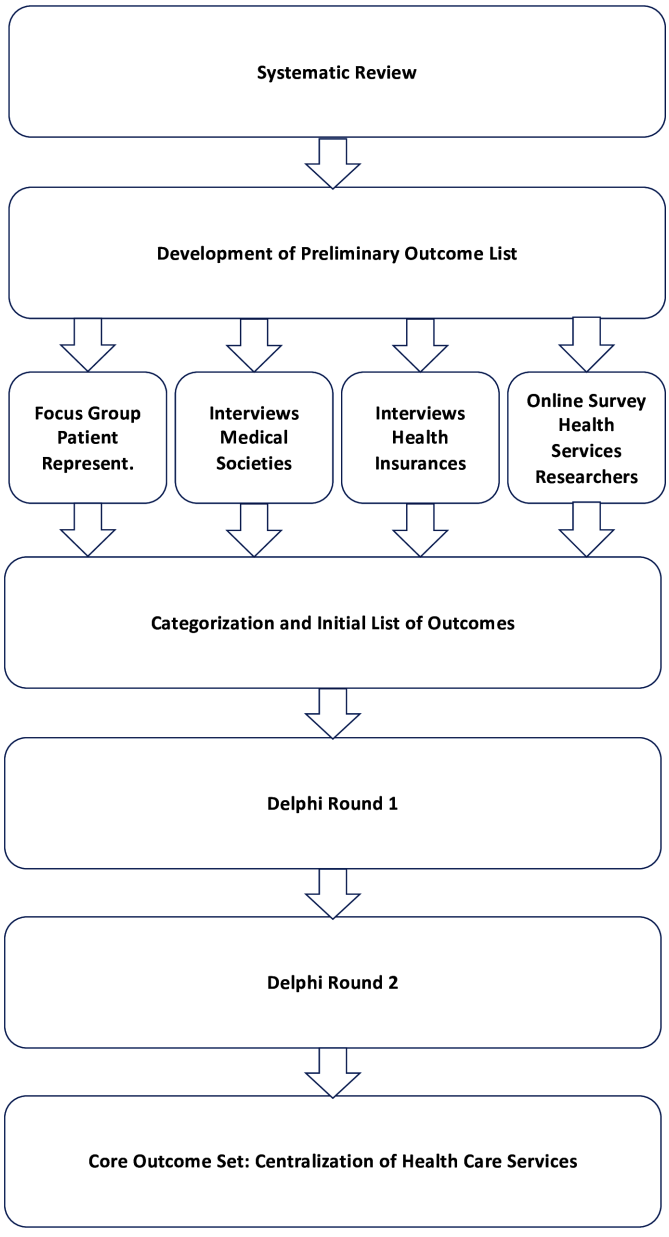

Figure 1 Development of a core outcome set for studies on centralisation of healthcare services.

the project, it is more important that participants have adequate knowledge of the healthcare system instead of the underlying disease. Therefore, patients' perspectives will be included through patient representatives, that is, people with lived experience, as well as patient advocates.

Across the entire project, patient representatives have been and will be involved in three ways: First, a patient representative of The German Council of People with Disabilities (DBR) as well as the Alliance of Chronic Rare Diseases Association (ACHSE e.V.) who also serves as alternate spokesman of the Quality Assurance Subcommittee in the Federal Joint Committee was involved in shaping and reviewing the research proposal. Second, patient representatives will be involved in answering the research question by being invited to take part in a focus group as well as in the following Delphi study on centralisation. Specifically, we will invite representatives of patient advocacy groups for diseases with current or future minimum volume standards, for example, patient advocacy groups representing kidney transplant patients or breast cancer patients. Further to this, representatives of the leading nationwide advocacy groups such as the German Council of People with Disabilities (DBR), the Federal Syndicate of Patient Interest Groups (BAGP), the German Syndicate of Self-Help Groups as well as the Federation of German Consumer Organizations will be invited to take part in the research. For their participation in the focus group as well as in the Delphi study (see below), participants will receive a compensation of expenses of €150.

Stakeholder involvement

Further stakeholder involvement consists of the establishment of a project advisory group including clinicians, health services researchers specifically in the fields of patient safety as well as members of the German Federal Joint Committee (G-BA), the highest decision-making body of the joint self-government in the German healthcare system.

Systematic review on minimum volume standards

We will first conduct a systematic review to investigate the effectiveness of minimum volume regulations. In this process, we will identify outcomes reported in studies on minimum volume regulations as well as in studies on centralisation of hospital procedures.

Search strategy

The following databases will be searched: MEDLINE (via PubMed), EMBASE (via EMBASE), CENTRAL (via Cochrane Library), CINHAL (via EBSCO), EconLIT (via EBSCO), PDQ-Evidence for Informed Health Policymaking, Health Systems Evidence, Open Grey and also trial registries. We will further search manually for additional studies by cross-checking the reference lists of all included primary studies as well as cross-checking the reference lists of relevant systematic reviews. Relevant key search terms will include centralization or centralisation, regionalization or regionalisation and minimum volume standard derived from previous literature. The search strategies will be published in the protocol for the systematic review.

Study selection and data extraction

We will apply no restrictions regarding language, publication date and publication status, the only restriction will be based on the study designs included. Thus, we will include the following study designs: (cluster) randomised controlled trials ((C)RCTs) with at least two intervention and control sites; non-randomised controlled trials (nRCTs) with at least two intervention and control sites; controlled before–after studies with at least two intervention and control sites; interrupted time series that have a clearly defined point in time when the intervention occurred and at least three data points before and three after the intervention. However, as randomisation in

healthcare systems is very challenging, we do not expect any CRCT to meet our inclusion criteria. Therefore, we will include other study designs as suggested by the Cochrane Effective Practice and Organization of Care Group (EPOC) following their guidelines. Abstract as well as full text screening will be conducted independently by two reviewers.

Data extraction will be independently performed by two reviewers using a standardised and piloted data collection form. The following data will be extracted: sample size (number of included patients and hospitals); study design; patients/hospitals eligibility criteria; type of hospitals (e.g. teaching hospital); surgeon characteristics (if applicable); year(s) of data collection; country/region; data source (clinical vs administrative); data-base/registry (if any); procedure or treatment; outcomes; (unadjusted and adjusted) effect measures with corresponding confidence intervals and/or p-values; statistical models; adjusting variables. Any discrepancies will be resolved by discussion.

For more information on the systematic review, please see the PROSPERO entry.[25]

Focus group with patient representatives

Outcomes with regard to centralisation identified in the systematic review on minimum volume standards may represent outcomes considered as important to researchers. To ensure that patients' perspectives are also taken into account while developing the COS, a focus group with patient representatives on the topics of centralisation of hospital health services as well as minimum volume standards will be conducted. Specifically, the aim of the focus group is to discuss potential implications of centralisation as well as minimum volume standards at all outcome levels and suggest potential outcomes.

We will aim to include eight to ten participants in the focus group. Sampling will be purposive, that is, we will contact patient advocacy groups for diseases for which minimum volume standards are already in effect in Germany such as liver transplantations or total knee replacement surgery or for which minimum volume standards are likely to come into effect such as colon cancer surgery.[26] Together with the invitation to take part in the project, all invitees will receive an information leaflet providing information on the hospital volume–outcome relationship as well as on minimum volume standards.

Prior to participating in the project, participants' consent will be taken in written form. Further to this, all participants will receive a written list of potential outcomes identified through the systematic review on minimum volume regulations.

Due to the geographical dispersion of potential participants as well as the pre-existing health conditions of patient representatives, the focus group will be held and recorded virtually via Webex. It will be scheduled for 90 min or until no further ideas are forthcoming. A topic guide based on previous literature will form the basis for the group's discussion. The recordings will be transcribed and imported to MAXQDA 2020. Data analysis will be based on qualitative content analysis according to Mayring.[27]

Interview studies with representatives of medical societies and statutory health insurance funds

To capture further important perspectives of stakeholders in the healthcare system, we will conduct two more qualitative studies with representatives of the German medical societies as well as representatives of German statutory health insurance funds on the topic of centralisation as well as minimum volume standards. Due to time restrictions of the stakeholders involved, we are opting for interviews instead of a focus group in this case.

Analogous to the sampling for the patient representatives, sampling for the interviews with representatives of the German medical societies will be purposive, that is, we will contact medical societies dealing with diseases for which minimum volume standards are already in effect in Germany or for which minimum volume standards are likely to come into effect. Our aim is to include approximately 15 interviewees depending on data saturation, that is, 'the degree to which new data repeat what was expressed in previous data'.[28]

With regard to the interviews with representatives of German statutory health insurance funds, we will start our sampling by size of the statutory health insurance fund and first invite representatives of the largest insurance funds in terms of the number of policy holders. Our aim, here, is also to include 15 interviewees.

Prior to participating in the project, participants' consent will be taken in written form. They, too, will receive a written list of potential outcomes identified through the systematic review on minimum volume regulations. Due to the geographical dispersion of potential interview partners, all interviews will be held and recorded either via telephone or virtually via Webex depending on the preference of the interviewee. All interviews will be scheduled for 30 to 45 min or until no further ideas are forthcoming. A topic guide based on previous literature will form the basis for all interviews. The recordings will be transcribed and imported to MAXQDA 2020. Data analysis will be separate for both stakeholder groups and will be based on qualitative content analysis according to Mayring.[27]

Online survey with health services researchers

Another important perspective on the topics of centralisation as well as minimum volume standards can be contributed by researchers in the field of health services, 'a multidisciplinary field of inquiry, both basic and applied, that examines the use, costs, quality, accessibility, delivery, organisation, financing and outcomes of healthcare services to increase knowledge and understanding of the structure, processes and effects of health services for individuals and populations'.[29] Health services researchers in this respect are researchers working in the described

area who seek solutions to 'problems that adversely affect access to care, quality, safety and cost of care'.[30]

We are planning to approach this stakeholder group by means of the DNVF (German Network for Health Services Research) newsletter. The DNVF is the German network of health services research, an interdisciplinary network open to all institutions, working groups and scientists involved in the improvement of health and healthcare from a scientific, practical or health policy point of view.[31] As of July 2022, the DNVF has 288 personal members. For the development of our COS, we are aiming to invite those members of the DNVF who have been working in the fields of clinical services reconfiguration, especially centralisation of healthcare services, and/or minimum volume regulations.

Analogous to the qualitative guidelines, the online survey will be developed based on previous literature and will contain open-ended as well as close-ended questions. The online survey will be conducted with the online survey tool REDCap. Participation will take 10 to 15 min. Data analysis will be carried out using SPSS Statistics 28.

Categorisation and initial list of outcomes

In our analysis of all qualitative data, that is, derived from the focus group, the interviews as well as from the open-ended questions of the online survey, we will largely follow a deductive approach. We will analyse each dataset of the four stakeholder groups separately using a coding scheme including direct and indirect outcomes.

For the direct outcomes, we will largely follow the categorisation scheme developed by the Cochrane EPOC group[32] which defines direct outcomes as (1) patient outcomes, for example, (hospital) mortality, functional measures; (2) quality of care, for example, adherence to clinical practice guidelines or clinical pathways; (3) utilisation, for example, travel times, distance to hospital; (4) resource use, for example, costs; (5) healthcare provider outcomes, for example, transition frequencies (i.e. number of hospitals increasing their volume to meet minimum volume standards) or (6) adverse effects or harms. Further to this, we will add a category of indirect outcomes including, for example, expected changes in physicians' training at hospitals, as more complex surgeries will not be carried out in smaller hospitals anymore and thus resident physicians in these hospitals might not reach the required number of a certain surgery for their residency programme.

All outcomes derived from the four studies will be put on separate lists of outcomes according to stakeholder groups. To ensure that every outcome on the list has its own original meaning, we will supplement every outcome with a short written description.[33]

These initial lists of outcomes will then be reviewed and refined by two researchers independently. Then, both reviewers will check each other's versions for completeness and accuracy prior to merging the four lists. Any discrepancies will be resolved by discussion. If no agreement can be reached, arbitration will be carried out by the senior researcher.

Delphi study

As a next step, to reach consensus on the COS for studies on centralisation of healthcare services, this study will employ a two-round online Delphi survey. The Delphi technique 'is a method of collecting opinion on a particular research question. It is based on the premise that pooled intelligence enhances individual judgement and captures the collective opinion of a group of experts without being physically assembled'.[34] All participants of the focus group, the interview studies as well as the online survey will be invited by email to take part in the Delphi study.

In the first Delphi round, a comprehensive list will be presented including all outcomes derived from all four study parts as well as their respective written descriptions. All participants will be invited to rate the importance of each outcome on a nine-point Likert scale: 1–3 (not important), 4–6 (important but not critical) and 7–9 (critically important).[35] An option 'unable to score' will be provided. Further to this, participants will be given the opportunity to provide reasons for their respective ratings. As our initial list may not be exhaustive, an open question asking for additional outcomes will be placed at the end of the first Delphi round.

As we are expecting differing stakeholder opinions with respect to the outcomes, a second online Delphi round will then be implemented in which participants of all stakeholder groups (i.e. patient representatives, representatives of statutory health insurance funds, representatives of the German medical societies as well as health services researchers) will be presented the mean values of the single stakeholder groups. Further to this, all new suggested outcomes from Delphi round 1 will be presented. All participants will then again be invited to rate the importance of each outcome on a nine-point Likert scale: 1–3 (not important), 4–6 (important but not critical) and 7–9 (critically important)[35] on the basis of the mean values of all stakeholder groups as well as on the basis of the reasonings of Delphi round 1.

As a next step, we will develop an outcome set for each of the four stakeholder groups (health services researchers, representatives of the German medical societies, representatives of statutory health insurance funds, representatives of patient advocacy groups). Consensus to include an outcome in the respective outcome set is when ≥75% of all participants in the respective stakeholder group rated 7–9 (critically important) for an outcome (minimum number of participants in each group is 5).[36 37] In doing so, we will be able to see how many outcomes are considered important by each group as well as to compare the outcomes of each stakeholder group. The rate of missing responses will be reported with the results of the Delphi survey.

As a final step, the COS for all stakeholder groups will consist of outcomes included in at least two outcome sets of stakeholder groups.

DISCUSSION

In view of ever-rising healthcare-related costs, lacking quality of care especially with respect to patient safety, more complex medical procedures as well as workforce constraints, centralisation of healthcare services needs to be extensively researched as a potential strategy for clinical service reconfiguration. To be able to compare and synthesise the necessary research, a COS for studies on centralisation taking into account minimum volume regulations as the most potential stimulus for centralisation is urgently needed.

Strengths

So far, no COS for studies on the centralisation of healthcare services has been proposed. Our aim is to develop such a COS using different methodological approaches and incorporating different perspectives including those of patient representatives.

Furthermore, we are aiming at considering all outcome levels including the health system level which so far has often been neglected. In our analyses of the suggested outcomes, we will largely follow the categorisation scheme developed by the Cochrane EPOC group.[32]

Limitations

In general, the scope of the COS is a very wide one, that is, we are aiming at developing a COS for all studies on the centralisation of healthcare services. This approach will probably lead to a COS including less specific outcomes than a COS for a study on a specific disease. However, as centralisation worldwide is underway and its effects ought to be evaluated, we are convinced that a COS for studies on the centralisation of healthcare services is indispensable.

Furthermore, all study parts, that is, the focus group study, the interview studies, online survey as well as Delphi survey will be conducted with German participants. This might limit the generalisability of our findings, for example, when it comes to outcomes with respect to physician training or outcomes prioritised by representatives of German statutory health insurance funds. In other words, the applicability of the COS may be limited to countries with similar healthcare systems. However, despite all differences with respect to education and insurance systems, healthcare systems worldwide face similar challenges, such as for example rising costs and workforce constraints. Furthermore, they choose similar strategies for dealing with them such as the centralisation of healthcare services.

Moreover, our sampling strategy for participants in the focus group aims at including as broad a spectrum as possible with respect to diseases affected by minimum volume regulations in Germany. This strategy might thus lead to a diversity in terms of diseases but not in terms of gender identity, ethnicity, and socioeconomic status.

With respect to the sampling strategy of interviewees, we aim at interviewing representatives of the German medical societies. This might possibly lead to an interview sample including more representatives of university hospitals than small hospitals in Germany which in general are more affected by minimum volume regulations than the bigger hospitals. However, in our recruitment of participants we will state clearly that we are aiming at interviewing our participants as representatives of their medical society and not as representatives of their specific hospital.

Similarly, non-responder bias may influence the outcomes included in the final COS. Further to this, for pragmatic reasons we apply different methodological approaches. This might lead to a difference in terms of the level of engagement with the topic of centralisation, in particular when comparing the focus group with patient representatives with the online survey with health services researchers.

ETHICS AND DISSEMINATION

All methods are carried out in accordance with relevant guidelines (Helsinki Declaration) and national law. According to the Research Ethics Committee at the Brandenburg Medical School Theodor Fontane (MHB), ethical approval is not necessary (waiver number E-01-20220630). All participants will give their written informed consent to participate in the study.

The anonymised datasets generated and/or analysed during the current study will be available in the Open Science Framework repository, https://osf.io in accordance with German data protection law.

We aim to publish the results of all aforementioned studies in international journals with open access. We will provide all materials as online supplemental file.

Furthermore, at the end of the project, a symposium will be held to present the findings to the public. Patient representatives, health services researchers, as well as representatives of the German medical societies and statutory health insurance funds, in particular those participating in the development of the COS, will be invited to participate. Participants taking part in the development of the COS will also be invited for a 1-day workshop after the symposium with the aim of formulating recommendations for considering outcomes in future studies evaluating minimum volume standards. These recommendations will be presented and published in the same way as the results of the review.

Contributors DP made substantial contributions to the conceptualisation, methodology, resources, writing the original draft, supervision, project administration and funding acquisition of this protocol. TM made substantial contributions to the methodology and review and editing of this protocol. CMK made substantial contributions to the review and editing of this protocol. JS made substantial contributions to the review and editing of this protocol. ES made substantial contributions to the review and editing of this protocol. TW made substantial contributions to the review and editing of this protocol. SP-H made substantial contributions to the methodology and wrote the original draft of this protocol. All authors approved the submitted version of the manuscript. The aforementioned authors also have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally

involved, are appropriately investigated, resolved and the resolution documented in the literature.

Funding This work was supported by the German Federal Ministry of Education and Research grant number 01KG2107.

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.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

Stefanie Pfisterer-Heise http://orcid.org/0000-0002-0138-4865

REFERENCES

1 Slawomirski L, Auraaen A, Klazinga NS. The economocs of patient safety: strenghtening a value-based approach to reducing patient harm at national level. *OECD Health Working Papers* 2018:96.
2 Imison C*et al*. *The reconfiguration of clinical services what is the evidence?* London: The King's Fund, 2014.
3 Bhattarai N, McMeekin P, Price C, *et al*. Economic evaluations on centralisation of specialised healthcare services: a systematic review of methods. *BMJ Open* 2016;6:e011214.
4 Luft HS, Hunt SS, Maerki SC. The volume-outcome relationship: practice-makes-perfect or selective-referral patterns? *Health Serv Res* 1987;22:157–82.
5 Morche J, Mathes T, Pieper D. Relationship between surgeon volume and outcomes: a systematic review of systematic reviews. *Syst Rev* 2016;5:204:204.:.
6 Pieper D, Mathes T, Neugebauer E, *et al*. State of evidence on the relationship between high-volume hospitals and outcomes in surgery: a systematic review of systematic reviews. *J Am Coll Surg* 2013;216:1015–25.
7 Nguyen Y-L, Wallace DJ, Yordanov Y, *et al*. The volume-outcome relationship in critical care: a systematic review and meta-analysis. *Chest* 2015;148:79–92.
8 Pieper D, Mathes T, Marshall MR. A systematic review of the impact of center volume in dialysis. *BMC Res Notes* 2015;8:812.
9 Kanhere MH, Kanhere HA, Cameron A, *et al*. Does patient volume affect clinical outcomes in adult intensive care units? *Intensive Care Med* 2012;38:741–51.
10 Obladen M. Minimum patient volume in care for very low birthweight infants: a review of the literature. *Z Geburtshilfe Neonatol* 2007;211:110–7.
11 Handford CD, Tynan AM, Rackal JM, *et al*. Setting and organization of care for persons living with HIV/AIDS. *Cochrane Database Syst Rev* 2006;2006:CD004348.
12 Kilsdonk MJ, Siesling S, van Dijk BAC, *et al*. What drives centralisation in cancer care? *PLoS One* 2018;13:e0195673.
13 Morche J, Renner D, Pietsch B, *et al*. International comparison of minimum volume standards for hospitals. *Health Policy* 2018;122:1165–76.
14 Bendzsak AM, Baxter NN, Darling GE, *et al*. Regionalization and outcomes of lung cancer surgery in Ontario, Canada. *J Clin Oncol* 2017;35:2772–80.
15 Afshar M, Goodfellow H, Jackson-Spence F, *et al*. Centralisation of radical cystectomies for bladder cancer in England, a decade on from the " improving outcomes guidance ": the case for super centralisation. *BJU Int* 2018;121:217–24.
16 Nelen SD, Heuthorst L, Verhoeven RHA, *et al*. Impact of centralizing gastric cancer surgery on treatment, morbidity, and mortality. *J Gastrointest Surg* 2017;21:2000–8.
17 Metcalfe D, Perry DC, Bouamra O, *et al*. Regionalisation of trauma care in England. *Bone Joint J* 2016;98-B:1253–61.
18 Elameer M, Price C, Flynn D, *et al*. The impact of acute stroke service centralisation: a time series evaluation. *Future Healthc J* 2018;5:181–7.
19 Eggink FA, Vermue MC, Van der Spek C, *et al*. The impact of centralization of services on treatment delay in ovarian cancer: a study on process quality. *Int J Qual Health Care* 2017;29:810–6.
20 Allareddy V, Ward MM, Allareddy V, *et al*. Effect of meeting leapfrog volume thresholds on complication rates following complex surgical procedures. *Ann Surg* 2010;251:377–83.
21 Kirkham JJ, Davis K, Altman DG, *et al*. Core outcome set-standards for development: the COS-STAD recommendations. *PLoS Med* 2017;14:e1002447.
22 Kirkham JJ, Gorst S, Altman DG, *et al*. Core outcome set-standardised protocol items: the COS-STAP statement. *Trials* 2019;20:116.
23 Kirkham JJ, Gorst S, Altman DG, *et al*. Core outcome set-standards for reporting: the COS-STAR statement. *PLoS Med* 2016;13:e1002148.
24 Pfisterer-Heise S*et al*. What outcomes should be measured in studies on centralization of healthcare services? establishing a core outcome set for research. 2022. Available: https://www.comet-initiative.org/Studies/Details/2077
25 Pieper D*et al*. *The effect of minimum volume standards in hospitals (MIVOS) - a systematic review*. National Institute for Health Research, 2022.
26 Gemeinsamer. *Beschluss des gemeinsamen bundesausschusses über die einleitung des beratungsverfahrens zur festlegung einer mindestmenge für die kolorektale chirurgie bei darmkrebs*. Berlin: G-BA, 2022.
27 Mayring P. Qualitative inhaltsanalyse: grundlagen und techniken. 2015.
28 Saunders B, Sim J, Kingstone T, *et al*. Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant* 2018;52:1893–907.
29 *Institute of medicine, health services research: work force and educational issues*. Washington, CD, 1995.
30 *National research council, research training in the biomedical, behavioral, and clinical research sciences*. Washington, DC, 2011.
31 Versorgungsforschung DN. Über das netzwerk. 2022. Available: https://www.dnvf.de/über-uns/über-das-netzwerk.html
32 Care CEP a. O o. EPOC resources for review authors. 2017. Available: epoc.cochrane.org/epoc-resources-review-authors
33 Young AE, Brookes ST, Avery KNL, *et al*. A systematic review of core outcome set development studies demonstrates difficulties in defining unique outcomes. *J Clin Epidemiol* 2019;115:14–24.
34 de Villiers MR, de Villiers PJT, Kent AP. The Delphi technique in health sciences education research. *Med Teach* 2005;27:639–43.
35 Williamson PR, Altman DG, Bagley H, *et al*. The comet Handbook: version 1.0. *Trials* 2017;18(Suppl 3):280.
36 Barrios M, Guilera G, Nuño L, *et al*. Consensus in the Delphi method: what makes a decision change? *Technological Forecasting and Social Change* 2021;163:120484.
37 Diamond IR, Grant RC, Feldman BM, *et al*. Defining consensus: a systematic review recommends methodologic criteria for reporting of delphi studies. *J Clin Epidemiol* 2014;67:401–9.