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Beating the empty pelvis syndrome: the PelvEx Collaborative core outcome set study protocol

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ABSTRACT

Introduction The empty pelvis syndrome is a significant source of morbidity following pelvic exenteration surgery. It remains poorly defined with research in this field being heterogeneous and of low quality. Furthermore, there has been minimal engagement with patient representatives following pelvic exenteration with respect to the empty pelvic syndrome. ‘PelvEx—Beating the empty pelvis syndrome’ aims to engage both patient representatives and healthcare professionals to achieve an international consensus on a core outcome set, pathophysiology and mitigation of the empty pelvis syndrome.

Methods and analysis A modified-Delphi approach will be followed with a three-stage study design. First, statements will be longlisted using a recent systematic review, healthcare professional event, patient and public engagement, and Delphi piloting. Second, statements will be shortlisted using up to three rounds of online modified Delphi. Third, statements will be confirmed and instruments for measurable statements selected using a virtual patient-representative consensus meeting, and finally a face-to-face healthcare professional consensus meeting.

Ethics and dissemination The University of Southampton Faculty of Medicine ethics committee has approved this protocol, which is registered as a study with the Core Outcome Measures in Effectiveness Trials Initiative. Publication of this study will increase the potential for comparative research to further understanding and prevent the empty pelvis syndrome.

Trial registration number NCT05683795.

INTRODUCTION

Pelvic exenteration encompasses radical, multivisceral surgery for locally advanced primary and locally recurrent pelvic malignancies. It is hypothesised that the empty space created following pelvic exenteration can result in a sequelae of complications such as infected pelvic collections, prolonged ileus, mechanical bowel obstruction, perineal sinus and enteroperineal fistula. This pathological process has been termed, ‘the empty pelvis syndrome’ (EPS). Morbidity relating to EPS is estimated to be responsible for up to 40% of complications following pelvic exenteration.¹

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study intends to internationally recruit diverse groups of patient representatives and healthcare professionals.
- ⇒ Patient representation has been sought from an early stage to ensure this project captures patient perspectives.
- ⇒ The protocol proposes to generate core outcome and core descriptor sets that are measurable.
- ⇒ Recruitment of international non-English patient representatives may be challenging as this study has been designed in the UK with chiefly UK-based patient advocacy groups.

EPS was first defined in 1993 by Barber, as ‘*A flulike illness with malaise, elevated temperature, and increased discharge from the perineal sinus that may continue for many years, particularly among those undergoing heavy irradiation.*’² The same condition has also been labelled as ‘the empty pelvic syndrome’ or ‘pelvic burn syndrome’.³ There is presently renewed interest in EPS, with 5 publications making reference to it between 1993 and 2014^{2 4-7} and 24 papers between 2015 and 2022.^{1 3 8-29} These citations give inconsistent definitions and outcomes for EPS. As a result, there is limited scope for meta-analyses that may help guide prevention and management of this syndrome. A recent systematic review on reconstructive techniques for EPS cited low quality evidence with small patient numbers, precluding the ability to provide evidence-based recommendations as to the most appropriate reconstructive technique.¹

The anatomical and pathophysiological mechanisms behind EPS are largely undefined. Major bone or nerve resections have been shown to result in surgical intervention for complications related to EPS. These factors may be surrogate markers for more extensive surgery.²⁵ In recent years, more radical pelvic exenterations have been performed along with the addition of intraoperative oncological strategies such as



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intraoperative radiotherapy, in an attempt to improve oncological outcomes for patients.^{19 30} The degree of morbidity and the number of patients affected by EPS are, therefore, likely to increase. The formulation of a consensus definition for EPS, with a measurable core outcome and core descriptor set would limit heterogeneity of data reporting, enhancing the quality of the evidence base, with the aim of improving outcomes for patients undergoing pelvic exenteration.

Patients are key stakeholders in this process, however, to date, they have not had an active role in design and participation in any research on EPS. The UK National Cancer Research Institute and James Lind Alliance partnership have defined the Living With and Beyond Cancer Top 10 Priorities, and this study dovetails with several of these priorities³¹:

- ▶ The consequences of EPS can be implicated in the persistent late effects of cancer treatments.
- ▶ Patients eligible for pelvic exenteration have complex needs with often several surgical and oncological teams involved in their care.
- ▶ The psychological impact of EPS is under-reported with no data captured in this area.
- ▶ The pathophysiology of EPS currently is poorly understood, and addressing this will lead to improved treatments.
- ▶ A defined core outcome set (COS) and core descriptor set will enable better prediction of which patients are at risk of developing EPS postsurgery.

The Core Outcome Measures in Effectiveness Trials (COMET) database was searched on 14 July 2022 and there were no references to pelvic exenteration, complex pelvic cancer or EPS. A three-stage study design using healthcare professionals and patient representatives as stakeholders will be followed:

1. Longlisting statements through systematic review, healthcare professional event, patient and public involvement (PPI) and piloting.
2. Shortlisting statements using up to three rounds of online modified Delphi.
3. Confirming statements with a patient-representative virtual consensus meeting, and a face-to-face healthcare professional consensus meeting.

Aims and objectives

The primary aim of this study is to define a measurable COS for EPS involving both healthcare professionals and patient representatives as stakeholders.

Secondary aims include:

- ▶ Establishing consensus on the pathophysiology of EPS with a view to forming a written definition and a measurable core descriptor set.
- ▶ Exploration of consensus on the reconstructive techniques that can be used to mitigate the effects of EPS.

METHODS AND ANALYSIS

This study has been designed in accordance with Guidance on Conducting and Reporting Delphi Studies, the

COMET handbook, Consensus-based Standards for the selection of health Measurement Instruments (COSMIN)/COMET guidance, COS-STANDARDISED Protocol Items statement and COS-STANDARDS for Reporting Guidelines.^{32–36} It has been registered on the COMET database³⁷ and ClinicalTrials.gov (NCT05683795).

Patient and public involvement

Two separate expert groups were formed for this study, patient representatives and healthcare professionals. PPI using local networks was established during the design stage of the study with patient representatives joining the project steering committee. Further PPI engagement was established by involving the Bowel Research UK People and Research Together (BRUK PaRT) programme, CommunitiesFirst, and World Federation of Incontinence and Pelvic Problems. This ensured patient facing study materials were appropriate, and that patient representatives contributed directly to creating the longlist of statements. Patients will be invited to participate in the study using these networks, with BRUK PaRT also advertising the study for patient representatives through social media.

Expert groups

The PelvEx Collaborative is a diverse international group of healthcare professionals from 140 hospitals across 5 continents that provide pelvic exenteration services. The PelvEx Collaborative has previously undertaken Delphi studies, therefore, this is an ideal, motivated and logistically convenient platform to undertake a Delphi study due to its expertise, access to patients as key stakeholders, and the opportunity to undertake a face-to-face consensus meeting at the PelvEx Collaborative annual scientific meeting.^{38 39}

In a Delphi study, there is no agreement on how a group of experts should be selected, and there is no need for a statistically representative sample to be obtained.⁴⁰ An inclusive convenience sampling strategy will be used for both healthcare professionals and patient representatives with no upper limits set on sample size, this will avoid bias from selecting participants. All members of the PelvEx Collaborative will be invited to be involved in the study, generating, multiprofessional and multinational representation. Members of the PelvEx Collaborative will also be encouraged to engage their individual institutional PPI networks to participate in the project.

Stage 1: creating an EPS statements longlist

Statements were divided into three domains:

1. An EPS COS.
2. Pathophysiology of EPS.
3. Mitigation of EPS.

A recent systematic review and subsequently published literature on EPS were searched for statements in keeping with these domains.^{1 25 26} The PelvEx Collaborative held an international face-to-face meeting in Amsterdam in 2022 where an empty pelvis initiative was presented, and

further statements were generated based on formal and informal discussions at this meeting. The study steering committee was then formed from an international group of nine healthcare professionals, three patient representatives who had undergone pelvic exenteration and PPI professionals from BRUK PaRT—further statements were then generated from opinions of this committee.

The study is sponsored by the University of Southampton who provide institutional access to the Qualtrics Survey software package. A pilot of the first Delphi round was produced based on the statements generated above and trialled with the study steering committee. This included open questions to generate further statements. The time taken for individuals to complete the pilot study was also timed to allow an approximation of the burden of time required by participants to be included in invitation letters. Following piloting, the study steering committee met to confirm the longlist of 70 statements for the first Delphi round, the number of statements for each domain was as follows:

1. An EPS COS—19 statements.
2. Pathophysiology of EPS—17 statements.
3. Mitigation of the EPS—34 statements.

It was decided that patient representatives would only be invited to participate in the COS domain, as it was felt they would be unlikely to have the experience in the other domains to provide helpful input into forming consensus. Statements in the COS domain will, therefore, be presented in lay terms with technical language following this in parentheses.

Stage 2: creating an EPS statement shortlist

Three Delphi rounds are likely to be required with two separate stakeholder groups taking part; patient representatives and healthcare professionals. Members of the PelvEx Collaborative are experts in providing pelvic exenteration with experience of EPS, the healthcare professional stakeholder group will be recruited by contacting this group. The inclusion criteria for patient representatives are any individual who has undergone pelvic exenteration, which is defined as surgery to remove multiple organs from the pelvis, including beyond total mesorectal excision plane operations. This will include patients with any cancer (i.e., primary or recurrent colorectal, gynaecological, urological and connective tissue malignancies). Patient representatives will be sought through BRUK PaRT, CommunitiesFirst, World Federation of Incontinence and Pelvic Problems, and by encouraging members of the PelvEx Collaborative to approach their individual institutional PPI networks. Patient representatives who do not speak English are also eligible to participate with translation of patient facing materials to be provided by Language Insight, and healthcare professionals from the PelvEx Collaborative able to appropriately translate information. In order to be able to describe the diversity of the stakeholder groups demographic information will be sought in the first Delphi round.

Potential participants will be emailed invitation letters along with a link to the Qualtrics first Delphi round. Before voting on statements Qualtrics will present participants with an informed consent form that must be completed first. Qualtrics will use the 'Force Response' function, therefore, participants must complete all of a Delphi round before being able to submit. This will eliminate missing data from the study.

The first Delphi round will include all longlisted statements generated from stage 1 arranged in alphabetic order to reduce leading questions or researcher bias. These will be scored by participants from 1 to 9 on a Likert scale, as recommended by the Grading of Recommendations Assessment, Development and Evaluation working group.⁴¹ With 1–3 representing 'not important', 4–6 representing 'important but not critical' and 7–9 representing 'critical for inclusion.' A score of '0' will also be included, which will mean 'unable to comment.' The final questions on each domain will be open in order to avoid early closure of ideas among participants, so that further insight not anticipated in stage 1 of the process is gathered with the intention to generate new statements for the second round of the Delphi.

There is no recognised formal way of defining consensus in Delphi studies, however, it is specified here a priori that in order for statements to progress they must obtain stricter consensus between subsequent rounds. To progress from the first round to the second round statements must be rated 7–9 by 50% or more of participants, and by 1–3 by no more than 15% of participants in at least one stakeholder group. Beyond round 2 retained items must be rated between 7–9 by over 70% of respondents, and by 1–3 by less than 15% by at least one stakeholder group. This method reduces the chance of dropping statements that may be rated more highly in subsequent rounds once participants have received feedback that may indeed reach consensus, in addition separating analysis for patient representatives and healthcare professionals reduces the chance of statements deemed very important for one group being excluded. From piloting there was concern that a large proportion of statements for the COS were rated as essential, therefore, it was decided a priori that if there are 10 or more COS statements reaching consensus by the end of a second round then a third Delphi round will take place, with higher level consensus required, defined as 95% participants voting 7–9 that the statement should be included. This would avoid the inclusion of too many statements that could place increased time constraints on the consensus meetings process, and potentially limit the overall focus of the final COS. These consensus agreement approaches are based on previous surgical COS studies.^{42 43}

Responses to open questions from the first round will undergo thematic analysis and will be used to formulate new statements for addition to subsequent rounds. Any comments that apply to particular statements, which are not able to be formulated into new statements will be presented verbatim in subsequent rounds alongside



relevant statements. Open questions will not be included from the second round.

It is anticipated that each round will be open for 1 month with personalised email reminders issued to participants at 2 weeks and 48 hours from the deadline to encourage responses. Any participants wishing to drop out will be asked to give a reason for doing so, to facilitate recognition of any systematic attrition bias. Only individuals who completed the previous round will be contacted to take part in a subsequent round; if attrition leads to participation dropping below 70% of a previous round, the Delphi study will be terminated as below this level, rigour cannot be guaranteed. The study would then proceed directly to stage 3.

Analysis for patient representatives and healthcare professionals between rounds will take place separately. It is anticipated that more healthcare professionals will participate, therefore, analysis of these two groups together would potentially reduce the importance given to the patient voice. There will be presentation of this separate analysis for subsequent rounds using medians and IQRs, with how individuals voted in a previous round also disseminated. Histograms will also be included to facilitate understanding for patient representatives unfamiliar with descriptive statistics.

If progression of the Delphi rounds deviates from the presented protocol, decisions on whether to stop or continue to the Delphi will be taken by the Delphi steering committee.

Stage 3: finalising EPS statements

Any statements reaching consensus by the end of stage 2 that are measurable will have options for instruments prepared in accordance with COSMIN/COMET guidance.³⁴ All potential instruments for measurement will be selected using the opinion of the study steering committee and reviews of the relevant literature, which will include instrument feasibility assessments. These options will then be presented at consensus meetings.

PelvEx 2023 is the international meeting of the PelvEx Collaborative and would be an ideal time to hold a face-to-face consensus meeting for participating healthcare professionals. It was felt this meeting would not be appropriate for patient representatives as it will involve significant travel, patients may be heavily influenced by the opinions of healthcare professionals and may not feel as able to voice their opinions in front of a large audience.

To increase the number of involved patient representatives a virtual consensus meeting for patient representatives will be held prior to, PelvEx 2023 which will be supported by BRUK PaRT. Participants will be sent results from the final round of the Delphi including their individual final votes. Any non-English-speaking patient representatives will also be invited to participate with an appropriate multilingual healthcare professional from the PelvEx Collaborative joining the meeting to allow translation. At the start of the meeting demographic information will be requested to allow reporting of

diversity. Any statements retained from the final Delphi round for the COS will be included and participants will be asked to anonymously vote on whether the statement should stay in, be removed, or whether they are unsure. Where there is no consensus or participants are unsure, then further discussion will take place with an effort to capture dissenting views to determine the nature of a polarised response, also considering whether statements overlap and can be combined. Further voting will take place, followed by further discussion; if there is persistent disagreement a final round of voting will take place using a majority rule.

For the COS statements felt to be important, possible instruments to measure these statements will be presented for approval. It is anticipated that selection of instruments for patients will be difficult as the evidence on their methodology is likely to be challenging to understand, however, it is hoped that with support from research facilitators that patients will be able to judge relevance, comprehensiveness and comprehensibility of the available instruments. This meeting will be recorded for analysis and potential presentation of patients speaking at PelvEx 2023 to help healthcare professionals understand patient experiences.

Prior to PelvEx 2023, the results of the final Delphi rounds, statements for voting and the patient virtual consensus meeting will be sent out to participants, including how individuals who participated voted in the final Delphi round. A list of delegates at PelvEx 2023 will be obtained along with demographic information, and whether or not they were involved in stage 2 of the project. Anonymous voting will be across all three domains and will follow the same pattern as the patient representative meeting.

Measurable statements that are included will have their predetermined instruments presented for voting. If there is only one possible feasible instrument then participants will be permitted to vote either for this instrument, or that a recommendation is made for development of new instruments or that additional validation studies are required. It is difficult to predict how many statements will be voted on and discussed. A further round of online voting or virtual consensus meetings following PelvEx 2023 may be required. This will be at the discretion of the study steering committee.

By the end of stage 3, the following should have been achieved for each domain:

1. A measurable COS for EPS.
2. Statements on pathophysiology of EPS generating a measurable core descriptor set and contributing to a written definition of EPS.
3. To have established where there is consensus on current reconstructive techniques used to mitigate EPS, which will be graded by strength of recommendation and level of evidence.⁴⁴

It is unclear what the anatomical and pathophysiological causes of EPS are, how it can be prevented and how its sequelae can be measured. EPS can be life-threatening

and its consequences difficult to manage. This represents an ongoing, urgent, unmet clinical and research need in this growing patient population. Through the longlisting process, this consensus study will be grounded in previous published work, expert opinion and PPI. The modified Delphi will be as inclusive as feasible, giving the opportunity for diverse groups of international stakeholders to suggest further statements and vote with an a priori consensus definition that will identify the most important aspects of EPS. Finally, by undertaking consensus meetings there will be an opportunity to highlight and address nuances that cannot be easily approached using an online survey platform. Obtaining agreement on core outcome and core descriptor sets that are measurable will generate consensus that can be immediately used to reduce research heterogeneity in this field.

ETHICS AND DISSEMINATION

Ethical approval for this protocol has been given from the University of Southampton under the ERGO II reference number 77306. Further ethical approval from other institutions may be sought to approach respective patient representatives as required.

Any deviations from this protocol will be described and justified. Once stage 3 of the project is completed the project will be reviewed by an external board prior to publication and dissemination. This will be paper by the PelvEx Collaborative as per previous work, with utilisation of CRedIT taxonomy to encourage collaborators to engage with the process.^{38 39 45} Publication will be in peer-reviewed journals and dissemination through professional collaborators and associated networks to ensure international adoption. In addition, the patient advocacy groups involved will also assist in dissemination of the research.

Collaborators PelvEx Collaborative: West CT, West MA, Dami I, Denys A, Glyn T, Sutton PA, Tiernan J, Behrenbruch C, Guerra G, Waters PS, Woodward N, Applin S, Charles SJ, Rose SA, Pape E, van Ramshorst GH, Mirnezami AH, Aalbers AGJ, Abdul Aziz N, Abecasis N, Abraham-Nordling M, Akiyoshi T, Alahmadi R, Alberda W, Albert M, Andric M, Angeles M, Angenete E, Antoniou A, Armitage J, Auer R, Austin KK, Aytac E, Aziz O, Bacalbasa N, Baker RP, Bali M, Baransi S, Baseckas G, Bebington B, Bedford M, Bednarski BK, Beets GL, Berg PL, Bergzoll C, Beynon J, Biondo S, Boyle K, Bordeianou L, Breclj E, Bremers AB, Brown K, Brunner M, Buchwald P, Bui A, Burgess A, Burger JWA, Burling D, Burns E, Campaign N, Carvalho S, Castro L, Caycedo-Marulanda A, Ceelen W, Chan KKL, Chang GJ, Chew MH, Chok AK, Chong P, Christensen HK, Clouston H, Collins D, Colquhoun AJ, Constantinides J, Corr A, Coscia M, Cosimelli M, Cotsoglou C, Coyne PE, Croner RS, Damjanovic L, Daniels IR, Davies M, Davies RJ, Delaney CP, de Wilt JHW, Denost QD, Deutsch C, Dietz D, Domingo S, Dozois EJ, Drozdz E, Duff M, Egger E, Eglinton T, Enrique-Navascues JM, Espin-Basany E, Evans MD, Eyjólfssdóttir B, Fahy M, Fearnhead NS, Fichtner-Feigl S, Flatmark K, Fleming F, Flor B, Folkesson J, Foskett K, Frizelle FA, Funder J, Gallego MA, Garcia-Granero E, Garcia-Sabrido JL, Gargiulo M, Gava VG, Gentilini L, George ML, George V, Georgiou P, Ghosh A, Ghouti L, Gil-Moreno A, Giner F, Ginther N, Glover T, Goffredo P, Golda T, Gomez CM, Griffiths B, Gwenael F, Harris C, Harris DA, Hagemans JAW, Hanchanale V, Harji DP, Helbren C, Helewa RM, Hellawell G, Heriot AG, Hochman D, Hohenberger W, Holm T, Holmström A, Hompes R, Hornung B, Hurton S, Hyun E, Ito M, Iversen LH, Jenkins JT, Jourand K, Kaffenberger S, Kandaswamy GV, Kapur S, Kanemitsu Y, Kaufman M, Kazi M, Kelley SR, Keller DS, Kelly ME, Kersting S, Ketelaers SHJ, Khan MS, Khaw J, Kim H, Kim HJ, Kiran R, Koh CE, Kok NFM, Kokelaar R, Kontovounisios C, Kose F, Koutra M, Kraft M, Kristensen HØ, Kumar S, Kusters M, Lago V, Lakkis Z, Lampe B, Langheinrich MC, Larach T, Larsen SG, Larson DW, Law WL, Laurberg S, Lee PJ, Limbert M, Loria A, Lydrup ML,

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Contributors PelvEx Collaborative members contributed to the design of this study 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 applicable.

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