






# Priority outcomes of pelvic exenteration for rectal cancer: a patient, carer, and clinician consensus

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## Introduction

Pelvic exenteration is the standard of care, and only potentially curative treatment option, for selected patients with locally advanced or recurrent rectal cancer. This complex procedure involves surgical resection of all anatomical structures involved by the tumour and typically requires the removal of multiple pelvic viscera, as well as major pelvic bone, blood vessels, and nerves, generally followed by complex reconstruction of these systems. Although potentially curative, such radical surgery may be associated with major morbidity (up to 60%), functional impairments, and reduction in quality of life<sup>1,2</sup>. Therefore, whether or not pelvic exenteration should be recommended for an individual patient is a major and often difficult decision. The consequences of surgery must be weighed against the potential for cure, with consideration given to a patient's individual treatment goals and priorities.

Currently, decision-making around whether to recommend pelvic exenteration is based on individual surgeon or team experiences and does not follow an evidence-based approach. These decisions have traditionally been made with anticipated survival benefit as the main outcome of interest, with relative neglect of quality-of-life and functional outcomes. Furthermore, the views of patients, carers, and clinicians regarding which outcomes are most important and should guide decision-making have not been previously determined. It is also clear from recent comparative studies that there are dramatic differences in practices between specialist exenteration centres with respect to both patient selection and treatment approach<sup>3,4</sup>. This unwarranted variation in treatment decision-making may be, at least in part, due to lack of a standardized, reproducible, evidence-based approach to decision-making in this group of patients.

The aim of this study was to identify the pelvic exenteration outcomes that are considered most important by patients with locally advanced or recurrent rectal cancer, their carers, and treating clinicians. This will inform the development of an evidence-based surgical decision-making tool that can be used at the time of diagnosis to predict a range of individual patient outcomes (beyond survival alone).

## Methods

This study was coordinated by the Surgical Outcomes Research Centre (SOuRCe) in conjunction with the Institute of Academic Surgery (IAS) at Royal Prince Alfred Hospital, Sydney, New South Wales, Australia. The study involved two phases. First, a longlist of outcomes of pelvic exenteration was generated by systematically reviewing the literature<sup>5</sup> and conducting in-depth interviews with patients who had undergone exenteration surgery and their carers<sup>6</sup>. Second, longlisted outcomes were reviewed by a multidisciplinary committee and used to populate a three-round Delphi survey of patients, carers, and clinicians to identify the outcomes of highest priority to these stakeholder groups. The study protocol was published a priori<sup>7</sup> and was reported according to the Conducting and REporting of DELphi Studies (CREDES) recommendations<sup>8</sup>. Ethical approval for this study was granted by the Royal Prince Alfred Hospital Human Research Ethics Committee (X22-0422 and 2022/ETH02659).

## Phase one: outcomes longlist

A systematic review of the contemporary literature (published between 1990 and 2023) was conducted to identify all reported outcomes of extended or exenterative multivisceral resections

Received: October 06, 2024. Accepted: November 04, 2024

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for locally advanced primary or recurrent rectal cancer<sup>5</sup>. Semi-structured interviews were then conducted to explore the experiences of patients who had undergone pelvic exenteration and their carers in depth, with a focus on the outcomes of surgery that they considered important<sup>6</sup>. Outcomes identified by the systematic review and interviews were then combined to generate a longlist. The longlist was reviewed by a multidisciplinary committee that included specialist surgeons, an experienced surgical outcomes researcher, a pelvic exenteration nurse specialist, and two patient advocates. During this review process, outcomes addressing the same or similar concepts were combined as 'standardized outcomes'. Standardized outcomes were excluded when they were considered to be of minimal clinical relevance by the committee. Standardized outcomes were assigned a domain and a lay definition, and were used to populate the first round of the Delphi survey. Domains were based on those proposed by the Core Outcome Measures in Effectiveness Trials Initiative, but modified for applicability to pelvic exenteration patients for the purposes of this study<sup>9</sup>.

## Phase two: Delphi survey

The Delphi process involved three iterative surveys, which were distributed using the online software known as Research Electronic Data Capture (REDCap), with reminders sent at 10 and 20 days for each round. Participants were recruited from three stakeholder groups:

- Clinicians with experience in pelvic exenteration for locally advanced and recurrent rectal cancer. An invitation to participate was distributed to members of the PelvEx Collaborative (an international collaborative of clinicians with experience managing advanced pelvic tumours), Australia and New Zealand pelvic exenteration multidisciplinary teams and to corresponding authors of publications identified in the systematic review described above<sup>5</sup>. Although the first-round invitation was sent to approximately 350 clinicians, participants were encouraged to forward the first-round invitation e-mail to their local networks, including multidisciplinary teams, and therefore the total number of invited clinicians is unknown.
- Patients who had undergone pelvic exenteration for locally advanced primary or recurrent rectal cancer. A total of 50 patients who had indicated an interest in participating in the second phase during the semi-structured interviews conducted in the first phase (see above) were invited to participate.
- Carers for patients who had undergone pelvic exenteration for locally advanced primary or recurrent rectal cancer. Patients who participated were invited to forward the invitation e-mail to their carers.

### First-round survey

The first-round survey was piloted on a patient representative, an experienced qualitative researcher, and two clinicians, and was then revised before distribution. The first section of the survey captured participant demographic information, including type of rectal cancer (primary or recurrent) and time since exenteration surgery (for patients), and information about specialty training and level of experience managing exenteration patients (for clinicians). The second section of the survey included a list of standardized outcomes identified during the first phase, with associated lay definitions. Participants rated the importance of each outcome using a nine-point Likert scale (limited importance, 1–3; important, but not critical, 4–6; and critically important, 7–9).

A final open question allowed participants to list additional outcomes using free text.

### Second-round survey

Outcomes with a mean score of one to three during the first round were discarded, whereas those scoring four to nine (important, but not critical, or critically important), and any additional unique outcomes suggested by participants, were included in the second-round survey. For each outcome, participants were provided with their score for the first round, as well as the mean score from their stakeholder group, and were asked to reflect on this information before scoring each outcome using the same nine-point Likert scale. Before the third round, each outcome was assessed for consensus according to criteria proposed by Williamson *et al.*<sup>10</sup>, which were defined a priori<sup>7</sup>:

- Consensus in: 70% or more of respondents within a participant group rate the outcome as critically important (7–9) and 15% or fewer rate the outcome as of limited importance (1–3).
- Consensus out: 70% or more of respondents within a participant group rate the outcome as of limited importance and 15% or fewer rate the outcome as critically important (7–9).
- No consensus: neither of the above criteria are met.

### Third-round survey

Outcomes meeting 'consensus in' criteria within all stakeholder groups during the second round were used to populate the third-round survey. Participants were asked to give each outcome a score between 0 (less important) and 100 (more important) to indicate its relative importance in relation to the other listed outcomes.

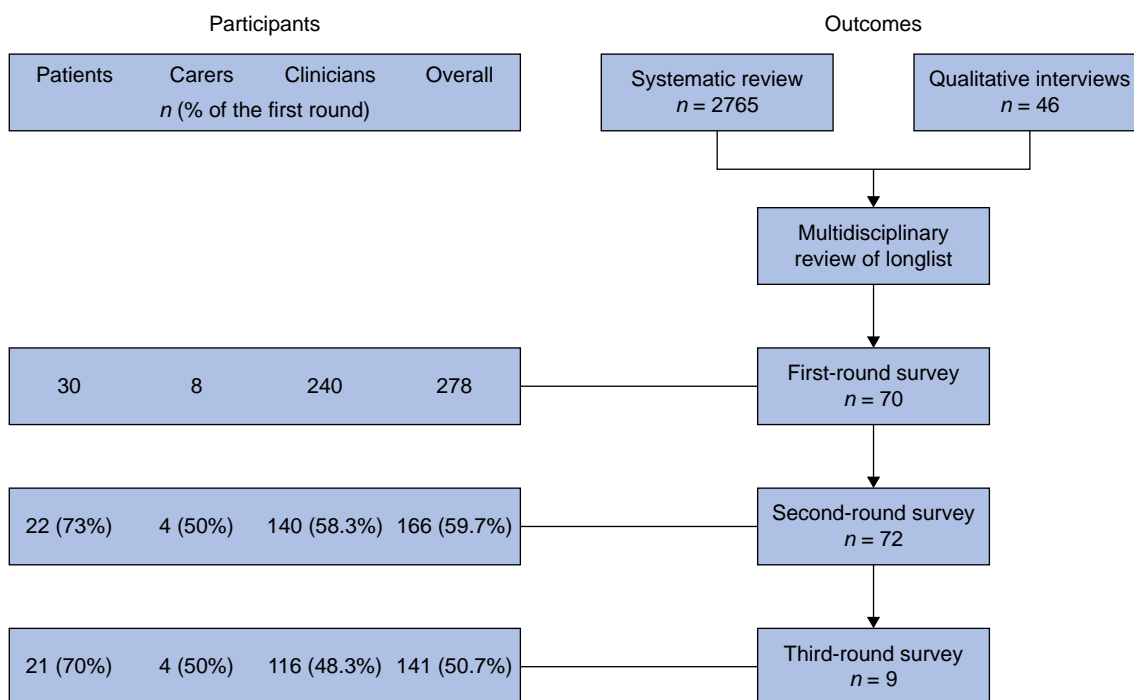
## Statistical analysis

Demographic information and survey results are summarized using descriptive statistics. During the third-round survey, outcomes were ranked from one to nine for each stakeholder group according to the median score (of importance) attributed by participants within that group (where the outcome with the highest median score was assigned a rank of '1' and the outcome with the lowest median score was assigned a rank of '9'). For each outcome, the ranks provided by stakeholder groups were summed to give a combined rank for the entire cohort, where the lowest value represented the most important outcome. This approach was adopted to ensure the final priority outcomes were equally representative of the three stakeholder groups, despite uneven numbers of participants within these groups.

## Results

### Phase one: outcomes longlist

Results of the systematic review and interviews with patients and their carers have been previously reported<sup>5</sup>. In brief, 2765 outcomes were identified from the literature (1157 after exclusion of duplicates) and combined with 46 outcomes extracted from transcripts of interviews with 34 patients and 5 carers. During the multidisciplinary committee evaluation process duplicates were removed before outcomes were reviewed, merged, and piloted. At the conclusion of this process, there were 70 standardized outcomes that were carried forward to the Delphi process and used to populate the first-round survey.



**Fig. 1** Flow chart outlining the numbers of participants and outcomes included in each round of the Delphi survey

## Phase two: Delphi survey

A total of 278 participants (30 patients, 8 carers, and 240 clinicians) responded to the invitation to participate and completed the first round of the survey, of which 166 (59.7%) completed the second round of the survey and 141 (50.7%) completed the third round of the survey (Fig. 1). Demographic information of the participating patients and carers who completed all three rounds of the Delphi survey are presented in Table 1 and the demographic information of the participating clinicians who completed all three rounds of the Delphi survey are presented in Table 2. In total, 11 (52%) and 10 (48%) patients had locally advanced primary and locally recurrent rectal cancer respectively and the median time since exenteration surgery was 36 (interquartile range 24–50) months. All four carers were spouses of patients who had undergone exenteration and all were female. The majority of clinicians were surgeons (78%); however, there was a range of multidisciplinary experts, including oncologists, nurses, radiologists, and dietitians.

### First-round survey

The mean score according to each stakeholder group for the 70 outcomes during the first round (and their lay definitions) is presented in Table S1. The participants suggested 46 additional outcomes in response to the open text question of the first round, from which 2 unique outcomes were identified and included in the second round ('decisional regret' and 'cost of treatment'). Because all outcomes had a mean score of 4–9, with no outcomes meeting the predefined criterion for exclusion after the first round (mean score of 1–3), 72 outcomes were carried forward to the second round.

### Second-round survey

The consensus status for the 72 outcomes included in the second round are included in Table S2. There were nine outcomes that met

**Table 1** Demographic information of the participating patients and carers who completed all three rounds of the Delphi survey (n = 25)

Characteristic	Value
<b>Patients (n = 21)</b>	
Age (years)	
30–50	3 (14)
51–70	13 (62)
>70	5 (24)
Sex	
Male	10 (48)
Female	11 (52)
Type of tumour	
Locally advanced primary rectal cancer	11 (52)
Locally recurrent rectal cancer	10 (48)
Time since exenteration surgery (months), median (interquartile range)	36 (24–50)
<b>Carers (n = 4)</b>	
Age (years)	
30–50	0
51–70	2 (50)
>70	2 (50)
Sex	
Male	0
Female	4 (100)
Relationship to patient who underwent exenteration	
Spouse	4 (100)
Immediate family	0
Other	0

Values are n (%) unless otherwise indicated.

'consensus in' criteria among all stakeholder groups (patients, carers, and clinicians) and were therefore considered the final priority outcomes.

### Third-round survey

The nine priority outcomes were distributed in the third round and scores of relative importance attributed to these outcomes

**Table 2 Demographic information of the participating clinicians who completed all three rounds of the Delphi survey (n = 116)**

Characteristic	Value
<b>Age (years)</b>	
<31	3 (2.6)
31–50	66 (56.9)
51–70	47 (40.5)
<b>Sex</b>	
Male	84 (72.4)
Female	32 (27.6)
<b>Profession</b>	
Surgeon	91 (78.4)
Nurse	7 (6.0)
Radiation oncologist	4 (3.4)
Anaesthetist	4 (3.4)
Medical oncologist	3 (2.6)
Dietitian	3 (2.6)
Radiologist	2 (1.7)
Nuclear medicine specialist	1 (0.8)
Administrator	1 (0.8)
<b>Region</b>	
Europe and Central Asia	57 (49.1)
Australasia and Pacific	31 (26.7)
North America	20 (17.2)
East Asia	3 (2.6)
Latin America	3 (2.6)
South Asia	2 (1.7)
<b>Dedicated exenteration training (surgeons only)</b>	
Yes	58 (50.0)
No	28 (24.1)
Not applicable	30 (25.9)
<b>Experience treating advanced and recurrent rectal cancer (years)</b>	
<5	29 (25.0)
5–10	29 (25.0)
11–20	38 (32.8)
>20	20 (17.2)
<b>Access to dedicated pelvic oncology MDT meeting</b>	
Yes	106 (91.4)
No	10 (8.6)
Annual centre pelvic exenteration case volume, median (interquartile range)	30 (18–50)

Values are n (%) unless otherwise indicated. MDT, multidisciplinary team.

by each stakeholder group are presented in [Table 3](#). The outcomes of highest importance to patients were ‘overall survival’ (median score = 90.0), ‘disease-free survival’ (median score = 89.0), ‘mobility’ (median score = 88.0), and ‘resection margins’ (median score = 88.0). The outcomes of highest importance to carers were ‘distant recurrence’ (median score = 94.5), ‘resection margins’ (median score = 92.5), and ‘local recurrence-free survival’ (median score = 91.0). The outcomes of highest importance to clinicians were ‘resection margins’ (median score = 90.0), ‘overall survival’ (median score = 85.0), ‘local recurrence-free survival’ (median score = 85.0), and ‘global quality of life’ (median score = 85.0). Patient responses demonstrated less discrimination in importance between outcomes (median score range 83.0–90.0) compared with carers (77.5–94.5) and clinicians (70.0–90.0). When the ranks of individual stakeholder groups were combined, the outcomes of highest importance to the overall cohort were ‘resection margins’, ‘local recurrence-free survival’, and ‘overall survival’.

## Discussion

This study identifies nine outcomes of pelvic exenteration surgery that are considered of highest priority by patients, carers, and clinicians. These nine ‘priority outcomes’ cover four broad

domains: survival (overall survival, disease-free survival, and local recurrence-free survival), cancer recurrence (distant recurrence), patient-reported outcomes and functioning (psychological functioning, physical functioning, global quality of life, and mobility) and pathological outcomes (resection margins). Priority outcomes were considered critically important by 70% or more of participants in each stakeholder group and were selected after a comprehensive review of 1157 unique outcomes reported in the contemporary literature (published between 1990 and 2023) and 46 additional outcomes from patient and carer interviews. Importantly, the rigorous consensus methodology used to identify the high-priority outcomes in this study ensured that patients, carers, and clinicians were equally represented.

When scored and ranked by participants according to relative importance, ‘resection margins’, ‘local recurrence-free survival’, and ‘overall survival’ were considered the most important outcomes of exenteration surgery for locally advanced primary and recurrent rectal cancer. Importantly, this rank order may be less discriminatory than it appears because all nine outcomes were, by definition, already considered critically important and were scored highly in the third-round survey, particularly by patients, with little discrimination as to the relative importance of outcomes. Therefore, it is difficult to draw conclusions about differences in priorities between stakeholder groups. Nonetheless, the finding that ‘resection margins’ was ranked highest overall by participants in this study is noteworthy. R0 resection is strongly associated with improved overall survival<sup>11,12</sup>, disease-free survival<sup>13</sup>, and local recurrence-free survival<sup>14</sup>, as well as lower patient-reported long-term pain scores<sup>15</sup> and quality of life<sup>16</sup>. On this basis, achieving clear resection margins has become the ‘holy grail’ of exenterative surgery and it is likely that patients and their carers are counselled extensively by their treating clinicians about the importance of pathology margin status. However, resection margins remain only a surrogate marker for the more clinically meaningful outcomes identified in this study: survival, disease recurrence, and quality of life.

The priority outcomes identified in this study will form the outcomes of interest of a risk prediction tool being developed for patients with locally advanced primary or recurrent rectal cancer<sup>7</sup>. Developed using prospectively collected data from Royal Prince Alfred Hospital, a high-volume exenteration centre, this tool aims to predict the priority outcomes of exenteration surgery for individual patients based on preoperative information (such as demographic and disease characteristics). The goal of the risk prediction tool is to support reproducible, evidence-based decision-making for patients with locally advanced and recurrent rectal cancer, by quantifying the predicted outcomes of surgery for individual patients. Importantly, unlike many risk prediction tools and nomograms, which generally predict survival as the single outcome of interest<sup>17,18</sup>, the outcomes identified in this study and included in the proposed risk prediction tool address a range of outcome domains considered critically important by patients and carers, as well as clinicians. Although treatment decision-making must always be individualized, with consideration given to a specific patient’s goals and priorities, the ability to predict the priority outcomes identified in this study may serve as a framework for decision-making. The broader goal is to address the issue of unwarranted variation in treatment decision-making both at the time of diagnosis (that is whether an individual patient should be referred to a specialist exenteration centre) and by

**Table 3 Final priority outcomes of pelvic exenteration, which met ‘consensus in’ criteria among patient, carer, and clinician stakeholder groups**

Priority outcome	Lay description	Patients (n = 21)		Carers (n = 4)		Clinicians (n = 116)		Combined rank
		Median	Rank	Median	Rank	Median	Rank	
<b>Survival</b>								
Overall survival	The length of time until death from any cause (including cancer and non-cancer causes)	90.0	1	77.5	9	85.0	2	3
Disease-free survival	The length of time a person lives without cancer coming back	89.0	2	88.5	5	80.0	5	4
Local recurrence-free survival	The length of time a person lives without cancer coming back in the pelvis	86.0	6	91.0	3	85.0	2	2
<b>Cancer recurrence</b>								
Distant recurrence	The cancer coming back elsewhere in the body, other than the pelvis	83.0	9	94.5	1	70.0	8	8
<b>Patient-reported outcomes and functioning</b>								
Psychological functioning	Ability to think, reason, remember, and make decisions, as well as experience and cope with emotions, including fear of the cancer coming back	84.0	8	80.5	8	76.0	7	9
Physical functioning	Ability to perform daily activities, such as walking, climbing stairs, and carrying out self-care tasks	87.0	5	88.0	6	80.0	5	5
Global quality of life	Overall well-being, including physical health, emotional well-being, social relationships, and life satisfaction	85.0	7	81.5	7	85.0	2	5
Mobility	Being able to walk or get around	88.0	3	90.5	4	70.0	9	5
<b>Pathological outcomes</b>								
Resection margins	Surgical removal of the entire tumour in one piece, with clear margins	88.0	3	92.5	2	90.0	1	1

The median score of relative importance and corresponding rank for each stakeholder group is presented, as well as the combined rank.

exenteration multidisciplinary teams (that is whether an individual patient should be offered surgery).

A possible secondary application of the priority outcomes is to direct future research, including selection of endpoints and outcomes in database and trial design. The priority outcomes identified in this study address four domains: survival, cancer recurrence, patient-reported outcomes and functioning, and pathological outcomes. In the systematic review component of this study, which included 156 studies of exenterative or multivisceral resections for locally advanced primary or recurrent rectal cancer, the most commonly reported domain was ‘complications’ (146 studies, 94%); however, no complication-related outcomes reached consensus criteria to be included as priorities in this study. Conversely, four of nine priority outcomes were categorized as ‘patient-reported outcomes and functioning’, which was the least commonly reported domain in the literature (26% of studies)<sup>5</sup>. This highlights the disparity between consensus-based priority outcomes (that is considering the views of patients and carers) and those commonly reported in the contemporary literature (that is by clinicians). In future, the identified priority outcomes should be considered during study design and, in particular, prospective patient-reported outcome measurement should be considered a mandatory component of audit and quality assessment at specialist exenteration units.

The strengths of this study include patient involvement in its design and conduct, particularly in the multidisciplinary review of outcomes and piloting of the first-round survey. Importantly, for participating patients, the median time since exenteration surgery was 36 months, which ensured that the views of those living with the long-term consequences of surgery were

captured (beyond the immediate recuperation interval). The outcome longlist development process was comprehensive, involving an extensive review of outcomes reported in the contemporary literature (2756 outcomes from 156 studies) and those extracted from in-depth interviews with a large sample of patients and carers (34 patients and 5 carers). This ensured that a wide range of outcomes was captured and considered during the Delphi phase of the study. The consensus criteria, which were defined a priori, ensured that the final priority outcomes reflected the shared priorities of patients, carers, and an international group of exenteration clinicians, despite unequal numbers of participants in each stakeholder group. The attrition rate across rounds was acceptable at 49% for the overall cohort. A limitation of the study is that the patients (and their carers) invited to participate were from one country (Australia) due to practical limitations with regard to seeking ethical approval in multiple countries. Importantly, the clinician cohort represented 22 countries. The number of clinicians invited to participate in the surveys (and therefore the denominator in the calculation of response rate) is unknown due to the use of snowball sampling, where participants were asked to forward the invitation to their local multidisciplinary teams.

The priority outcomes identified in this study reflect the shared priorities of patients who have undergone pelvic exenteration for locally advanced or recurrent rectal cancer, their carers, and treating clinicians. These priorities include survival, cancer recurrence, quality of life, and resection margin status. These findings will inform the development of a risk prediction tool, which aims to predict these consensus-based priority outcomes for individual patients using information available at the point of diagnosis and to facilitate reproducible,

evidence-based decision-making, thus addressing the issue of unwarranted variation in treatment decision-making in this group of patients.

## Collaborators

### EviSurg Collaborative Group

Nabila Ansari (Royal Prince Alfred Hospital, Sydney, Australia); Kirk Austin (Royal Prince Alfred Hospital, Sydney, Australia); Wendy Brown (Royal Prince Alfred Hospital, Sydney, Australia); Phyllis Butow (University of Sydney, Sydney, Australia); Chris Byrne (Royal Prince Alfred Hospital, Sydney, Australia); Sharon Carey (Royal Prince Alfred Hospital, Sydney, Australia); Alix Dumitrescu (Royal Prince Alfred Hospital, Sydney, Australia); Sophie Hatcher (Royal Prince Alfred Hospital, Sydney, Australia); Lisa Horvath (Chris O'Brien Lifehouse Cancer Centre, Sydney, Australia); Cherry Koh (Royal Prince Alfred Hospital, Sydney, Australia); Peter Lee (Royal Prince Alfred Hospital, Sydney, Australia); Kate Mahon (Chris O'Brien Lifehouse Cancer Centre, Sydney, Australia); Kate McBride (Royal Prince Alfred Hospital, Sydney, Australia); Glen Salkeld (University of Wollongong, Wollongong, Australia); Charbel Sandroussi (Royal Prince Alfred Hospital, Sydney, Australia); David Yeo (Royal Prince Alfred Hospital, Sydney, Australia).

## Funding

K.G.M.B. is the recipient of the Mitchell J Notaras Fellowship in Colorectal Surgery from the University of Sydney. This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

## Acknowledgements

The authors would like to thank Don Robertson and Alexandra Crawford, for participating in the multidisciplinary advisory meeting, and Mr Michael Kelly from the PelvEx Collaborative, for distributing the survey invitation.

## Author contributions

Kilian G. M. Brown (Conceptualization, Data curation, Formal analysis, Writing—original draft), James Morkaya (Conceptualization, Data curation, Formal analysis, Writing—review & editing), Michael J. Solomon (Conceptualization, Methodology, Supervision, Writing—review & editing), Kheng-Seong Ng (Conceptualization, Formal analysis, Methodology, Writing—review & editing), Kate White (Conceptualization, Data curation, Methodology, Writing—review & editing), Paul Sutton (Conceptualization, Methodology, Writing—review & editing), Desmond C. Winter (Conceptualization, Data curation, Writing—review & editing), Daniel Steffens (Conceptualization, Methodology, Data curation, Supervision, Writing—review & editing), and EviSurg Collaborative Group (Conceptualization, Methodology)

## Disclosure

The authors declare no conflict of interest.

## Supplementary material

Supplementary material is available at BJS online.

## Data availability

Data can be made available, upon reasonable request, but requires ethical approval.

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