# **BMJ Open** Financial burden of postoperative complications following oesophagectomy: a scoping review protocol

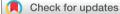
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## ABSTRACT

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#### **Correspondence to**

Dr Laurence Weinberg; laurence.weinberg@austin. org.au oesophageal adenocarcinoma has resulted in an increasing number of patients undergoing oesophagectomy. Although novel surgical techniques are enhancing surgical outcomes, postoperative complications remain pervasive. Despite this, there are limited reviews mapping the cost of postoperative complications following oesophagectomy, and none has compared cost differences between patient groups. Such information would be invaluable in appreciating the financial burden on the healthcare system and serving to guide hospital financing decisions. This scoping review protocol outlines an approach to reviewing the literature to precipitate and inform discussions surrounding financing oesophagectomy procedures as well as funding requirements for upper gastrointestinal surgical units.

Introduction The rapid rise in the incidence of

Methods and analysis Adhering to the pertinent components of the Preferred Reporting Items for Systematic Review and Meta-Analysis Extension for Scoping Review Protocols guidelines, a systematic exploration will be conducted across electronic databases, including MEDLINE, EMBASE, the Cochrane Library and Econolit, with further reference tracking of eligible studies. This review will encompass studies related to the costs associated with complications following oesophagectomy. All studies published prior to 31 October 2023 are eligible for inclusion. The process of screening and extracting data will be undertaken by two independent reviewers. Subsequently, the amassed data will be pooled and subjected to comprehensive analysis and presented descriptively, using both a mixed methods and a narrative approach.

Ethics and dissemination Ethics approval was not required. The results will be communicated through established professional networks, conference presentations and publication in peer-reviewed journals.

## **BACKGROUND AND RATIONALE**

Oesophageal cancer represents the eighth most common cancer globally and is characterised by a poor prognosis, with a 5-year survival rate of less than 20%.<sup>1</sup> Squamous cell carcinomas, comprising over 85% of oesophageal cancer,<sup>2</sup> are often associated with tobacco and alcohol consumption,

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This review will help facilitate the structuring of funding for healthcare networks performing oesophagectomies.
- ⇒ It will compare costs of open versus minimally invasive or robotic surgical techniques.
- $\Rightarrow$  We will evaluate costs of oncologic versus non-oncologic surgeries.
- ⇒ Costs between high-volume versus low-volume, and public versus private surgical centres will be evaluated.
- $\Rightarrow$  The quality of the evidence summarised may be heterogenous.

while adenocarcinomas are primarily linked to obesity and gastro-oesophageal reflux. Attributed to rising rates of obesity and gastrooesophageal reflux disease, the incidence of adenocarcinomas is increasing, whereas the decline in smoking contributes to a decrease in cases of squamous cell carcinomas.<sup>2</sup>

≥ The traditional mainstay of treatment for oesophageal cancer is oesophagectomy frequently combined with neoadjuvant Bu chemoradiotherapy.<sup>3</sup> This procedure, while used primarily in treating oesophageal cancer, is also used to manage an array of other <u>0</u> pathologies. Oesophagectomies are most commonly performed on patients in their sixth or seventh decade of life,<sup>4 5</sup> as oesophageal cancer is less common in younger individuals and older individuals are generally o poorer surgical candidates. The advancement of surgical techniques and anaesthetic  $\overline{\mathbf{g}}$ practices has translated into a burgeoning number of favourable outcomes for patients following oesophagectomy.<sup>6</sup>

While oesophagectomies are a potentially life-saving intervention, the postoperative phase is frequently accompanied by an array of potential complications. These include anastomotic leak, conduit necrosis or failure, chyle leak, stricture formation,

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gastrointestinal dysfunction, reflux, recurrent larvngeal nerve injury and others.<sup>7</sup>

Despite the well-recognised risks of complications following oesophagectomy, there are limited systematic or scoping reviews quantifying the economic burden of such complications. Such estimates can inform healthcare funding to better support upper gastrointestinal surgical units to manage these complications.

In addition to the direct medical costs of postoperative complications,<sup>8</sup> there are also indirect costs and systemwide costs. Prolonged hospitalisation, additional procedures or interventions, further diagnostic tests and an additional or extended intensive care stay all contribute to the direct costs of complications following oesophagectomy. Indirect costs include lost productivity, carer costs and reduced quality of life, whereas system-wide consequences include cost redistribution within healthcare systems and increased healthcare utilisation. The extent of these indirect costs and system-wide consequences is difficult to quantify. Particularly in healthcare systems where expenses are largely out-of-pocket, awareness of the economic burden of postoesophagectomy complications, in addition to the risks and benefits of the procedure, enables patients to make better-informed healthcare choices.

This review aims to determine the extent of the existing literature, map the fundamental concepts within this research domain, and offer an overview of available studies, their sources and their level of evidence.9 10 Due to the anticipated scarcity of published evidence, our methodology centres on amalgamating both peerreviewed and grey literature discussing or referencing 'postoperative complications', 'oesophagectomy', 'cost' and related terms. Hence, this protocol for the scoping review is crafted to pinpoint gaps in knowledge within the research, guiding future research endeavours aimed at elucidating the economic implications of complications following oesophagectomy.

## **Review objectives**

The primary objective of this scoping review will be to map the financial burden of complications following oesophagectomy, for both oncologic and non-oncologic pathologies. Specifically, this review will aim to:

- Identify the direct costs associated with complications following oesophagectomy. Direct costs will include fees to the payers, for example, to the patients, private insurance companies, or government subsidised insurance agencies, or other health providers. Direct costs will be calculated from theatre, pathology, radiology, medication, medical services, for example, anaesthesia, surgical, intensive care physician and other medical specialty costs, and nursing and allied health costs. Direct cost of intensive care or high dependency unit stay, ward costs, readmission costs and community care costs will also be identified.
- Identify indirect costs of complications. This will include the costs of the impact of complications to

delay access to surgical or oncological care, and the costs of complications impacting on return to work and loss of income, loss of productivity in the workplace and additional health burdens, such as qualityof-life costs.

- Identify the direct and indirect costs associated with both short-term and long-term oesophagectomyspecific complications. These include anastomotic leak, conduit necrosis or failure, chyle leak, reflux, recurrent laryngeal nerve injury, stricture formation and disease recurrence.
- Identify absolute and relative costs of complications, that is, absolute costs will be defined as the actual monetary value of the cost of the complication, while relative costs will be defined as the costs of one complication in relation to another complications, igh or the cost of complication from minimally invasive surgery relative to open surgery. We will compare the cost differences between the following patient groups: ត
  - luding Open versus minimally invasive versus robotic surgical techniques
  - ð Oncologic versus non-oncologic indication for surgery
  - Public versus private hospitals
  - High-volume versus low-volume surgical centres
  - Costs between countries
  - uses related to text Costs trends over time (consumer price index (CPI) adjusted)
- Evaluate and describe postoperative complication rates.
- and data m Identify the costs of unplanned intensive care unit admissions.
- Identify the costs of unplanned hospital readmissions.

## **METHODS**

The scoping review will adhere to the guidelines from . ح the Preferred Reporting Items for Systematic Review and Meta-Analysis Extension for Scoping Review Protocols (PRISMA-ScR), allowing for a systematic review of the existing literature in a rigorous and methodological manner. The methodological framework outlined by Ы Arskey and O'Malley, and expanded on by Levac, will be similar techno employed to guide this review process.<sup>11 12</sup>

## Protocol and registration

Following consultation with senior perioperative physicians, surgeons and anaesthesiologists working in B upper gastrointestinal surgery, this protocol was developed to assess the economic burden of complications postoesophagectomy. Outcomes of interest will include on the rate of complications and the costs associated with each complication, in addition to other factors including readmission to intensive care. This protocol has been submitted to an open-access, peer-reviewed journal to guarantee its dissemination, transparency, public accessibility and incorporation of feedback from key stakeholders.

	Inclusion		Exclusion
Population	<ul> <li>Human participants aged 18 years or older</li> </ul>		<ul> <li>Human participants aged less than 18 years</li> <li>Animal studies</li> </ul>
Concept	<ul> <li>Studies that evaluate postoperative of oesophagectomies</li> <li>Studies that evaluate the economic of oesophagectomies</li> </ul>		
Context	<ul> <li>Exploring the economic burden of complications following oesophagectomy</li> </ul>		
Types of evidence	<ul> <li>Primary empirical research studies (eg, randomised controlled trials, cohort studies, cross-sectional studies, case reports, economic studies)</li> <li>Full-text articles</li> <li>Full-text conference proceedings</li> <li>Grey literature produced by organisations outside of the traditional publishing and distribution channels including hospital annual reports and government documents reporting on costs of complications postoesophagectomy</li> <li>Articles written in English</li> </ul>		<ul> <li>Editorial articles (eg, perspective pieces, position statements)</li> <li>Protocols for planned studies</li> <li>Abstracts or posters</li> <li>Articles for which we cannot obtain the full text</li> <li>Articles that are not written in Englis</li> <li>Dissertations</li> </ul>
conducted on ME (OVID interface), T Register of Contro	will be located through searches DLINE (OVID interface), EMBASE EconoLit and the Cochrane Central lled Trials (Cochrane Library). All rior to 31 October 2023 are eligible	<ul><li>We will exclude ↓</li><li>Total gastrector</li><li>oesophageal ju</li></ul>	or laryngo-pharyngectomy, with resea

## Search strategy

Retrieved studies will be located through searches conducted on MEDLINE (OVID interface), EMBASE (OVID interface), EconoLit and the Cochrane Central Register of Controlled Trials (Cochrane Library). All studies published prior to 31 October 2023 are eligible for inclusion. The search strategy is presented in the online supplemental file. Complementary literature will be identified through reference tracking of eligible studies. Search strategies will employ medical subject headings and relevant text terms associated with complications following oesophagectomy.

## **Types of studies**

Primary empirical research studies meeting the criteria for eligibility will be included, whereas editorials, planned studies, dissertations and abstracts will be excluded from consideration (see table 1). We will include any grey literature produced by organisations outside of the traditional publishing and distribution channels including hospital annual reports and government documents that report on the costs of complications postoesophagectomy.

## **Eligibility criteria**

Publications reporting data on patients aged  $\geq 18$  years will be included. As the primary aim of this review is to provide a wide overview of complications following oesophagectomy, our eligibility criteria will include surgical procedures that include:

- Transthoracic oesophagectomy
- Transhiatal oesophagectomy
- Partial oesophagectomy
- Complete/radical oesophagectomy
- Minimally invasive oesophagectomy
- Oesophagectomy with conduit anastomosis

- Oesophagogastrectomy with only partial gastrectomy We will exclude the following procedures:
- Total gastrectomy, including the cardia or gastrooesophageal junction
- Laryngectomy, or laryngo-pharyngectomy, with resection of the upper oesophagus

Abstracts not available in English will be omitted. a Should an abstract, meeting eligibility criteria, be available in English while the primary manuscript is not, then the complete manuscript will be translated into English for inclusion. Although confining the search to English may introduce bias towards English-speaking nations and G limit its generalisability to non-English-speaking coun-⊳ tries, this approach was accepted considering the scoping training, and sim nature of the review, rather than intending to inform evidence-based practice.

## Screening procedure

This review will be undertaken using Covidence, a webbased systematic review platform. A three-step screening process encompassing evaluation of titles, abstracts and full-text content will be undertaken. First, two reviewers will independently assess titles and abstracts for their eligibility. To enhance the reliability of this dual-review approach, a pilot test, based on the outlined eligibility **2** criteria, will be executed on a randomly selected subset of 50 articles. Subsequently, the  $\kappa$  statistic will be calculated to determine the extent of inter-rater agreement regarding study inclusion.<sup>13</sup> The kappa result is interpreted as follows: values  $\leq 0$  indicating no agreement, 0.01-0.20 indicating no to slight agreement, 0.21-0.40 indicating fair agreement, 0.41-0.60 indicating moderate agreement, 0.61-0.80 indicating substantial agreement and 0.81-1.00 indicating almost perfect agreement. A

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pre-established a priori threshold for acceptance will be set between 0.8 and 0.90 for the kappa value, indicating a strong level of agreement. A kappa value of 0.8 to 0.90 (ie, a strong level of agreement) will be the a priori defined threshold for acceptance. Any discrepancies will prompt discussion and subsequent resolution by a third reviewer. If necessary, the data-charting form will be revised based on discrepancies identified by the third reviewer.

Following this, two reviewers will independently retrieve and examine the full-text versions of all pertinent and potentially relevant studies. A third reviewer will once more address discrepancies, leading to the exclusion of studies that do not meet the inclusion criteria. A preliminary test on the first 50 records screened will be conducted to ensure feasibility and adherence to our data collection instruments, as well as to identify any potential challenges or deficiencies within the scoping review protocol prior to its full implementation. This process will allow the screening team members to become acquainted with the protocol's procedures. The inclusion and exclusion criteria will be clarified to ensure consistent application of the selection standards. The reasons for excluding studies that undergo full-text assessment will be documented. This entire process will be documented as a PRISMA flowchart.

## **Data extraction**

The included studies will be systematically organised using a customised data extraction template to gather pertinent information from each study. This data extraction process will be carried out independently by two reviewers, and any disparities will be reviewed and resolved with the input of a third reviewer. To effectively address the objectives of this review, summarised tables will be generated to underscore the underlying evidence and address the aims of this review. The following data will be extracted to address these primary and secondary objectives.

- ► First author
- ► Year of publication
- ► Years of data collection
- Study design and research methodology
- ► Size of the study population
- ► Country of surgery
- Characteristics of the participants recruited (age, sex, health status, socioeconomic status and race/ ethnicity)
- ▶ Operative procedure and surgical approach
- Indication for surgery
- Private versus public healthcare facilities
- High-volume versus low-volume surgical centres
- Postoperative complications
- Costs of complications
- Costs of intensive care stay
- Costs of hospital admission

## **Data synthesis**

The data analysis will be conducted using statistical software (StataCorp 2023 Stata Statistical Software, Release 18;

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College Station, Texas: StataCorp LLC) and summarised descriptively. The presented data will encompass counts (proportions), medians (IQRs) and ranges (minimum to maximum values). The characteristics of the included studies will be tabulated, graphically represented and summarised in the text through a narrative approach. When possible, inferential statistics will be employed to derive probabilities of observed differences between specific groups. Research gaps will be identified through a comparative analysis of the study and participant characteristics. Both mixed methods and a narrative approach will be applied to present the results. Costs of complications will be derived either from the

Costs of complications will be derived either from the stated value within the study or by calculating the cost gradifference between the groups with and without complications. Costs will be converted to USD (\$) based on the annual average conversion rate of the specified base grurency year, or the year of publication if a currency year, was not reported. Costs will be inflated to January 2024 from January of the specified or assumed cost year using the Bureau of Labor Statistics CPI inflation calculator.

## **Ethics and dissemination**

This proposed study will not involve human participants or use unpublished secondary data. Consequently, approval from the Human Research Ethics Committee was not required. The outcomes of the scoping review will be shared via established professional networks, conference presentations and publication in a scientific journal.

## Patient and public involvement

None.

## DISCUSSION

ğ Through consolidating this body of evidence, this ≥ scoping review seeks to enhance understanding of the trair economic impact associated with complications following oesophagectomy. While limited by the potential heteroğ geneity of data being analysed, this review endeavours to map the landscape of postoperative complications and evaluate their associated costs. Specifically, a strength of this study will be elucidating the differences in economic burden between various patient groups: open versus minimally invasive versus robotic surgical techniques, oncologic versus non-oncologic indications for surgery, public versus private care and more. These findings have the potential to pinpoint prevailing gaps in current knowledge. Addressing these gaps may facilitate informed discussions surrounding financing oesophagectomy procedures. The broader discussion of our results will also encompass identifying future pathways for research and healthcare planning.

**Contributors** All authors (VB, JB, DL, PL, LW) contributed meaningfully to the preparation, drafting and editing of this scoping review protocol. LW (guarantor) conceived the idea and guided the research team throughout the protocol development. VB, DL and LW (corresponding author) conceptualised the research questions, core research plan details and data extraction tool, subsequently

generating the initial draft of this manuscript. JB and PL performed the search strategy. Following multiple rounds of editing and iterations, all authors reviewed and endorsed the final version of the submitted manuscript and agreed to be accountable for all aspects of this protocol.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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