NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Oesophago-gastric cancer: assessment and management in adults

Topic

The Department of Health in England and NHS England have asked NICE to develop a clinical guideline on the diagnosis and management of oesophago-gastric cancer.

Following discussion with stakeholders, the title has been changed from 'diagnosis and management' to 'assessment and management'.

This guideline will also be used to develop the NICE quality standard for oesophago-gastric cancer.

For more information about why this guideline is being developed, and how the guideline will fit into current practice, see the context section.

Who the guideline is for

- Healthcare professionals involved in the multidisciplinary care of people with oesophago-gastric cancer, including:
  - upper gastrointestinal surgeons
  - gastroenterologists
  - clinical and medical oncologists
  - histopathologists
  - radiologists
  - clinical nurse specialists
  - cancer services managers
  - dieticians
  - palliative care workers.

28 - Commissioners of oesophago-gastric cancer services (including Clinical
29 Commissioning Groups and NHS England Specialised Commissioning)

30 It may also be relevant for:

31 - People using oesophago-gastric cancer services, their family members and
32 carers, and the public.
33 - Healthcare professionals in primary care.

34 NICE guidelines cover health and care in England. Decisions on how they
35 apply in other UK countries are made by ministers in the Welsh Government,
36 Scottish Government, and Northern Ireland Executive.

37 *Equality considerations*

38 NICE has carried out an equality impact assessment [add hyperlink in final
39 version] during scoping. The assessment:

40 - lists equality issues identified, and how they have been addressed
41 - explains why any groups are excluded from the scope.

42 1 What the guideline is about

43 *1.1 Who is the focus?*

44 **Groups that will be covered**

45 - Adults (18 years and over) with newly diagnosed or recurrent oesophago-
46 gastric cancer.

47 **Groups that will not be covered**

48 - Adults (18 years and over) in primary care with suspected oesophago-
49 gastric cancer.
50 - Adults (18 years and over) referred to secondary care with suspected
51 oesophago-gastric cancer.
52 - People with gastrointestinal stromal tumours (GIST), neuroendocrine
53 tumours, sarcoma, melanoma or lymphomas in the oesophagus or
54 stomach.

55 • People with familial gastric cancer.

56 1.2 Settings

57 **Settings that will be covered**

58 • All settings in which NHS care is provided.

59 1.3 Activities, services or aspects of care

60 **Key areas that will be covered**

61 1 Information and support needs specific to people with oesophago-gastric
62 cancer and their carers.
63 2 Organisation of specialist teams.
64 3 Assessment of oesophago-gastric cancer:
65 – staging before curative treatment
66 – HER-2 (human epidermal growth factor receptor 2) testing.
67 4 Management of oesophago-gastric cancer:
68 – curative treatment
69 – palliative treatment
70 – nutritional support.
71 5 Follow-up of people with oesophago-gastric cancer.
72 Note that guideline recommendations will normally fall within licensed
73 indications; exceptionally, and only if clearly supported by evidence, use
74 outside a licensed indication may be recommended. The guideline will
75 assume that prescribers will use a medicine's summary of product
76 characteristics to inform decisions made with individual patients.

77 ***Areas from other published guidance that will be updated***

78 1 The section on organisation of specialist teams for curative surgery for
79 people with oesophago-gastric cancer from the Improving Outcomes
80 Guidance on Upper Gastro-intestinal Cancers (Department of Health,
81 2001).

82 **Areas that will not be covered**

83 1 Identification in primary care of people with suspected oesophago-
84 gastric cancer and their referral to secondary care.
85 2 Initial diagnosis of oesophago-gastric cancer.

86 *1.4 Economic aspects*

87 We will take economic aspects into account when making recommendations.
88 We will develop an economic plan that states for each review question (or key
89 area in the scope) whether economic considerations are relevant, and if so
90 whether this is an area that should be prioritised for economic modelling and
91 analysis. We will review the economic evidence and carry out economic
92 analyses, using an NHS and personal social services (PSS) perspective, as
93 appropriate.

94 *1.5 Key issues and questions*

95 While writing this scope, we have identified the following key issues, and key
96 questions related to them:

97 1 Information and support needs specific to people with oesophago-gastric
98 cancer and their carers
99 – What are the specific information and support needs after surgical
100 treatment of people with oesophago-gastric cancer?
101 – What are the information and support needs to manage dysphagia in
102 people with oesophago-gastric cancer?
103 2 Organisation of specialist teams
104 – What is the most effective organisation of specialist care teams for
105 people with oesophago-gastric cancer (including curative surgery)?
106 – What is the optimal provision of surgical services for curative
107 treatment for people with oesophago-gastric cancer (for example, size
108 of catchment population, number of curative operations per year,
109 enhanced recovery)?
110 3 Assessment of oesophago-gastric cancer
111 – What is/are the optimal choice and sequence of staging investigations
112 to identify metastatic disease and determine suitability for curative

113 treatment of oesophageal and gastro-oesophageal junctional cancer
114 after diagnosis with endoscopy and whole-body CT scan (for
115 example, endoscopic ultrasound, PET-CT, staging laparoscopy)?

116 – What is/are the optimal choice and sequence of staging investigations
117 to identify metastatic disease and determine suitability for curative
118 treatment of gastric cancer after diagnosis with endoscopy and whole-
119 body CT scan (for example, endoscopic ultrasound, PET-CT, staging
120 laparoscopy)?

121 – Which pathological subtypes of gastric cancer should be HER-2
122 tested?

123 4 Management of oesophago-gastric cancer

124 – What is the optimal neo-adjuvant therapy (chemotherapy, chemo-
125 radiotherapy or no treatment) for oesophageal and gastro-
126 oesophageal junctional cancer?

127 – What is the optimal choice and timing of
128 chemotherapy/chemoradiotherapy in relation to surgical treatment for
129 gastric cancer?

130 – Does radical lymph node dissection (for example, D2) improve
131 outcomes in people with oesophago-gastric cancer?

132 – What is the most effective surgical treatment (laparoscopic versus
133 open surgery) for oesophago-gastric cancer?

134 – What is the most effective curative treatment (chemoradiotherapy with
135 or without surgery) of squamous cell carcinoma of the oesophagus?

136 – What is the optimal treatment for people with local disease in the
137 oesophagus or stomach that is not suitable for surgery?

138 – What is the optimal management (endoscopic mucosal resection
139 versus surgery) of T1N0 oesophageal cancer?

140 – What is the optimal first-line chemotherapy for locally advanced and
141 metastatic oesophago-gastric cancer?

142 – What is the optimal second-line chemotherapy for locally advanced
143 and metastatic oesophago-gastric cancer?

144 – What nutritional interventions improve outcomes for people with
145 oesophago-gastric cancer receiving curative treatment (for example,
146 during chemoradiotherapy, or before and after operations)?
147 – What nutritional interventions (for example, supplementary feeding)
148 improve outcomes for people with oesophago-gastric cancer receiving
149 palliative treatment?
150 – What is the optimal treatment of dysphagia for people with
151 oesophago-gastric cancer receiving palliative treatment?
152 5 Follow-up of people with oesophago-gastric cancer
153 – What is the most effective follow-up protocol for people with
154 oesophago-gastric cancer?
155 The key questions may be used to develop more detailed review questions,
156 which guide the systematic review of the literature.

157 ## *1.6 Main outcomes*

158 The main outcomes that will be considered when searching for and assessing
159 the evidence are:

160 1 Overall survival.
161 2 Disease-free survival.
162 3 Disease-related morbidity.
163 4 Treatment-related morbidity.
164 5 Treatment-related mortality.
165 6 Health-related quality of life.
166 7 Patient-reported outcome measures.

167 168 # 2 Links with other NICE guidance, NICE quality standards, and NICE Pathways

169 ## *2.1 NICE guidance*

170 **NICE guidance about the experience of people using NHS services**

171 NICE has produced the following guidance on the experience of people using
172 the NHS. This guideline will not include additional recommendations on these
173 topics unless there are specific issues related to oesophago-gastric cancer:

174 - Patient experience in adult NHS services (2012) NICE guideline CG138
175 - Medicines adherence (2009) NICE guideline CG76

176 **NICE guidance in development that is closely related to this guideline**

177 NICE is currently developing the following guidance that is closely related to
178 this guideline:

179 - Ramucirumab for treating advanced gastric cancer or gastro-oesophageal
180 junction adenocarcinoma after chemotherapy. Publication expected
181 January 2016.
182 - Improving supportive and palliative care in adults, including service delivery
183 (update). NICE guideline. Publication expected January 2018.

184 ## *2.2 NICE Pathways*

185 NICE Pathways bring together all related NICE guidance and associated
186 products on a topic in an interactive topic-based flow chart.

187 When this guideline is published, the recommendations will be added to a new
188 NICE pathway. An outline of this pathway, based on the scope, is included
189 below. It will be adapted and more detail added as the recommendations are
190 written during guideline development.

191 NICE Pathways bring together all related NICE guidance and associated
192 products on a topic in an interactive topic-based flow chart.

193 When this guideline is published, the recommendations will be added to a new
194 NICE pathway, which will be accessible from the existing pathway on
195 gastrointestinal cancers.

196 Links to other relevant guidance will also be added to the new pathway,
197 including:

198 • Trastuzumab for the treatment of HER2-positive metastatic gastric
199 cancer (2010) NICE technology appraisal guidance 208

200 • Capecitabine for the treatment of advanced gastric cancer (2010) NICE
201 technology appraisal guidance 191

202 • Minimally invasive oesophagectomy (2011) NICE interventional
203 procedure guidance 407

204 • Endoscopic submucosal dissection of oesophageal dysplasia and
205 neoplasia (2010) NICE interventional procedure guidance 355

206 • Endoscopic submucosal dissection of gastric lesions (2010) NICE
207 interventional procedure guidance 360

208 • Laparoscopic gastrectomy for cancer (2008) NICE interventional
209 procedure guidance 269

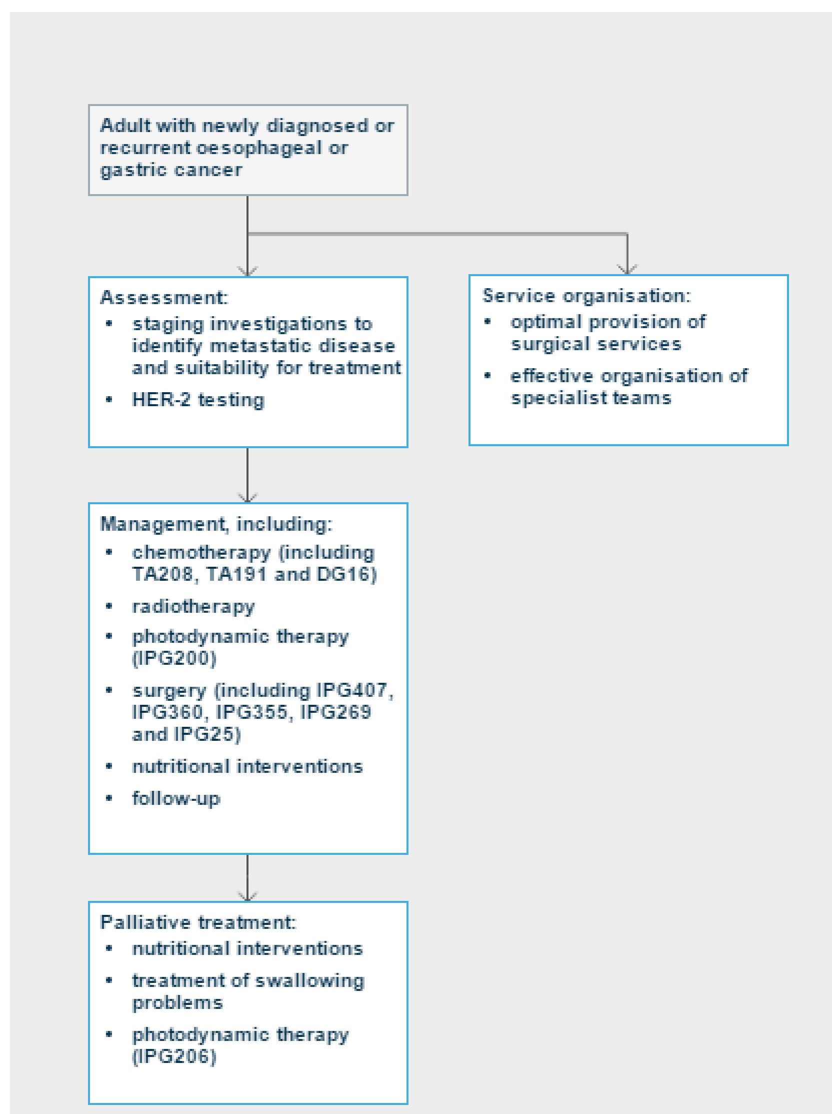
210 • Palliative photodynamic therapy for advanced oesophageal cancer
211 (2007) NICE interventional procedure guidance 206

212 • Photodynamic therapy for early oesophageal cancer (2006) NICE
213 interventional procedure guidance 200

214 • Laparo-endogastric surgery (2003) NICE interventional procedure
215 guidance 25

216 • Fluorouracil chemotherapy: the My5-FU assay for guiding dose
217 adjustment (2014) NICE diagnostics guidance 16

218 An outline of the new pathway, based on the scope, is included below. It will
219 be adapted and more detail added as the recommendations are written during
220 guideline development.



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223 # 3 Context

224 ## *3.1 Key facts and figures*

225 Oesophageal cancer is the 8th most common cancer in the world, with just
226 under half a million new cases a year. It causes approximately 400,000
227 deaths per year. The prevalence of the disease varies significantly around the

228 world, and is more common in men than women. There are two common
229 histological subtypes: squamous cell carcinoma and adenocarcinoma.

230 Oesophageal cancer is the 13th most common cancer in the UK. In 2011,
231 8300 people were diagnosed with the disease.

232 Most oesophageal cancers are linked to lifestyle and other risk factors, mainly
233 tobacco smoking, obesity and alcohol. Oesophageal cancer rates have
234 increased by 56% in men and 14% in women since the mid 1970s.
235 Oesophageal cancer is the 6th most common cause of cancer deaths in the
236 UK, accounting for about 5% of all cancer deaths. In 2012, 7700 people died
237 of oesophageal cancer in the UK, and there were twice as many men than
238 women. Almost half of those who died of oesophageal cancer were aged over
239 75. The UK mortality rate is the highest in Europe for both men and women.

240 Gastric (or stomach) cancer is the 5th most common cause of cancer in the
241 world and the 3rd most common cause of death from cancer worldwide. The
242 global incidence in 2012 was 950,000, with 723,000 deaths.

243 Gastric cancer is the 11th most common cancer in men and the 15th most
244 common cancer in women in the UK, with 7100 people diagnosed with the
245 disease in 2011. The incidence has halved in the UK since the late 1980s. It is
246 the 10th most common cause of cancer death in the UK, with 4800 deaths in
247 2012. Approximately a third of gastric cancers are linked to H. Pylori infection,
248 an avoidable risk factor.

249 Survival rates for both oesophageal and gastric cancers are improving and
250 have tripled in the UK in the last 40 years. But survival remains poor, with only
251 3 in 20 (15%) of people diagnosed with oesophageal cancer and around a fifth
252 (19%) of people diagnosed with stomach cancer in 2010-11 in England and
253 Wales expected to survive their disease for 5 years or more.

254 Over the past few years there has been a rapid increase in incidence of
255 tumours at the junction of the oesophagus and stomach. These are called
256 'junctional' tumours. These tend to come from changes in the lining of the
257 oesophagus in turn leading to adenocarcinoma of the lowest part of the

258 oesophagus, which goes across the gastro-oeosphageal junction. Tumours of
259 the middle of the oesophagus have decreased in incidence over the past few
260 years.

261 3.2 Current practice

262 Current UK practice for managing oesophago-gastric cancers follows a
263 relatively straightforward pathway after diagnosis. When appropriate, people
264 with oesophago-gastric cancer are staged and discussed within an
265 oeosphago-gastric multidisciplinary team (MDT). For those people whose
266 disease is thought suitable for treatment with curative intent, further staging
267 investigations and fitness assessments are made. This is usually within the
268 context of a specialist MDT.

269 Radical surgery is within the context of a specialist surgical unit.

270 For many people, curative surgery or chemoradiotherapy is not possible and
271 appropriate palliative care is needed. This may include palliative radiotherapy
272 or chemotherapy, inserting an oesophageal stent or simply appropriate
273 supportive care.

274 As such, managing people's disease may be complex and needs
275 collaboration and discussion between the person, their family and the medical
276 teams involved.

277 3.3 Policy, legislation, regulation and commissioning

278 **Policy**

279 Department of Health (2013) Helping more people survive cancer

280 Department of Health (2012) Commissioning cancer services

281 Department of Health (2015) Achieving world-class cancer outcomes - A
282 strategy for England 2015-2020

283 **Legislation, regulation and guidance**

284 Department of Health (2001) Improving outcomes in upper gastro-intestinal
285 cancers

286 British Society of Gastroenterology (2011) Guidelines for the management of
287 oesophageal and gastric cancer

288 European Society of Medical Oncology (2013) Oesophageal cancer: ESMO
289 Clinical Practice Guidelines for diagnosis, treatment and follow-up

290 European Society of Medical Oncology (2013) Gastric cancer: ESMO–ESSO–
291 ESTRO Clinical Practice Guidelines for diagnosis, treatment and follow-up

292 Royal College of Pathologists (2007) Dataset for the histopathological
293 reporting of oesophageal carcinoma (2nd edition)

294 Royal College of Pathologists (2007) Dataset for the histopathological
295 reporting of gastric carcinoma (2nd edition)

296
4 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 23 November to 18 December 2015.

The guideline is expected to be published in [Month Year].

You can follow progress of the guideline. [Hyperlink 'guideline' to its web page.]

[After consultation, delete the first paragraph above and replace it with 'This is the final scope, incorporating comments from registered stakeholders during consultation'.]

Our website has information about how NICE guidelines are developed.

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