National Institute for Health and Care Excellence

Version 1.0 Pre-consultation

Oesophago-gastric cancer

Assessment and management in adults

Appendix A
Scope
15 June 2017

Draft for Consultation

Developed by the National Guideline Alliance, hosted by the Royal College of Obstetricians and Gynaecologists

Disclaimer

Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and/or their guardian or carer.

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Appendix A: Scope

A.1 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.

A.2 Who the guideline is for

- People using oesophago-gastric cancer services, their family members and carers, and the public.
- Healthcare professionals involved in the multidisciplinary care of people with oesophagogastric cancer, including:
- upper gastrointestinal surgeons
- gastroenterologists
- clinical and medical oncologists
- histopathologists
- radiologists
- clinical nurse specialists
- cancer services managers
- dieticians
- palliative care specialists
- therapeutic radiographers
- specialist (cancer) pharmacists.
- Commissioners of oesophago-gastric cancer services (including Clinical Commissioning Groups and NHS England Specialised Commissioning).

It may also be relevant for:

Healthcare professionals in primary care.

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

A.3 Equality considerations

NICE has carried out an equality impact assessment during scoping. The assessment:

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

A.4 What the guideline is about

A.4.1 Who is the focus?

A.4.1.1 Groups that will be covered

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

A.4.1.2 Groups that will not be covered

- Adults (18 years and over) in primary care with suspected oesophago-gastric cancer.
- Adults (18 years and over) referred to secondary care with suspected oesophago-gastric cancer.
- People with gastrointestinal stromal tumours (GIST), neuroendocrine tumours, sarcoma, melanoma or lymphomas in the oesophagus or stomach.
- · People with familial gastric cancer.

A.4.2 Settings

A.4.2.1 Settings that will be covered

All settings in which NHS care is provided.

A.4.3 Activities, services or aspects of care

A.4.3.1 Key areas that will be covered

- Information and support needs specific to people with oesophago-gastric cancer and their carers.
- 2. Organisation of specialist teams.
- 3. Assessment of oesophago-gastric cancer:
 - a. staging before curative treatment
 - b. HER-2 (human epidermal growth factor receptor 2) testing.
- 4. Management of oesophago-gastric cancer:
 - a. curative treatment
 - b. palliative treatment
 - c. nutritional support.
- 5. Follow-up of people with oesophago-gastric cancer.

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

A.4.3.2 Areas that will not be covered

- Identification in primary care of people with suspected oesophago-gastric cancer and their referral to secondary care.
- Initial diagnosis of oesophago-gastric cancer.
- Management of Barrett's oesophagus.

A.4.4 Economic aspects

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

A.4.5 Key issues and questions

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

- Information and support needs specific to people with oesophago-gastric cancer and their carers:
- 1.1 What are the specific information and support needs after surgical treatment of people with oesophago-gastric cancer?
- 1.2 What are the information and support needs to manage dysphagia in people with oesophago-gastric cancer?
- 2. Organisation of specialist teams:
- 2.1 What is the most effective organisation of specialist care teams for people with oesophago-gastric cancer (including curative surgery)?
- 2.2 What is the optimal provision of surgical services for curative treatment for people with oesophago-gastric cancer (for example, size of catchment population, number of curative operations per year, enhanced recovery)?
- 3. Assessment of oesophago-gastric cancer:
- 3.1 What is the optimal choice and sequence of staging investigations to identify metastatic disease and determine suitability for curative treatment of oesophageal and gastro-oesophageal junctional cancer after diagnosis with endoscopy and whole-body CT scan (for example, endoscopic ultrasound, PET-CT, staging laparoscopy)?
- 3.2 What is the optimal choice and sequence of staging investigations to identify metastatic disease and determine suitability for curative treatment of gastric cancer after diagnosis with endoscopy and whole-body CT scan (for example, endoscopic ultrasound, PET-CT, staging laparoscopy)?
- 3.3 Which pathological subtypes of gastric and gastro-oesophageal junctional cancer should be HER-2 tested?
- 4. Management of oesophago-gastric cancer:
- 4.1 What is the optimal choice and timing of chemotherapy or chemo-radiotherapy in relation to surgical treatment for people with localised oesophageal and gastro-oesophageal junctional cancer?
- 4.2 What is the optimal choice and timing of chemotherapy or chemoradiotherapy in relation to surgical treatment for people with gastric cancer?
- 4.3 Does radical lymph node dissection (for example, D2) improve outcomes in people with oesophago-gastric cancer?
- 4.4 What is the most effective surgical treatment (minimally invasive, open or hybrid approaches) for oesophago-gastric cancer?

- 4.5 What is the most effective curative treatment (chemoradiotherapy with or without surgery) of squamous cell carcinoma of the oesophagus?
- 4.6 What is the optimal treatment for people with local disease in the oesophagus or stomach that is not suitable for surgery?
- 4.7 What is the optimal management of T1N0 oesophageal cancer?
- 4.8 What is the optimal first-line chemotherapy for locally advanced and metastatic oesophago-gastric cancer?
- 4.9 What is the optimal second-line chemotherapy for locally advanced and metastatic oesophago-gastric cancer?
- 4.10 What nutritional interventions improve outcomes for people with oesophago-gastric cancer receiving curative treatment (for example, during chemoradiotherapy, or before and after surgery)?
- 4.11 What nutritional interventions (for example, supplementary feeding) improve outcomes for people with oesophago-gastric cancer receiving palliative treatment?
- 4.12 What is the optimal treatment of dysphagia for people with oesophago-gastric cancer receiving palliative treatment?
- 5. Follow-up of people with oesophago-gastric cancer:
- 5.1 What is the most effective follow-up protocol for people with oesophago-gastric cancer?

The key questions may be used to develop more detailed review questions, which guide the systematic review of the literature.

A.4.6 Main outcomes

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

- 1. Overall survival.
- 2. Disease-free survival.
- 3. Disease-related morbidity.
- 4. Treatment-related morbidity.
- 5. Treatment-related mortality.
- 6. Health-related quality of life.
- 7. Patient-reported outcome measures.

A.5 Links with other NICE guidance, NICE quality standards, and NICE Pathways

A.5.1 NICE guidance

NICE guidance about the experience of people using NHS services

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

Patient experience in adult NHS services (2012) NICE guideline CG138

• Medicines adherence (2009) NICE guideline CG76

NICE guidance in development that is closely related to this guideline

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

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

<u>NICE Pathways</u> bring together all related NICE guidance and associated products on a topic in an interactive topic-based flow chart.

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

<u>NICE Pathways</u> bring together all related NICE guidance and associated products on a topic in an interactive topic-based flow chart.

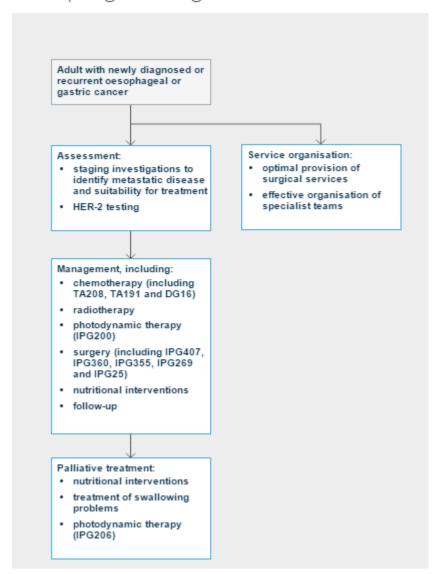
When this guideline is published, the recommendations will be added to a new NICE pathway, which will be accessible from the existing pathway on <u>gastrointestinal cancers</u>. There is also a separate pathway on <u>Barrett's oesophagus</u>.

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

- <u>Trastuzumab for the treatment of HER2-positive metastatic gastric cancer</u> (2010) NICE technology appraisal guidance 208
- <u>Capecitabine for the treatment of advanced gastric cancer</u> (2010) NICE technology appraisal guidance 191
- Minimally invasive oesophagectomy (2011) NICE interventional procedure guidance 407
- Endoscopic submucosal dissection of oesophageal dysplasia and neoplasia (2010) NICE interventional procedure guidance 355
- <u>Endoscopic submucosal dissection of gastric lesions</u> (2010) NICE interventional procedure guidance 360
- Laparoscopic gastrectomy for cancer (2008) NICE interventional procedure guidance 269
- <u>Palliative photodynamic therapy for advanced oesophageal cancer</u> (2007) NICE interventional procedure guidance 206
- <u>Photodynamic therapy for early oesophageal cancer</u> (2006) NICE interventional procedure guidance 200
- Laparo-endogastric surgery (2003) NICE interventional procedure guidance 25
- <u>Fluorouracil chemotherapy: the My5-FU assay for guiding dose adjustment</u> (2014) NICE diagnostics guidance 16

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

Oesophageal and gastric cancer overview



A.6 Context

A.6.1 Key facts and figures

Oesophageal cancer is the 8th most common cancer in the world, with just under half a million new cases a year. It causes approximately 400,000 deaths per year. The prevalence of the disease varies significantly around the world, and is more common in men than women. There are two common histological subtypes: squamous cell carcinoma and adenocarcinoma.

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

Most oesophageal cancers are linked to lifestyle and other risk factors, mainly tobacco smoking, obesity and alcohol. Oesophageal cancer rates have increased by 56% in men and 14% in women since the mid-1970s. Oesophageal cancer is the 6th most common cause of cancer deaths in the UK, accounting for about 5% of all cancer deaths. In 2012, 7700 people died of oesophageal cancer in the UK, and there were twice as many men than women.

Almost half of those who died of oesophageal cancer were aged over 75. The UK mortality rate is the highest in Europe for both men and women.

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

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

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

Over the past few years there has been a rapid increase in incidence of tumours at the junction of the oesophagus and stomach. These are called 'junctional' tumours. These tend to come from changes in the lining of the oesophagus in turn leading to adenocarcinoma of the lowest part of the oesophagus, which goes across the gastro-oeosphageal junction. Tumours of the middle of the oesophagus have decreased in incidence over the past few years.

A.6.2 Current practice

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

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

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

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

A national oesophagogastric cancer audit is undertaken annually by the Health and Social Care Information Centre.

A.6.3 Policy, legislation, regulation and commissioning

Policy

Department of Health (2013) Helping more people survive cancer

Department of Health (2012) Commissioning cancer services

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

Legislation, regulation and guidance

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

British Society of Gastroenterology (2011) <u>Guidelines for the management of oesophageal</u> and gastric cancer

European Society of Medical Oncology (2013) <u>Oesophageal cancer: ESMO Clinical Practice</u> Guidelines for diagnosis, treatment and follow-up

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

Royal College of Pathologists (2007) <u>Dataset for the histopathological reporting of</u> oesophageal carcinoma (2nd edition)

Royal College of Pathologists (2007) <u>Dataset for the histopathological reporting of gastric carcinoma (2nd edition)</u>

A.7 Further information

This is the final scope, incorporating comments from registered stakeholders during consultation.

Our website has information about how NICE guidelines are developed.