

Oesophago-gastric cancer

Consultation on draft guideline - Stakeholder comments table

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

| Stakeholder organisation name | Doc | Page No | Line No | Comments | Developer response |
|-------------------------------|------|---------|---------|--|--|
| Action Against Heartburn | Full | 14 | 2.2 | <p>Recommendations 1-3 Provision of Information</p> <p>Having personally spoken to and communicated with many dozens of patients who have undergone oesophagectomy operations, I believe and agree that this recommendation is very important. The wording should be stronger. Access to the clinical nurse specialist and specialist dietician should be positively offered rather than merely considered. The role of these practitioners is vital, and needs to be reflected in their seniority and experience. The expertise for dietitians is very important for those recovering from curative surgery; much less so for palliative care (agreeing with paragraph 10.2.6.3). This is because the surgically altered digestive system creates its own issues (eg 'dumping syndrome', insulin spikes, malabsorption, and small intestine bacterial overgrowth) which may well not be recognised by non-specialists.</p> <p>There can be considerable assaults on quality of life after surgery, as recognised by gastroenterologists like Jervoise Andreyev of Royal</p> | <p>Thank you for your comments. The Committee have reconsidered this recommendation and given the good evidence that people require dietetic support the recommendations have been changed to 'offer specialist dietetic support' and 'offer access to a clinical nurse specialist'. In relation to your second comment about the access to dietitians following radical treatment, this recommendation has also been changed from 'consider' to 'offer specialist dietetic support'. However, as there is a separate section of the guideline (section 10) that covers nutritional support this recommendation has been removed from the information and support section and is now in the nutritional support recommendations.</p> |

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| | | | | Marsden, and the late consequences of cancer treatment should not be under estimated. | |
| Action Against Heartburn | Full | 448 | 33 | Paragraph 10.1.7.6 - Dieticians need to be either specialist or to have good familiarity with the specialist potential after-effects of oesophagectomies because of the consequences of this surgery on the digestive system and the ways in which patents need advice that is significantly different from general dietetic support. A minority of patients suffer chronic urgent diarrhoea issues where referral to specialist gastroenterological support is important. Cancer treatment ought to leave surviving patients with a reasonable quality of life, not blighted by digestive issues than can be resolved by specialist treatment. | Thank you for your comment. The Committee agree with all these statements and have changed the recommendation for people with oesophago-gastric cancer before, during and after radical treatments to 'offer' specialist dietetic support'. |

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| Action Against Heartburn | Full | General | General | <p>The references to clinical judgement and experience in assessing various trial results, some of which were some years old, are accepted without question; the same principle should apply, however, to judgement and experience for initiatives in the dietetics area where randomised controlled trial results may not be so immediately available, and where there is a good case for improving patient experience. Patients would not welcome their expensive and time consuming surgery and chemotherapy treatments being compromised from being fully complete by lack of access to good dietetic and gastroenterological support that would bring them back to better health and strength.</p> | <p>Thank you for your comment. The Committee agree with all these statements and have changed the recommendation for people with oesophago-gastric cancer before, during and after radical treatments to offer specialist dietetic support'.</p> |
| Bristol-Myers Squibb | Full | 335- 393 | general | <p>In the "palliative management" section of the document (pages 335-393), the draft guidance does not distinguish or stratify by tumour type or histology. The recommendations therefore seem only applicable for certain types of gastro and/or oesophageal cancers. Whilst section 9.1 refers to "non-metastatic oesophageal cancer", the recommendations from chapter 9.2. And 9.3 only consider gastro-oesophageal junction cancers or gastric adenocarcinomas, but seem inapplicable to squamous tumour types. Recommendations in chapter 8 (radical treatment) are clearly</p> | <p>Thank you for your comment. Many trials of palliative chemotherapy have not stratified by histological subtype and hence the evidence derived from them is from mixed tumour types. Where possible the Committee have tried to look for outcomes specific to either adeno-carcinoma or squamous cell carcinoma but frequently this data is not available. The Committee support the future planning of trials that only concentrate on single pathological types of tumour.</p> |

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| | | | | distinguished by tumour location (and histology). Since this is not the case for the recommendations in chapter 9, it is more difficult to distinguish the palliative management guideline by tumour type, location and histology. | |
| Bristol-Myers Squibb | Full | 335- 393 | general | For the “palliative treatment” section (pages 335-393), the draft scope considers a range of conventional therapies such as chemotherapy as well as specialised therapies (such as trastuzumab for HER2 mutations in oesophago-gastric cancer). However, we would like to highlight that there are multiple trials on going using immunotherapy with some initial phase 2 trials published with promising results. We recommend the guidelines make mention of immunotherapy to allow for future treatments in this field which are likely to come in over the next 1-2 years. | Thank you for your comment. The Committee are very aware of the ongoing trials of immunotherapy, but immunotherapy for palliative treatment was not prioritised for review in the scope of the guideline and so was not considered. Also, there is no published evidence for the routine use of immunotherapy and this is still a research topic. Further evidence will be forthcoming and the Committee look forward to supporting it. |
| Bristol-Myers Squibb | Full | 374-395 | General | The draft scope currently does not consider treatments beyond 2 line in the palliative management setting. We understand that it might have not been relevant until a couple of years ago, but since the last two years, research has opened up opportunities for treatments beyond 2 line therapy. | Thank you for your comment. Palliative therapy beyond 2 nd line was not considered for two reasons – firstly, there is very little RCT evidence available in this area and secondly, given the unclear situation around 2 nd line therapy, the Committee agreed that resources were better devoted to this difficult area, rather than 3 rd line therapy. |

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| Bristol-Myers Squibb | <p>Full</p> <p>Short version</p> | <p>343 344 374</p> <p>8 9</p> | <p>14 13/14 11/12</p> <p>10 12</p> | <p>We appreciate that the guidance cannot recommend one chemotherapy treatment over another, but when considering the optimal choice of chemotherapy in the different palliative management settings, it would be helpful to have an understanding which specific type of chemotherapy treatments the guideline refers to (taxanes, platines, anthracyclines or others?).</p> | <p>Thank you for your comment. The evidence for 1st line palliative chemotherapy allowed some recommendations about specific drug combinations to be made (see section 9.2.8) but for second line chemotherapy there was no conclusive evidence from a Network Meta-analysis that allowed specific types of chemotherapy to be recommended.</p> |
| Bristol-Myers Squibb | Appendix E | 66 | General | <p>Despite the fact that there has been an increasing interest in immunotherapy for different types of cancers in recent years, the guideline only includes the search term “immunotherapy” in the gastric cancer section for the Embase search strategy (page 66). Immunotherapy as search term is not included in any other section of the search strategy or in any other cancer type, which is likely to under-represent the number of currently ongoing trials in different types of gastric, oesophageal or gastro-oesophageal junction cancers, as well as the data that have already been published and presented at international cancer congresses.</p> | <p>Thank you for your comment. The Committee are very aware of the ongoing trials of immunotherapy, but at the time of the guideline development there was no published evidence for the use of immunotherapy and this is still considered a research topic. The Committee were particularly aware of an ongoing trial in gastric cancer which was nearer to publication and this was why immunotherapy was included as a search term for gastric cancer. However, this trial was only reported in abstract form before the guideline was written and so did not meet the criteria to be included.</p> |

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| British Dietetic Association (BDA) –Specialist Oncology Group | Full | General | General | Supports the need for more high quality research in nutrition support for this patient group as majority of the evidence presented is low to very low quality. | Thank you for your comment. The Committee also agreed that much more research is needed to demonstrate the benefits of nutrition support in this group of patients. |
| British Dietetic Association (BDA) –Specialist Oncology Group | Full | 17 | 26 | Could ‘consider’ be changed to ‘offer’. | Thank you for your comment. The Committee have reconsidered this recommendation and given the good evidence that people require dietetic support the recommendation has been changed to ‘offer specialist dietetic support’. |
| British Dietetic Association (BDA) –Specialist Oncology Group | | 17 | 34 | Could we incorporate nutrition screening into this recommendation or have as a separate recommendation as screening is the first stage in identifying patients at risk of malnutrition. | Thank you for your comment. The Committee agreed that in the palliative setting there was not a validated screening tool and therefore they would rather leave the recommendation as it stands. |
| British Dietetic Association (BDA) –Specialist Oncology Group | | 17 | 34 | Could ‘consider’ be changed to ‘offer’. | Thank you for your comment. The Committee agreed that there was some evidence that people undergoing palliative treatment require dietetic support but in the palliative setting the requirement for dietitian input was more variable and thus it was not appropriate to change this recommendation to ‘offer’. |

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| <p>British Dietetic Association (BDA) –Specialist Oncology Group</p> | | <p>103</p> | <p>29</p> | <p>Could by 'specialist cancer-specific dietitian' be added on the end of the sentence.</p> | <p>Thank you for your comment. As this section of the guideline relates to the general provision of information and support the Committee thought that some of this information might be provided by other members of the healthcare team such as a clinical nurse specialist and so it was not appropriate to specify that this should be always be by a dietitian.</p> |
| <p>British Dietetic Association (BDA) –Specialist Oncology Group</p> | | <p>104</p> | <p>34</p> | <p>Could 'consider' be changed to 'offer'.</p> | <p>Thank you for your comment. The Committee have reconsidered this recommendation and given the good evidence that people require dietetic support the recommendation has been changed to 'offer specialist dietetic support'. However, as there is a separate section of the guideline (section 10) that covers nutritional support this recommendation has been removed from the information and support section and is now in the nutritional support recommendations.</p> |
| <p>British Dietetic Association (BDA) –Specialist Oncology Group</p> | | <p>133</p> | <p>27</p> | <p>Could 'consider' be changed to 'offer'.</p> | <p>Thank you for your comment. The Committee agreed that there was some evidence that people undergoing palliative treatment require dietetic support but in the palliative setting the requirement for specialist input was more variable and thus it was not appropriate to change this recommendation to 'offer'.</p> |

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| <p>British Dietetic Association (BDA) –Specialist Oncology Group</p> | | <p>136</p> | <p>30</p> | <p>In this section could a list of members of the MDT be included</p> | <p>Thank you for your comment. The Committee agreed that although they had named the two vital members of the MDT, the actual composition would vary locally and so it was not appropriate to list all the members.</p> |
| <p>British Dietetic Association (BDA) –Specialist Oncology Group</p> | | <p>434</p> | <p>General</p> | <p>In the introduction section could reference to nutrition screening be incorporated as identifying patients as early as possible ensures proactive approach</p> | <p>Thank you for your comment. As this section refers to people undergoing radical treatment for oesophago-gastric cancer the Committee agreed these people would be assessed by a dietitian and that they would therefore not usually require nutrition screening. The word ‘assessment’ was added to the introduction in preference to screening so that the terminology used in the introduction was in-line with that used in the recommendations.</p> |
| <p>British Dietetic Association (BDA) –Specialist Oncology Group</p> | | <p>447</p> | <p>38</p> | <p>If include other comments regarding nutrition screening then could ‘nutrition screening’ be added into this sentence.</p> | <p>Thank you for your comment. As this section refers to people undergoing radical treatment for oesophago-gastric cancer the Committee agreed these people would be assessed by a dietitian and that they would therefore not usually require nutrition screening.</p> |

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| <p>British Dietetic Association (BDA) –Specialist Oncology Group</p> | | <p>449</p> | <p>5</p> | <p>Could ‘consider’ be changed to ‘offer’ and add in ‘nutrition screening’.</p> | <p>Thank you for your comment. The Committee have reconsidered this recommendation and given the good evidence that people require dietetic support the recommendation has been changed to ‘offer specialist dietetic support’. As this section refers to people undergoing radical treatment for oesophago-gastric cancer the Committee agreed these people would be assessed by a dietitian and that they would therefore not usually require nutrition screening.</p> |
| <p>British Dietetic Association (BDA) –Specialist Oncology Group</p> | | <p>457</p> | <p>24</p> | <p>Could ‘consider’ be changed to ‘offer’.</p> | <p>Thank you for your comment. The Committee agreed there was that there was some evidence that people undergoing palliative treatment require dietetic support but in the palliative setting the requirement for dietitian input was more variable and thus it was not appropriate to change this recommendation to ‘offer’.</p> |
| <p>British Dietetic Association (BDA) –Specialist Oncology Group</p> | <p>Full</p> | <p>General</p> | <p>General</p> | <p>Supports the need for more high quality research in nutrition support for this patient group as majority of the evidence presented is low to very low quality.</p> | <p>Thank you for your comment. The Committee also agreed that much more research is needed to demonstrate the benefits of nutrition support in this group of patients and have made a number of research recommendations.</p> |

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| <p>British Nuclear Medicine Society</p> | <p>Full</p> | <p>14</p> | <p>12 and 28</p> | <p>Recommendation 12 and 18 appear contradictory could they be combined into a single simple recommendation. Also as there are many types of PET-CT scan the term PET-CT should be replaced by F-18 FDG PET-CT throughout the whole text</p> | <p>Thank you for your comment. Recommendation 12 relates to assessment of oesophageal and gastro-oesophageal junctional tumours and recommendation 18 relates to gastric cancer so they are not contradictory as they refer to different populations. We have amended the wording of the recommendations to include the population to make this clearer.</p> <p>We have replaced PET-CT with F-18 FDG PET-CT throughout the guideline</p> |

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| British Nuclear Medicine Society | Full | 154 | 31 | <p>The comments concerning the use of FDG PET in the primary tumour is correct but the situation for nodal disease is more complex. Small peri-oesophageal nodes can be positive but missed on F-18 FDG PET-CT partly because of “spill-over” of signal from the primary tumour. However F-18 FDG PET-CT can be very useful in finding local nodal disease away from the primary remembering that in oesophageal cancer local nodes can arrive anywhere from the infra-clavicular to coeliac nodes. The comments concerning metastases is correct. Please note about 5% of oesophageal and a higher proportion of gastric cancers such as mucinous and signet cell types may not accumulate F-18 FDG. Care must be taken in reporting a negative study in these disease types.</p> | <p>Thank you for your comment. The Committee agree with the statements you have made here, and the issues with mucinous and signet cell types were discussed by the Committee (see section 7.1.9.5).</p> |
| British Nuclear Medicine Society | Full | 14 | 9-30 | <p>The imaging requirements are very vague. Most centres would perform CT for initial staging, if a radical option is possible F-18 FDG PET-CT and if possible EUS will be done to complete accurate TNM staging. Junctional type 3 tumours may also need a diagnostic laparotomy. For Gastric cancers, F-18 FDG PET-CT as stated should be used to confirm metastatic disease, CT, endoscopy, EUS and diagnostic laparotomy should be the primary staging investigations</p> | <p>Thank you for your comment. The context in which these recommendations is made is clarified in the short guideline and the sections of the long guideline, as being applicable to people who have already had an endoscopy and a CT scan. We agree with the rest of your comments, although the Committee agreed that F-18 FDG PET-CT would not always be used in gastric cancer, and this is clarified in recommendation 18.</p> |

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| <p>British Society of Gastroenterology</p> | <p>Full</p> | <p>General</p> | <p>General</p> | <p>Whilst the size of the draft guidance document is impressive, there is grave concern from the BSG about the lack of specialist contributors to a project of this scope. For example there is only one gastroenterologist contributor, despite the fact that gastroenterologists are generally at the centre of diagnostic and endoscopic assessment services and increasingly contribute to radical treatment. Furthermore despite involvement of two upper GI surgeons in the authorship, the BSG also has significant concerns around shortcomings in surgical recommendations. These concerns are itemised in further detail below.</p> | <p>Thank you for your comments. Two gastroenterologists were sought to be members of the Committee but only one eligible candidate applied. However, although there was only one gastroenterologist on the Committee there were two gastro-intestinal surgeons with a strong interest in gastroenterology and who were able to provide expert advice</p> <p>We have addressed your comments about the surgical recommendations below.</p> |
| <p>British Society of Gastroenterology</p> | <p>Full</p> | <p>15</p> | <p>20,26</p> | <p>Recommendations 14 and 17 are the same. Remove one and renumber thereafter</p> | <p>Thank you for your comment. Recommendation 14 relates to oesophageal or gastro-oesophageal cancer and recommendation 17 relates to gastric cancer, but the format pulls the recommendations into a list at the front of the full guideline which doesn't make this clear. We have amended the wording of the recommendations so even when they are read in isolation the condition to which they relate is clear.</p> |

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| <p>British Society of Gastroenterology</p> | <p>Full</p> | <p>15</p> | <p>46</p> | <p>Recommendation 24 refers only to open or hybrid oesophagectomy, but, by inference, excludes the use of totally minimally invasive oesophagectomy. Sufficient data supports the use of total minimally invasive oesophagectomy in the right centres with established expertise. (Both in the NHS and elsewhere – Richard van Hildesberg, Utrecht Netherlands Page 291 states that The committee agreed that there was insufficient evidence to either recommend or not recommend that minimally invasive procedures are performed.” So the recommendation 24 should read “.Open, hybrid, or totally minimally invasive oesophagectomy...”</p> <p>Please note reference: Comparing open and minimally invasive surgical procedures for oesophagectomy in the treatment of cancer: the ROMIO (Randomised Oesophagectomy: Minimally Invasive or Open) feasibility study and pilot trial. Metcalfe C, Avery K, Berrisford R, Barham P, Noble SM, Fernandez AM, Hanna G, Goldin R, Elliott J, Wheatley T, Sanders G, Hollowood A, Falk S, Titcomb D, Streets C, Donovan JL, Blazeby JM. Health Technol Assess. 2016 Jun;20(48):1-68. doi: 10.3310/hta20480. PMID: 27373720</p> | <p>Thank you for your comment. The Committee reconsidered the evidence in light of this comment and agreed that a change to the recommendation was warranted. We have reworded this recommendation to ‘...open or minimally invasive (including hybrid)...’ as there was no evidence to recommend one option over the other. This allows the surgeon to make the choice of operative approach.</p> <p>We have accessed some of the van Hillegersberg data but it relates to robotic surgery and therefore was not applicable to be included in this review. Also, the Metcalfe study is already discussed in the evidence to recommendations section, but this is a feasibility study only, and the Committee had already noted that the results of this study when it is completed may well provide additional information in this area. For this reason the details of this study have been passed to the NICE surveillance team.</p> |
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| British Society of Gastroenterology | Full | 51-98 | NA | <p>The formatting uses a narrow column to describe “Findings or theme” and wastes a lot of space. Consider alternative formatting with a foot-noted text box across the lower part of each page for the extended results or findings. This would make the tabulation easier to follow, the narrative easier to read and the overall pages reduced.</p> | <p>Thank you for your comment. This is the format used across all NICE guidelines for consistency so we have not been able to make your suggested change. We have noted your feedback on the formatting of GRADE tables for future qualitative reviews.</p> |
| British Society of Gastroenterology | Full | 105 | 3 | <p>Support for patients undergoing radical treatment; please note the following references:</p> <p>What surgeons tell patients and what patients want to know before major cancer surgery: a qualitative study. McNair AG, MacKichan F, Donovan JL, Brookes ST, Avery KN, Griffin SM, Crosby T, Blazeby JM. BMC Cancer. 2016 Mar 31;16:258. doi: 10.1186/s12885-016-2292-3. PMID:27036216</p> <p>Standardising the reporting of outcomes in gastric cancer surgery trials: protocol for the development of a core outcome set and accompanying outcome measurement instrument set (the GASTROS study). Alkhaffaf B, Glenny AM, Blazeby JM, Williamson P, Bruce IA. Trials. 2017 Aug 9;18(1):370. doi: 10.1186/s13063-017-2100-7. PMID:28793921</p> | <p>Thank you for your comment. We note these additional references that you have suggested in relation to this research recommendation. We had already included the McNair paper in the evidence review (see section 5.1.3). The core outcomes suggested in the Avery paper look very useful to ensure consistency and comparability when designing future studies, such as that suggested by our research recommendation. We note that the recently published Alkhaffaf study is a protocol publication which may lead to the development of core outcomes too. We agree that both these references about outcomes may be useful for the future design of studies, but as Alkhaffaf and Avery defined outcomes but did not provide qualitative evidence that addressed the review question we did not include them in the evidence review.</p> |

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| | | | | <p>Development of a Core Outcome Set for Clinical Effectiveness Trials in Esophageal Cancer Resection Surgery. Avery KN, Chalmers KA, Brookes ST, Blencowe NS, Coulman K, Whale K, Metcalfe C, Blazeby JM; ROMIO Study Group; CONSENSUS Esophageal Cancer Working Group. Ann Surg. 2017 Mar 10. doi: 10.1097/SLA.0000000000002204. [Epub ahead of print] PMID: 28288055</p> | |
| British Society of Gastroenterology | Full | 134 | 1 | <p>Organisation of Services: The 2001 Improving Outcomes Guidance is referenced but this should be complemented with more up-to-date guidance documents including: - http://www.augis.org/wp-content/uploads/2014/05/AUGIS_Provision_of_Services_Document.pdf and https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2014/03/b11-cancer-oesop-gast.pdf</p> | <p>Thank you for your comment. The Committee were aware that the Improving Outcomes Guidance (IOG) is now quite an old document but it has not been superseded. We note that AUGIS have produced excellent best practice guidance, and that the NHS England service specification builds on the IOG and refers back to it. We have included details of both of these documents in the chapter introduction</p> |

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| <p>British Society of Gastroenterology</p> | <p>Full</p> | <p>155, 156, 179</p> | <p>NA</p> | <p>Economic evidence for EUS in OG cancer : References to EUS – should include the UK HTA sponsored study entitled Cognate trial (cancer of oesophagus or gastricus- new assessment of technology of endosonography (cognate): report of pragmatic randomised trial. IT Russell, RT Edwards, AE Gliddon, DK Ingledew, D Russell, R Whitaker, ...NIHR Journals Library 2013). This was a randomised clinical trial of the value and cost effectiveness in using EUS in the UK.</p> | <p>Thank you for your comment and for highlighting this relevant study. It has been added to the economic evidence review for the topic, and showed that EUS staging was less costly and more effective ('dominant') compared to non-EUS staging.</p> <p>It should be noted, however, that the strategies considered in Cognate differ somewhat from the strategies considered in the de novo economic analysis. Our analysis takes the view that EUS is an established modality in this setting and sought to assess whether it could be used more selectively. The results of our comparison are therefore for EUS staging in all patients compared to EUS staging in selected patients, and so do not directly correlate with the Cognate study results.</p> |
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| British Society of Gastroenterology | Full | 186,187 | NA | As per comment 5, the Cognate data should again inform the discussion | <p>Thank you for your comment and for highlighting this relevant study.</p> <p>It has been added to the economic evidence review for the topic and showed that EUS staging was less costly and more effective ('dominant') compared to non-EUS staging.</p> <p>It should be noted however, that the strategies considered in Cognate differ somewhat from the strategies considered in the de novo economic analysis. Our analysis takes the view that EUS is an established modality in this setting and sought to assess whether it could be used more selectively. The results of our comparison are therefore for EUS staging in all patients compared to EUS staging in selected patients, and so do not directly correlate with the Cognate study results.</p> |
| British Society of Gastroenterology | | 190 | 21 | <p>Staging Recommendations: reference should be made to the role of peritoneal lavage cytology at staging laparoscopy: Surg Endosc. 2013 Nov;27(11):4049-53. doi: 10.1007/s00464-013-3058-5. Epub 2013 Jul 9.</p> <p>The incremental benefit of two quadrant lavage for peritoneal cytology at staging laparoscopy for oesophagogastric adenocarcinoma. Munasinghe A, Kazi W, Taniere P, Hallissey MT, Alderson D, Tucker O.</p> | <p>Thank you for your comment. The role of peritoneal lavage as a separate staging investigation was not included in the review. However, the Committee agreed this would be routinely done at the same time as staging laparoscopy. The suggested study (Munasinghe 2013), was included in the review (see section 7.1.3), because it provided evidence on staging laparoscopy rather than because it provided evidence on the incremental benefit of peritoneal lavage.</p> |

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| <p>British Society of Gastroenterology</p> | <p>Full</p> | <p>193</p> | <p>26</p> | <p>Should include further references: <i>Haidry R1, Lovat L. Long-term durability of radiofrequency ablation for Barrett's-related neoplasia. Curr Opin Gastroenterol. 2015 Jul;31(4):316-20. doi: 10.1097</i> <i>Weusten B, Bisschops R, Coron E, Dinis-Ribeiro M, Dumonceau JM, Esteban JM, Hassan C, Pech O, Repici A, Bergman J, di Pietro M. Endoscopic management of Barrett's oesophagus: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement. Endoscopy. 2017 Feb;49(2):191-198. doi: 10.1055/s-0042-122140</i> <i>Phoa KN, Pouw RE, Bisschops R, Pech O, Ragnath K, Weusten BL, Schumacher B, Rembacken B,</i> <i>Meining A, Messmann H, Schoon EJ, Gossner L, Mannath J, Seldenrijk CA, Visser M, Lerut T, Seewald S, ten Kate FJ, Ell C, Neuhaus H, Bergman JJ. Multimodality endoscopic eradication for neoplastic Barrett oesophagus: results of an European multicentre study (EURO-II). Gut. 2016 Apr;65(4):555-62. doi: 10.1136</i></p> | <p>Thank you for your comment. The population for this review question was those with T1N0 oesophageal cancer and therefore these studies with a population of people with Barrett's oesophagus were not included in the evidence review. However, as there is existing NICE guidance on Barrett's oesophagus (NICE clinical guideline 106, published in 2010) we have included a cross reference to this in our recommendations.</p> |
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| <p>British Society of Gastroenterology</p> | <p>Full</p> | <p>193</p> | <p>NA</p> | <p>The references are almost entirely to Japanese /Far eastern studies of oesophageal squamous carcinoma. Yet in the UK by far the commonest circumstance of T1N0 cancer in the oesophagus occurs in the context of Barrett's oesophagus with High Grade dysplasia and /or T1 invasive cancer. There should be reference to European (Dutch led) and (German led) studies, supported by the UK National Register of EMR in Barrett's oesophagus. In the UK the finding of T1No cancer outside the context of Barrett's oesophagus is very rare. The emphasis in this guideline reveals a lack of knowledge and understanding by the guideline committee. See further detail below:</p> | <p>Thank you for your comment. The Committee were aware of the limitations of the data from the Japanese studies, and discussed this in section 8.1.7.2. The studies that your refer to relate to the management of Barrett's oesophagus and the population of interest for this evidence review were those with T1N0 cancer The Committee were aware that T1N0 is rare, and usually found during Barrett's oesophagus surveillance but that as there is a lack of evidence to guide management currently, the Committee made recommendations that would provide useful guidance for the management of T1N0 cancer. However, as there is existing NICE guidance on Barrett's oesophagus (NICE clinical guideline 106, published in 2010) we have included a cross reference to this in our recommendations.</p> |
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| <p>British Society of Gastroenterology</p> | <p>Full</p> | <p>193</p> | | <p>The document exhibits a marked under representation of current activity internationally and nationally in the management of patients with mucosal and superficial submucosal OAC where there has been a total paradigm shift from surgery to EET (Endoscopic eradication therapy with EMR and RFA).</p> <p>The role of EET is for patient with BE neoplasia of ALL grade now – EMR followed by sequential thermal ablation with RFA in the majority of cases (with APC and Cryotherapy looking for efficacy data to become part of the ablation portfolio). There is one sentence on this – patient selection, treatment, follow up etc. is not discussed and further now with over 2000 UK patients in the RFA registry this has not been referenced.</p> <p>Further references: Shaheen NJ, Sharma P, Overholt BF <i>et al.</i> Radiofrequency ablation in Barrett's esophagus with dysplasia. <i>N Engl J Med</i> 2009;360(22):2277-88. Fitzgerald RC, di Pietro M, Ragunath K, Ang Y, Kang JY, Watson P, et al. British Society of Gastroenterology guidelines on the diagnosis and management of Barrett's oesophagus. <i>Gut.</i> 2014;63(1):7–42. Weusten B, Bisschops R, Coron E, Dinis-Ribeiro M, Dumonceau J-M, Esteban J-M, et al. Endoscopic management of Barrett's esophagus: European Society of Gastrointestinal Endoscopy (ESGE)</p> | <p>Thank you for your comment. We agree that there has been a shift away from surgery and this is why this question was included in the guideline. The Committee were also frustrated by the paucity of evidence available (as discussed in 8.1.7.2) and had hoped for more evidence on endoscopic eradication techniques, including the use of radiofrequency ablation, but none was found that met the protocol criteria.</p> <p>The population of interest was those with T1N0 disease and management of Barrett's oesophagus is covered in existing NICE guidance on this topic (NICE clinical guideline 106, published in 2010). For this reason the studies you have listed (Shaheen 2009, Fitzgerald, Weusten, Phoa, Shaheen 2015) do not meet the inclusion criteria and so would not have been included in the guideline.</p> <p>The Pech 2014 is a non-comparative study so did not meet the inclusion criteria for this review and in Haidry 2013 and Haidry 2014 all the oesophageal cancer patients underwent endoscopic mucosal resection and then radiofrequency ablation and the study did not have any control group, so again they did not meet the inclusion criteria.</p> |
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| | | | | <p>Position Statement. <i>Endoscopy</i>. 2017;49(2):191–8.</p> <p>Pech O, May A, Manner H, Behrens A, Pohl J, Weferling M, et al. Long-term efficacy and safety of endoscopic resection for patients with mucosal adenocarcinoma of the esophagus. <i>Gastroenterology</i>. 2014;146(3):652–660e1.</p> <p>Phoa KN, Pouw RE, Bisschops R, Pech O, Ragnath K, Weusten BL a M, et al. Multimodality endoscopic eradication for neoplastic Barrett oesophagus: results of an European multicentre study (EURO-II). <i>Gut</i>. 2015;1–8.</p> <p>Shaheen NJ, Falk GW, Iyer PG, Gerson L. ACG Clinical Guideline: Diagnosis and Management of Barrett’s Esophagus. <i>Am J Gastroenterol</i>. 2015;108(8):1238–49.</p> <p>Haidry RJ, Dunn JM, Butt MA <i>et al</i>. Radiofrequency ablation and endoscopic mucosal resection for dysplastic barrett's esophagus and early esophageal adenocarcinoma: outcomes of the UK National Halo RFA Registry. <i>Gastroenterology</i> 2013;145(1):87-95.</p> <p>Haidry RJ, Butt MA, Dunn JM <i>et al</i>. Improvement over time in outcomes for patients undergoing endoscopic therapy for Barrett's oesophagus-related neoplasia: 6-year experience from the first 500 patients treated in the UK patient registry. <i>Gut</i> 2014. * * (Data showing improved outcomes over time in large cohort of patients)</p> | |
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| <p>British Society of Gastroenterology</p> | <p>Full</p> | <p>193</p> | <p>T1b cancer: The direction of travel over the next 5 years will likely be a more aggressive approach of minimally invasive therapy for T1b cancer. Most international societies now acknowledge that in good prognosis SM1 cancer the loco-regional LN recurrence is lower than surgical mortality and that this should be considered as therapy of choice. References: Manner H, Pech O, Heldmann Y, May A, Pauthner M, Lorenz D, et al. The frequency of lymph node metastasis in early-stage adenocarcinoma of the esophagus with incipient submucosal invasion (pT1b sm1) depending on histological risk patterns. Surg Endosc Other Interv Tech. 2015; Schölvinck D, Künzli H, Meijer S, Seldenrijk K, van Berge Henegouwen M, Bergman J, et al. Management of patients with T1b esophageal adenocarcinoma: a retrospective cohort study on patient management and risk of metastatic disease. Surg Endosc. 2016;4102–13. Manner H, Wetzka J, May A, Pauthner M, Pech O, Fisseler-Eckhoff A, et al. Early-stage adenocarcinoma of the esophagus with mid to deep submucosal invasion (pT1b sm2-3): The frequency of lymph-node metastasis depends on macroscopic and histological risk patterns. Dis Esophagus. 2016;1–11. We are concerned that the documents authorship demonstrates</p> | <p>Thank you for your comment. The Committee are aware that this is an evolving field, that endoscopic management is likely to become more common, but that currently the evidence to support this is sparse. For this reason the Committee made a research recommendation addressing exactly the point you have raised (see 8.1.9).</p> <p>Thank you for the list of studies. We have checked these papers and found they did not meet the inclusion criteria for the review for the reasons given below: Manner 2015 – this study did not compare interventions of interest and compared the rate of metastasis development in low risk and high risk patients. Scholvinck 2016 – this study compared surgery and conservative management which was not a comparison included in the review protocol. Manner 2016 – this is a non-comparative study.</p> <p>Thank you for your comments on the authorship. Two gastroenterologists were sought to be members of the Committee but only one eligible candidate applied. However, although there was only one gastroenterologist on the Committee there were two gastro-intestinal surgeons with a strong interest in gastroenterology and who were able to provide expert advice</p> |
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| | | | | limited expertise in the major areas of therapy, with for example over-representation of oncologists, and only one gastroenterologist. The resulting document is therefore poor with misrepresentation in some areas of therapy. | |
| British Society of Gastroenterology | Full | 195 | 6 | This needs comparatives for EMR versus oesophagectomy in European studies in early cancer in Barrett's oesophagus | Thank you for your comment. We agree that European comparative studies of EMR versus oesophagectomy are needed in early disease, and that is why a research recommendation was made to this effect (see section 8.1.9) |
| British Society of Gastroenterology | Full | 197 | 22 | The BSG Oesophageal section would not accept the paragraph 8.1.7.5 that there is limited evidence regarding the eradication of Barrett's mucosa by ablation after EMR in patient with early adenocarcinoma in Barrett's oesophagus. There is an extensive literature on this topic. | Thank you for your comment. We have clarified the wording of this section to explain that as Barrett's oesophagus was not in the scope, the Committee did not look for evidence for this. The limited evidence was for T1N0 disease which was the population of interest. |
| British Society of Gastroenterology | Full | 200-334 | NA | The variations of surgery, chemo radiotherapy, and chemotherapy in combinations occupy from 200 – 334. The data on palliative management describes palliative chemo or radiotherapy until page 395. The value to a patient is not well described and the data presented in a manner which fails to show true clinical benefit from a patient perspective. The emphasis in this guideline on | Thank you for your comment. The Committee gave equal importance to all areas regardless of the amount of evidence available. The Committee felt that second line palliative chemotherapy was important to include due to the multiplicity of regimens offered against a background of little efficacy. However, the Committee agree that the balance of clinical benefit to the patient (compared to potential harms and impact on quality of life) is important in |

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| | | | | <p>first and second line chemo therapy for advanced oesophago-gastric cancer (200 pages) where very small benefits are described indicates a bias by this committee in fostering this relatively unsuccessful approach to palliation.</p> <p>Please note the reference: Long-term results and recurrence patterns from SCOPE-1: a phase II/III randomised trial of definitive chemoradiotherapy +/- cetuximab in oesophageal cancer. Crosby T, Hurt CN, Falk S, Gollins S, Staffurth J, Ray R, Bridgewater JA, Geh JI, Cunningham D, Blazeby J, Roy R, Maughan T, Griffiths G, Mukherjee S. Br J Cancer. 2017 Mar 14;116(6):709-716. doi: 10.1038/bjc.2017.21. Epub 2017 Feb 14. PMID:28196063</p> | <p>the palliative setting and have added some more detail about the absolute survival benefits to the evidence and in the discussion of the benefits and harms for both the palliative sections (9.2 and 9.3) to provide a more true representation of the clinical benefits from a patient perspective, as requested.</p> <p>Thank you for the Crosby reference. This was identified in the literature search but excluded from the evidence review as cetuximab was not an intervention of interest due to the fact that it is no longer used in current clinical practice in this setting.</p> |
| British Society of Gastroenterology | Full | 265 | 3 | <p>Recommendations for Localised oesophageal and gastro-oesophageal junctional adenocarcinoma: the evidence to choose between chemotherapy and chemo radiotherapy is weak and encouragement should be given to recruitment into the NeoEGIS trial which is designed to answer this question.</p> | <p>Thank you for your comment. The Committee recognised the lack of evidence and the existence of the ongoing Neo-AEGIS study and discussed this in section 8.4.7.5. The details of this study have also been passed the NICE surveillance team. The recommendation has been amended to encourage participation in relevant clinical trials.</p> |

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| British Society of Gastroenterology | Full | 395-458 | NA | <p>Only 38 pages are devoted to stenting (395 – 433) and nutrition occupy just 23 pages (435 – 458). Although this highlights the lack of literature it hides the fact that these modalities are used effectively and patients need to have access to these with clear algorithms to endure timely interventions and support.</p> | <p>Thank you for your comment. The Committee gave equal importance to all areas regardless of the amount of evidence available. The Committee made recommendations for both nutrition and stenting which they hope will increase equity of access to interventions and support.</p> |
| British Society of Gastroenterology | | 433 | 1 | <p>Luminal obstruction: The recommendations should differentiate clearly between intraluminal radiotherapy (brachytherapy) and external beam radiotherapy including the following reference: Lancet. 2004 Oct 23-29;364(9444):1497-504. Single-dose brachytherapy versus metal stent placement for the palliation of dysphagia from oesophageal cancer: multicentre randomised trial. Homs MY¹, Steyerberg EW, Eijkenboom WM, Tilanus HW, Stalpers LJ, Bartelsman JF, van Lanschot JJ, Wijrdeman HK, Mulder CJ, Reinders JG, Boot H, Aleman BM, Kuipers EJ, Siersema PD.</p> | <p>The Committee found limited evidence to compare brachytherapy and external beam radiotherapy and so could not recommend one over the other for the shorter term management of dysphagia.</p> <p>The suggested study (Homs 2004) was included in the evidence review but was not utilised by the Committee to make recommendations as they did not prioritise the comparison between brachytherapy and bare metal stents. This was due to the fact that the Committee agreed that bare metal stents are no longer used and have been replaced in clinical practice with self-expanding metal stents.</p> |

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| British Society of Gastroenterology | Full | 449 | 12 | The BSG Oesophageal section would strongly support the need for research into methods of nutritional support in OG cancer, both before and after resection, and also in the context of non-surgical palliative management. (10.1.9) and (10.2) | Thank you for your comment and support of these research recommendations. |
| Intuitive Surgical Sarl | Full | 200 | 40 | <p>In contrast to the statement “robotic approach compared with any open approach. No published evidence was found for this comparison”, Intuitive’s Clinical Affairs Team identified 8x publications at Oxford Level 2c or higher for oesophagectomy and 31 publications at Oxford Level 2c or higher for gastrectomy – as below.</p> <p>Reference list: 1b (1)</p> <p>Wang, G.,et al. (2016). "Assessing the safety and efficacy of full robotic gastrectomy with intracorporeal robot-sewn anastomosis for gastric cancer: A randomized clinical trial." <u>Journal of Surgical Oncology</u> 113(4): 397-404.</p> | <p>Thank you for your comment and for providing these references. We have checked them against the review protocol for the question in section 8.2 of the guideline, the surgical treatment of oesophageal cancer and provided responses for all papers below: Wang 2016, Caruso 2017, Chuan 2014, Duan 2017, Guerra 2017, He 2015, Hyun 2013, Kostakis 2016, Liao 2013a(PLoS ONE), Liao 2013b(Asian Pacific Journal of Cancer Prevention), Liu 2016, Magouliotis 2016, Marano 2013, Shen 2014, Xiong 2012, Xiong 2013, Yang 2016, Zong 2014, Kim 2015, Kim 2017, Kong 2017, Liu 2016, Eom 2016, Glenn 2015,</p> <p>Greenleaf 2016, Khorgami 2016, Leung 2017, Rhome 2017 and Wormer 2013 did not meet the inclusion criteria because we did not consider gastric cancer in this review. Maeso 2010 did not meet the inclusion criteria as the surgery was not specific for oesophageal cancer). Berelavichus 2015 did not meet the inclusion criteria as the study included people with gastrointestinal stromal</p> |

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| | | | | <p>2a (18)</p> <p>Caruso, S., et al. (2017). "Robot-assisted laparoscopic vs open gastrectomy for gastric cancer: Systematic review and meta-analysis." <u>World Journal of Clinical Oncology</u> 8(3): 273-284.</p> <p>Chuan, L., et al. (2014). "Meta-analysis of the short-term outcomes of robotic-assisted compared to laparoscopic gastrectomy." <u>Minim Invasive Ther Allied Technol</u> 24(3): 127-134.</p> <p>Duan, B. S., et al. (2017). "Robotic Versus Laparoscopic Gastrectomy for Gastric Cancer: A Pooled Analysis of 11 Individual Studies." <u>Surgical Laparoscopy, Endoscopy and Percutaneous Techniques</u> 27(3): 147-153.</p> <p>Guerra, F., et al. (2017). "Pancreas-related complications following gastrectomy: systematic review and meta-analysis of open versus minimally invasive surgery." <u>Surgical Endoscopy and Other Interventional Techniques</u>: 1-11.</p> | <p>tumor (GIST). Giugliano 2016 did not meet the inclusion criteria as the search technique was not systematic, or not described as systematic Gurusamy 2016 did not meet the inclusion criteria as this considered non-randomised studies. Oor 2016 did not meet the inclusion criteria as the main outcome of this study, which is hiatal hernia, was not part of the protocol and the indication for oesophagectomy performed in this study was unclear. Stizenberg 2015 did not meet the inclusion criteria because the population included patients with bladder, lung, pancreas and oesophagus cancer and the focus of this study, was to examine the association between travel distances and readmission rates and survival outcomes, which was not part of the protocol. Strandby 2017, Kang 2015, Weksler, Yerokun 2016 did not meet the inclusion criteria as these are nonrandomised studies. Only randomised studies were considered for this review 8.2.</p> <p>Many of the studies in the reference list mention cost outcomes. However they were not included in the economic evidence review because they did not meet the inclusion criteria. Specifically, they did not report cost-effectiveness outcomes (such as a cost per QALY). Studies reporting costs alone can sometimes be included but only if they</p> |
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| | | | | <p>He, W., et al. (2015). "Surgical interventions for gastric cancer: A review of systematic reviews." <u>International Journal of Clinical and Experimental Medicine</u> 8(8): 13657-13669.</p> <p>Hyun, M. H., et al. (2013). "Systematic review and meta-analysis of robotic surgery compared with conventional laparoscopic and open resections for gastric carcinoma." <u>British Journal of Surgery</u> 100(12): 1566-1578.</p> <p>Kostakis, I. D., et al. (2016). "Comparison Between Minimally Invasive and Open Gastrectomy for Gastric Cancer in Europe: A Systematic Review and Meta-analysis." <u>Scandinavian Journal of Surgery</u>.</p> <p>Liao, G., et al. (2013). "Robotic versus open gastrectomy for gastric cancer: a meta-analysis." <u>PLoS ONE</u> 8(12): e81946.</p> <p>Liao, G. X., et al. (2013). "Meta-analysis of Outcomes Compared between Robotic and Laparoscopic Gastrectomy for Gastric</p> | <p>are applicable to the UK health care system. In this case, the studies consider the US health care system and so the costs could differ substantially from the UK. Furthermore, in many cases, the populations included in the cost studies do not match our population of interest (as they consider broader populations than patients with OG cancer).</p> |
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| | | | | <p>Cancer." <u>Asian Pacific Journal of Cancer Prevention</u> 14(8): 4871-4875.</p> <p>Liu, G., et al. (2016). "[Robotic versus laparoscopic gastrectomy for gastric cancer: a meta-analysis]." <u>Zhonghua Wei Chang Wai Ke Za Zhi</u> 19(3): 328-333.</p> <p>Maeso, S., et al. (2010). "Efficacy of the da vinci surgical system in abdominal surgery compared with that of laparoscopy: a systematic review and meta-analysis." <u>Annals of Surgery</u> 252(2): 254-262.</p> <p>Magouliotis, D. E., et al. (2016). "Robotic versus Laparoscopic Sleeve Gastrectomy for Morbid Obesity: a Systematic Review and Meta-analysis." <u>Obesity Surgery</u>.</p> <p>Marano, A., et al. (2013). "Robotic versus Laparoscopic versus Open Gastrectomy: A Meta-Analysis." <u>J Gastric Cancer</u> 13(3): 136-148.</p> <p>Shen, W. S., et al. (2014). "A meta-analysis of robotic versus laparoscopic gastrectomy for gastric cancer." <u>Surgical Endoscopy</u>.</p> | |
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| | | | | <p>Xiong, B. M., L.; Zhang, C. (2012). "Robotic versus laparoscopic gastrectomy for gastric cancer: A meta-analysis of short outcomes." <u>Surgical Oncology</u>.</p> <p>Xiong, J., et al. (2013). "Comparison of Short-Term Clinical Outcomes Between Robotic and Laparoscopic Gastrectomy for Gastric Cancer: A Meta-analysis of 2495 Patients." <u>Journal of Laparoendoscopic and Advanced Surgical Techniques. Part A</u>.</p> <p>Yang, Y., et al. (2016). "Robotic gastrectomy versus open gastrectomy in the treatment of gastric cancer." <u>Journal of Cancer Research and Clinical Oncology</u>: 1-10.</p> <p>Zong, L., et al. (2014). "Efficacy evaluation of subtotal and total gastrectomies in robotic surgery for gastric cancer compared with that in open and laparoscopic resections: a meta-analysis." <u>PLoS ONE</u> 9(7): e103312.</p> | |
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| | | | | <p>2b (5) Berelavichus, S. V., et al. (2015). "[Minimally invasive surgical treatment of gastrointestinal stromal tumor]." <u>Khirurgiia (Mosk)</u>(3): 38-41.</p> <p>Kim, H. I., et al. (2015). "Multicenter Prospective Comparative Study of Robotic Versus Laparoscopic Gastrectomy for Gastric Adenocarcinoma." <u>Annals of Surgery</u>.</p> <p>Kim, M., et al. (2017). "Real-time vessel navigation using indocyanine green fluorescence during robotic or laparoscopic gastrectomy for gastric cancer." <u>Journal of Gastric Cancer</u> 17(2): 145-153.</p> <p>Kong, S. H., et al. (2017). "A Feasibility Study and Technical Tips for the Use of an Articulating Bipolar Vessel Sealer in da Vinci Robot-Assisted Gastrectomy." <u>Journal of Laparoendoscopic and Advanced Surgical Techniques. Part A</u>.</p> <p>Liu, X. X., et al. (2016). ""Fast-track" and "Minimally Invasive" Surgery for Gastric Cancer." <u>Chinese Medical Journal</u> 129(19): 2294-2300.</p> | |
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| | | | | <p>2c (7)</p> <p>Eom, B. W., et al. (2016). "Korean gastric cancer association nationwide survey on gastric cancer in 2014." <u>Journal of Gastric Cancer</u> 16(3): 131-140.</p> <p>Glenn, J. A., et al. (2015). "Minimally invasive gastrectomy for cancer: current utilization in US academic medical centers." <u>Surgical Endoscopy</u>.</p> <p>Greenleaf, E. K., et al. (2016). "Minimally invasive surgery for gastric cancer: the American experience." <u>Gastric Cancer</u>: 1-11.</p> <p>Khorgami, Z., et al. (2016). "Cost of bariatric surgery and factors associated with increased cost: An analysis of national inpatient sample." <u>Surgery for Obesity and Related Diseases</u>.</p> <p>Leung, K., et al. (2017). "Minimally invasive gastrectomy for gastric cancer: A national perspective on oncologic outcomes and overall survival." <u>Surgical Oncology</u> 26(3): 324-330.</p> | |
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| | | | | <p>Rhome, R. M., et al. (2017). "Predictors of Positive Margins After Definitive Resection for Gastric Adenocarcinoma and Impact of Adjuvant Therapies." <u>International Journal of Radiation Oncology Biology Physics</u> 98(5): 1106-1115.</p> <p>Wormer, B. A., et al. (2013). "The first nationwide evaluation of robotic general surgery: a regionalized, small but safe start." <u>Surgical Endoscopy</u> 28(3): 767-776.</p> <p>2. Oesophagectomy evidence found:</p> <p>2a (3)</p> <p>Giugliano, D. N., et al. (2016). "Total minimally invasive esophagectomy for esophageal cancer: approaches and outcomes." <u>Langenbeck's Archives of Surgery</u> 401(6): 747-756.</p> <p>Gurusamy, K. S., et al. (2016). "Laparoscopic versus open transhiatal oesophagectomy for oesophageal cancer." <u>Cochrane Database of Systematic Reviews</u> 2016(3).</p> | |
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| | | | | <p>Oor, J. E., et al. (2016). "Hiatal Hernia After Open versus Minimally Invasive Esophagectomy: A Systematic Review and Meta-analysis." <u>Annals of Surgical Oncology</u> 23(8): 2690-2698.</p> <p>2b (1)</p> <p>Strandby, R. B., et al. (2017). "Plasma pro-atrial natriuretic peptide to estimate fluid balance during open and robot-assisted esophagectomy: a prospective observational study." <u>BMC Anesthesiol</u> 17(1): 20.</p> <p>2c (4)</p> <p>Kang, C. H., et al. (2015). "Current Trend of Robotic Thoracic and Cardiovascular Surgeries in Korea: Analysis of Seven-Year National Data." <u>Korean J Thorac Cardiovasc Surg</u> 48(5): 311-317.</p> <p>Stitzenberg, K. B., et al. (2015). "Exploring the burden of inpatient readmissions after major cancer surgery." <u>Journal of Clinical Oncology</u> 33(5): 455-464.</p> | |
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| | | | | <p>Weksler, B. and J. L. Sullivan (2017). "Survival After Esophagectomy: A Propensity-Matched Study of Different Surgical Approaches." <u>Annals of Thoracic Surgery</u>.</p> <p>Yerokun, B. A., et al. (2016). "Minimally Invasive Versus Open Esophagectomy for Esophageal Cancer: A Population-Based Analysis." <u>Annals of Thoracic Surgery</u>.</p> | |
| Intuitive Surgical Sarl | Full | 217 | 2 | <p>2a (3)</p> <p>Giugliano, D. N., et al. (2016). "Total minimally invasive esophagectomy for esophageal cancer: approaches and outcomes." <u>Langenbeck's Archives of Surgery</u> 401(6): 747-756.</p> <p>Gurusamy, K. S., et al. (2016). "Laparoscopic versus open transhiatal oesophagectomy for oesophageal cancer." <u>Cochrane Database of Systematic Reviews</u> 2016(3).</p> <p>Oor, J. E., et al. (2016). "Hiatal Hernia After Open versus Minimally Invasive Esophagectomy: A Systematic Review and Meta-analysis." <u>Annals of Surgical Oncology</u> 23(8): 2690-2698.</p> | <p>Thank you for your comment and for providing these references. We have checked them against the review protocol for the question in section 8.2 of the guideline, the surgical treatment of oesophageal cancer and provided responses for all papers below:</p> <p>Giugliano 2016 did not meet the inclusion criteria as it is unclear from the abstract whether systematic search was performed or not. For the systematic review to have for full paper assessment, the study must meet the review protocol and the abstract must mention that the systematic search was undertaken.</p> <p>Gurusamy 2016 did not meet the inclusion criteria as the study considered non-randomised studies. Oor 2016 did not meet the inclusion criteria as the main outcome of this study, which is hiatal hernia, was not part of the protocol and the indication for oesophagectomy performed in this</p> |

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| | | | | <p>2b (1)</p> <p>Strandby, R. B., et al. (2017). "Plasma pro-atrial natriuretic peptide to estimate fluid balance during open and robot-assisted esophagectomy: a prospective observational study." <u>BMC Anesthesiol</u> 17(1): 20.</p> | <p>study was unclear. Stitzenberg 2015 did not meet the inclusion criteria as the population considered was very broad (e.g. patients with bladder, lung, pancreas and oesophagus cancer were included) and the focus of this study, which is to examine the association between travel distances and readmission rates and survival outcomes, was not part of the protocol.</p> |
| | | | | <p>2c (4)</p> <p>Kang, C. H., et al. (2015). "Current Trend of Robotic Thoracic and Cardiovascular Surgeries in Korea: Analysis of Seven-Year National Data." <u>Korean J Thorac Cardiovasc Surg</u> 48(5): 311-317.</p> <p>Stitzenberg, K. B., et al. (2015). "Exploring the burden of inpatient readmissions after major cancer surgery." <u>Journal of Clinical Oncology</u> 33(5): 455-464.</p> <p>Weksler, B. and J. L. Sullivan (2017). "Survival After Esophagectomy: A Propensity-Matched Study of Different Surgical Approaches." <u>Annals of Thoracic Surgery</u>.</p> | <p>Strandby 2017, Kang 2015, Weksler, Yerokun 2016 did not meet the inclusion criteria as these are nonrandomised studies. Only randomised studies were considered for this review 8.2.</p> <p>Stitzenberg et al. 2015 was not included in the economic evidence review as it did not meet the inclusion criteria as the population considered was very broad (e.g. patients with bladder, lung, pancreas and oesophagus cancer were included) and the focus of this study, which is to examine the association between travel distances and readmission rates and survival outcomes, was not part of the protocol.</p> |

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| | | | | Yerokun, B. A., et al. (2016). "Minimally Invasive Versus Open Esophagectomy for Esophageal Cancer: A Population-Based Analysis." <u>Annals of Thoracic Surgery.</u> | |
| Mencap | Short | General | General | There is higher incidence of cancers related to gallstones and oesophageal reflux and those of the oesophagus, stomach and gallbladder in people with a learning disability ¹ . In addition, constipation, dysphagia and gastro-oesophageal reflux disease are common in this population group ² . These factors mean that that oesophago-gastric cancer services have a high likelihood of treating or diagnosing people with a learning disability. The chance of survival with cancer is helped by early diagnosis and prompt treatment ³ , we know that people with a learning disability can experience significant barriers to accessing both diagnosis and treatment across health services ⁴ . We recommend that | Thank you for your comment. We find that the reference you have cited for an increased incidence of oesophageal and gastric cancers in people with a learning disability relates to gallbladder cancer. However, the Committee recognised that there will be people with learning disabilities who may present later with oesophago-gastric cancer due to difficulties in expressing their needs or explaining symptoms, and that reasonable adjustments will have to be made for these people when they are being assessed and managed by healthcare services. This has been reflected in the Equalities Impact Assessment which forms part of the final guideline but is a separate document to the guideline and has been discussed in the 'linking |

¹ Cancer Research UK; 2008; Inequalities in Cancer Experienced by Those with Learning Disabilities

² NHS Digital; 2016; Health and Care of People with Learning Disabilities

³ NHS Digital; 2016; Health and Care of People with Learning Disabilities

⁴ Norah Fry Research Centre; 2013; Confidential Inquiry into Premature Deaths of People with Learning Disabilities (CIPOLD)

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| | | | | <p>this information is highlighted in the early contextual organisation of the</p> <p>guidance and the need to make reasonable adjustments to ensure equal access to treatment.</p> <p>We also understand that this guidance will be linked to Patient Experience in Adult NHS Services. We feel this document does not contain sufficient information specific to patients with a learning disability to support services to make the reasonable adjustments required. We feel guidance is needed for oesophago-gastric cancer services on how to support patients with a learning disability, either by providing this as an annex, linking to another guideline or by embedding it in the guidance itself.</p> | <p>evidence to recommendations section' at 5.1.7.5, where we have also noted</p> <p>that a NICE guideline on 'Care and support of older people with learning disabilities' is due to be published in April 2018. The recommendation on the provision of information (1.1.2) has also been amended to emphasise that information must be provided in a format that is appropriate for the person.</p> |
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| <p>NHS England – Specialised Commissioning.</p> | <p>Full</p> | <p>153</p> | <p>General</p> | <p>There is good evidence (including that presented in the draft document) that a volume/outcome relationship exists for OG cancer but this is less apparent as the unit volumes get higher. From the evidence review conducted there is no detrimental impact of higher volume centres and a trend exists until at least 60 cases per centre. It would be useful if this wording could be reviewed and clarified.</p> <p>Consolidation of services is based on more than just volume/outcome relationships and consideration needs to be given to the sustainability of services for the future. It would be therefore be imprudent to state that further configuration of services would not be appropriate given that consolidation is usually driven by a multitude of factors. It would perhaps be wise to acknowledge that the consolidation of services can be driven by other factors (other than unit volumes) and review the statement included in the clinical guideline around there being no clinical evidence to support further configuration of services.</p> | <p>Thank you for your comments. The wording of section 6.2.6.5 has been amended to add that there is no evidence of a detrimental effect of higher volume centres.</p> <p>The Committee made their recommendations based on the clinical evidence available to them but recognise that there are other factors that impact on decisions to consolidate services and have amended the wording at section 6.2.6.5 to reflect this.</p> |
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| <p>Royal College of Physicians and Surgeons of Glasgow</p> | <p>Full</p> | <p>General</p> | <p>General</p> | <p>The Royal College of Physicians and Surgeons of Glasgow welcomes this NICE Guideline on Oesophago-Gastric Cancer which can be a devastating disease for some individuals. It welcomes the review of the rationale for treatment which affects over 13000 people in England and causes 10,000 deaths per year. No assessment is made of individuals affected in other parts of the United Kingdom. It however welcomes the review of investigation, management (including radical and palliative aspects). It also welcomes the recommendation of support for the person and their families The document also recommends research priorities in this disease.</p> <p>The document was sent to two reviewers. One welcomed the whole document and had no specific comment. Our second reviewer comments on Section 9</p> | <p>Thank you for your comment. We agree this is a devastating disease. NICE guidelines cover health and care in England (see page 3) and that is why we have focused on the data for England.</p> |
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| <p>Royal College of Physicians and Surgeons of Glasgow</p> | <p>Full</p> | <p>Section 9</p> | <p>Our reviewer notes the section covers the palliative management of oesophago-gastric cancer. However, it only covers palliative chemo-radiotherapy and the management of luminal obstruction. He points out that a common symptom at presentation/diagnosis is GI bleeding. This may persist in patients not receiving treatment with curative intent causing morbidity e.g. from recurrent anaemia +/- requirement for IP admission and/or transfusion. This of course will affect quality of life.</p> <p>We consider that it would be useful if the approach to management of recurrent / refractory GI bleeding could be addressed by the guidelines.</p> <p>In particular:</p> <ol style="list-style-type: none"> 1. Should this be treated with laser? 2. Is there a role for other thermoablative therapy which may be more widely available (e.g. high-dose APC)? 3. What is the role of radiotherapy? 4. Can interventional radiology procedures help? 5. Any benefit in giving tranexamic acid (and what does this do to the risk of VTE in such patients with active cancer)? <p>If the evidence is not available and answers to the above are not known, this would be a suitable 'research recommendation'</p> | <p>Thank you for your comment. Unfortunately the management of GI bleeding in this context was not prioritised for inclusion in this guideline, as other areas of variation and uncertainty were considered higher priorities for investigation by the guideline.</p> |
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