Greater Manchester &
Cheshire Cancer Network

Clinical Guidelines for the management of oesophageal and gastric cancer and cancer of the oesophago-gastric junction

The Clinical Sugroup have adopted the following clinical guidelines:

Guidelines for the management of oesophageal and gastric cancer Allum WH, Blazeby JM, Griffin SM, et al. Gut (2011). doi:10.1136/gut.2010.228254
http://www.augis.org/pdf/Gut-2011-Allum-gut-2010-228254.pdf

The following guidelines document supplements the above by providing some background information as well as the network agreed pathway and guidelines for High Grade Dysplasia. They should be read in conjunction with:

- A Consensus View and Recommendations on the Development and Practice of Minimally Invasive Oesophagectomy. The Association of Upper Gastrointestinal Surgeons (AUGIS) and The Association of Laparoscopic Surgeons of Great Britain & Ireland (ALS)
  http://www.augis.org/pdf/MIO_Consensus.pdf

- NICE Interventional Procedures Guidances www.NICE.org.uk
  - NICE 82 Aug 2004 -Photodynamic Therapy for high grade dysplasia in Barrett's oesophagus
  - NICE 200 Sep 2006 -Photodynamic therapy for early stage oesophageal cancer.
  - NICE 206 Jan 2007 -Palliative photodynamic therapy for advanced oesophageal cancer
  - NICE 269 July 2008- Laparoscopic gastrectomy for cancer
  - NICE 344 May 2010 - Epithelial radiofrequency ablation of Barrett's oesophagus
  - NICE 407 Sept 2011 - Minimally invasive oesophagectomy

- Network agreed guidelines for Pathology, Oncology and Imaging
  http://www.gmccn.nhs.uk/hp/Groups/ClinicalSubGroups/OGUpperGI/Documents/GMCCNClinicalGuidelines

Preface

May 2012
Review Date: May 2013
(As part of the annual updating of the OG CSG Constitution and Terms of Reference)

The Greater Manchester and Cheshire Cancer Network Clinical Oesophago-Gastric Clinical Subgroup have agreed to adopt the 'Guidelines for the management of oesophageal and gastric cancer' Allum et al. Gut (2011). These guidelines replace the Guidelines for the Management of Oesophageal and Gastric Cancer for Greater Manchester & Cheshire 2011.

Overview

Patients with oesophageal and gastric cancer, and cancer of the oesophagogastric junction are managed in at least twelve Trusts with Greater Manchester & Cheshire. Components of diagnosis and treatment occur at different hospital sites and by different Trusts (see Constitution and Terms of Reference for Oesophago-Gastric CSG). Defined pathways of care and effective communication between clinicians at different locations and with patients and their carers is central to good care. All patients with a diagnosis of oesophagogastric cancer should be referred to a local multidisciplinary team for oesophago-gastric cancer (Local MDT) for discussion of their clinical management in accordance with the Manual of Cancer Services 2008. Patients may receive investigation and treatment at a local hospital or may require further assessment and treatment at a centre specializing in the surgical management of oesophagogastric cancer. Delivery of oncology and radiotherapy treatment whether for palliation or for cure is undertaken at The Christie NHS Foundation Trust.

Local MDT discussion should incorporate all aspects of care including issues relating to control of symptoms, nutrition, pain control and psychosocial support whether this is within the context of surgical treatment, chemotherapy, radiotherapy, or a combination of these treatments with either curative or palliative intent. The majority of patients have incurable disease at presentation so services should be designed to accommodate their needs. Up to 50% of all patients with oesophagogastric cancer survive no more than 6 months from diagnosis. All patients should be discussed with a specialist oesophagogastric MDT, whether treatment occurs locally or at a centre which specialises in the surgical management of oesophageal and gastric cancer. Currently three centres are described in Greater Manchester & Cheshire for delivery of surgical treatment which are the sites of specialist MDT. The surgical centres work in

accordance with the AUGIS 'Consensus View and Recommendations on the Development and Practice of Minimally Invasive Oesophagectomy'.

Timely communication with patients, discussion of diagnosis and the options of treatment are central to delivery of good care. National standards exist for timely delivery of treatment from suspicion of diagnosis, diagnosis, clinical staging and treatment.

All patients are allocated a key worker with whom they communicate throughout their treatment. The key worker is a core member of an MDT

Staging

TNM version 7 should universally be used across the Greater Manchester and Cheshire Cancer Network for staging all oespophago-gastric tumours.

Patient support groups

National Oesophageal Patients Association (OPA) contact details – enquiries@opa.org.uk

Network Agreed Guidelines for High Grade Dysplasia

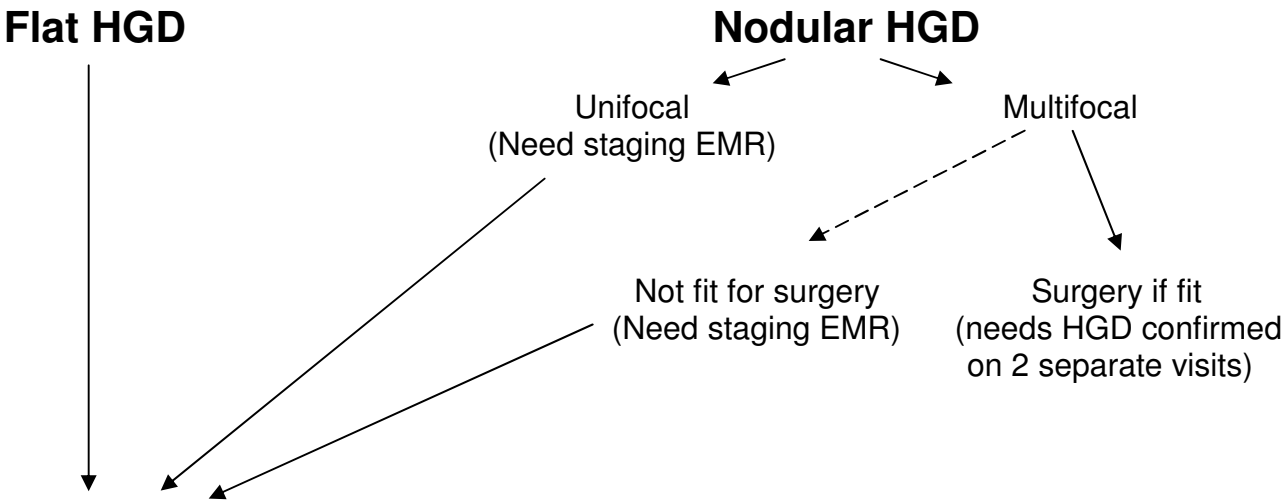
1. All patients with Barrett's high grade dysplasia (HGD) should be discussed at a specialist OG MDT. Agreed with Histopathology Cross-cutting group that this will occur from 1st April 2012
2. In flat HGD neither CT nor EUS are required prior to endoscopic therapy.
3. In flat HGD all patients should be given the opportunity to discuss endoscopic therapies with a therapeutic endoscopist who can provided such treatments (including EMR / ESD /HALO RFA).
4. In focal nodular HGD an endoscopic mucosal resection should be used as the primary staging modality to exclude underlying invasive carcinoma and then endoscopic therapies be offered.
5. In multifocal nodular HGD surgery should be the preferred modality of treatment if fit. If not fit for surgery then staging EMR should be undertaken.

6. If surgery is being considered for treatment of HGD then 2 separate gastroscopies with biopsies should be taken to confirm the diagnosis.
7. For patients undergoing HALO radiofrequency ablation a maximum of 4 treatment sessions is to be used and all patients' data should be collected as part of the national RFA registry.
8. For patients who have had RFA they should remain under the treating centre and have annual surveillance gastroscopies with biopsies (as per the national protocol).
9. For patients who fail endoscopic therapies for HGD they should be rediscussed at the specialist OG MDT.
10. Patients with persistent low grade dysplasia can be assessed for HALO RFA as part of the national research registry trial and should be given an opportunity to discuss this at a treating centre.

Barrett's High Grade Dysplasia Network Pathway

All patients with confirmed Barrett's HGD should be discussed at a sMDT before considering endoscopic therapy as an alternative to surgery.

All HGD patients should have had detailed endoscopic assessment (including narrow band imaging +/- zoom magnification and Prague classification[1]).



Barrett's Care Pathway (see appendix 2 NICE guidance 106 Aug 2010[2])

Patient to be seen in clinic by endoscopist who is experienced in offering the available therapies as below. To discuss risks & benefits & treatment options (ablative versus endoscopic resection).

Ablative Therapy
(HALO RFA / PDT)

All patients should have data collected as part of National RFA Registry and audited locally for outcomes and complications.

Endoscopic Resection
(EMR / ESD)

Additional ablative therapy may be required to remove residual flat Barrett's.

(see appendix 3 NICE interventional procedure guidance 344 May 2010[3])

All patients treated with endoscopic therapy require long term endoscopic surveillance by the treating centre after eradication to monitor and audit long term outcomes.

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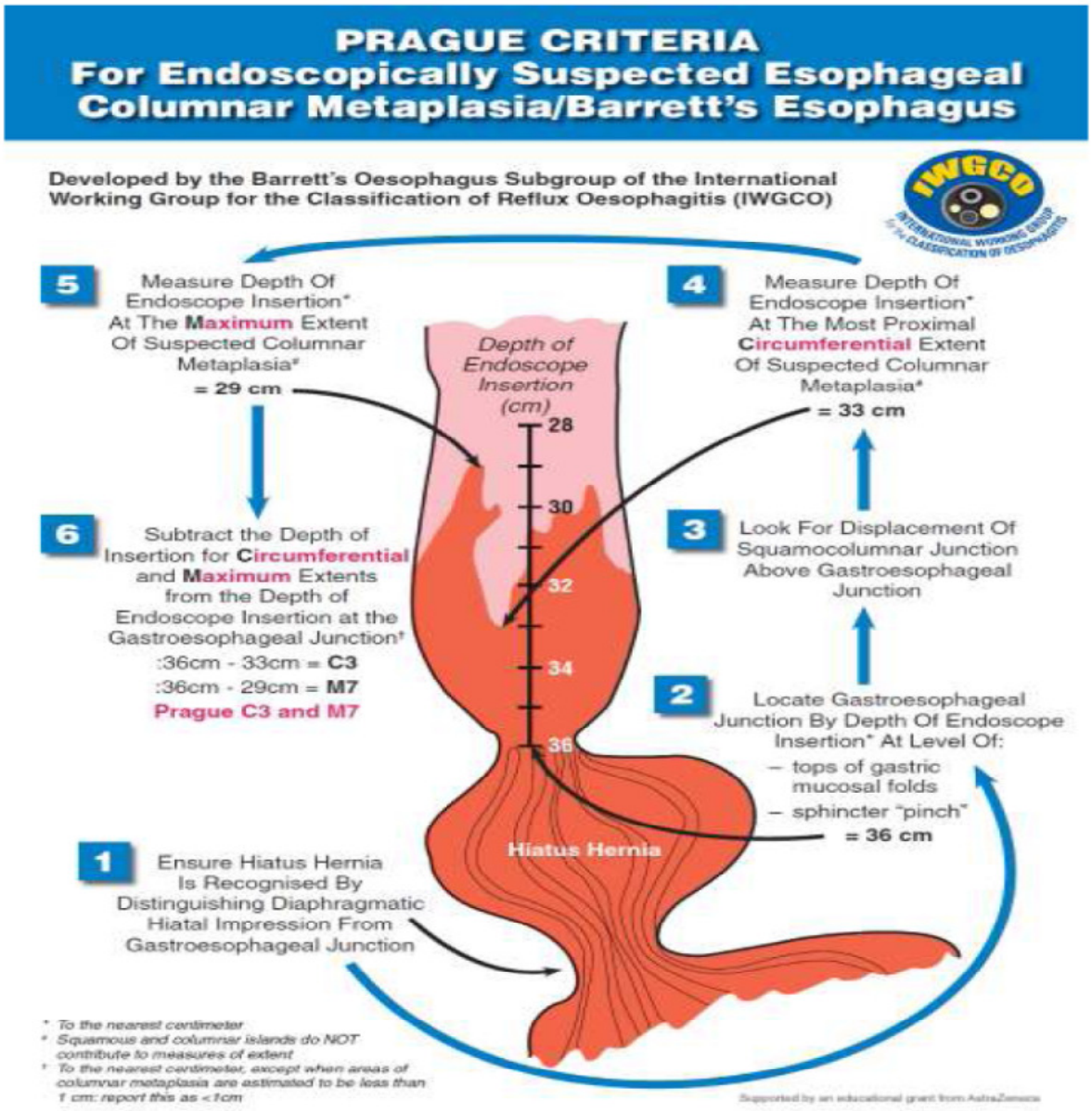
References:

Prague Classification. Sharma et al Gastroenterology (2006) 131:1392-1399 – see appendix 1.

Barrett's Oesophagus Ablative therapy Aug 2010. http://guidance.nice.org.uk/CG106 - see appendix 2

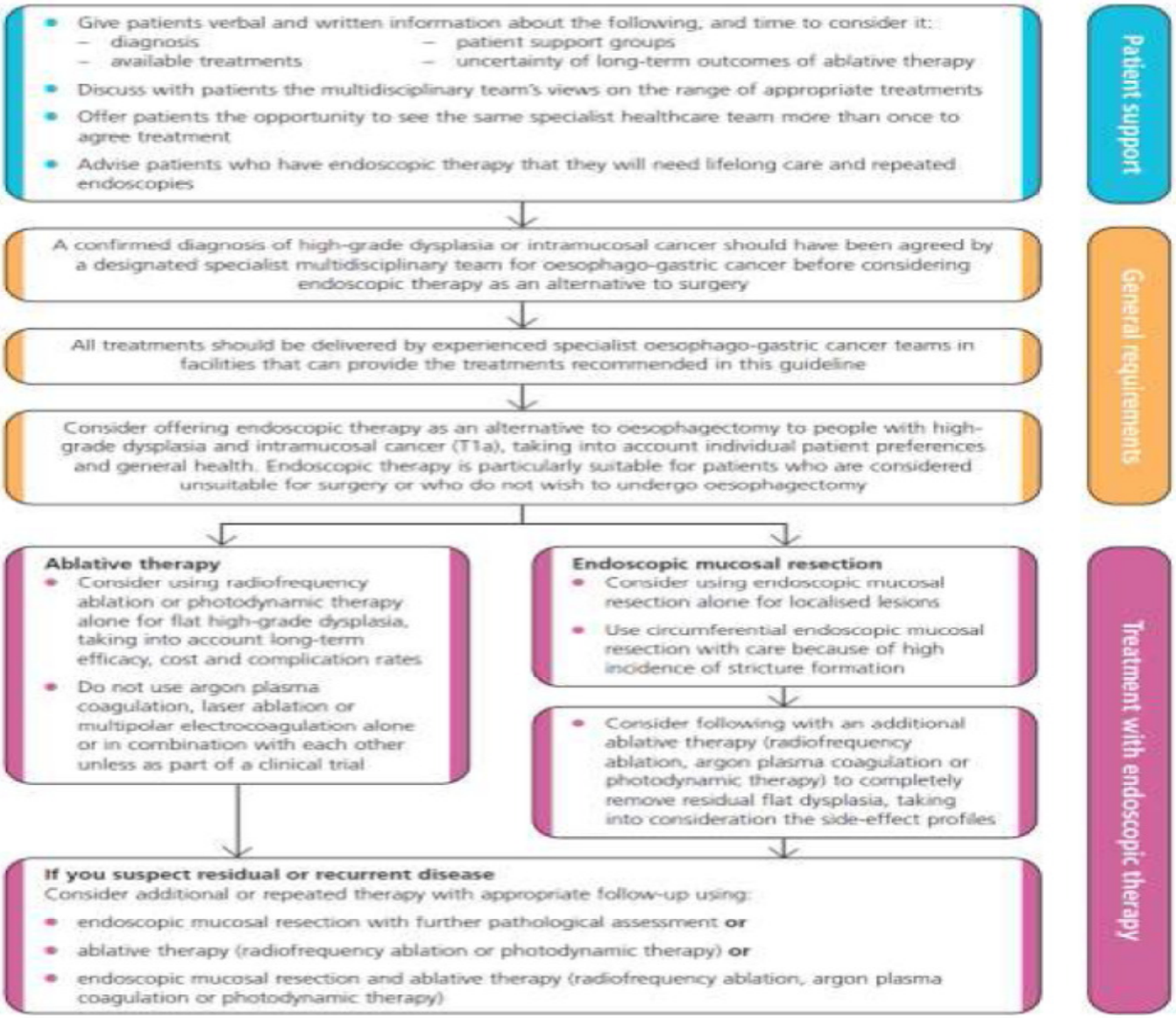
Epithelial RFA for Barrett's Oesophagus May 2010. http://guidance.nice.org.uk/IPG344 - see appendix 3.

Appendix 1. Prague Classification.



Appendix 2. NICE Guidance Barrett's oesophagus Ablative Therapy.

Care pathway



NICE clinical guideline 106 Quick reference guide

May 2012
Review Date: May 2013
(As part of the annual updating of the OG CSG Constitution and Terms of Reference)

Appendix 3. NICE Guidance RFA for Barrett's.

Issue date: May 2010

NHS
National Institute for Health and Clinical Excellence

Epithelial radiofrequency ablation for Barrett's oesophagus

This document replaces previous guidance on circumferential epithelial radiofrequency ablation for Barrett's oesophagus (interventional procedure guidance 244).

1 Guidance

1.1 Current evidence on the efficacy of epithelial radiofrequency ablation (RFA) in patients with Barrett's oesophagus with high-grade dysplasia (HGD) is adequate, provided that patients are followed up in the long term. There are no major safety concerns. Therefore this procedure may be used in patients with Barrett's oesophagus with HGD provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Current evidence on the efficacy and safety of epithelial RFA in patients with Barrett's oesophagus with either low-grade dysplasia (LGD) or no dysplasia is inadequate in quality and quantity, and the balance of risks and benefits is not clear. Therefore, in these patients, this procedure should be used only with special arrangements for clinical governance, consent and audit or research.

1.3 Clinicians wishing to undertake epithelial RFA in patients with Barrett's oesophagus with either LGD or no dysplasia should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG344/publicinfo).
- Audit and review clinical outcomes of patients with Barrett's oesophagus with LGD or no dysplasia having epithelial RFA (see section 3.1).

1.4 Patient selection for epithelial RFA for Barrett's oesophagus should be done by a multidisciplinary team experienced in the management of Barrett's oesophagus.

1.5 Epithelial RFA for Barrett's oesophagus should only be carried out by endoscopists with specific training in this procedure.

1.6 NICE encourages further research into epithelial RFA for Barrett's oesophagus. This should address the balance of risks and benefits of the procedure in patients with Barrett's oesophagus and either LGD or no dysplasia, and long-term outcomes in patients with Barrett's oesophagus of any histological type.

2 The procedure

2.1 Indications and current treatments

2.1.1 Barrett's oesophagus is a condition characterised by abnormal epithelium of the oesophagus. In some patients, Barrett's oesophagus may progress, through metaplasia and dysplasia, to oesophageal adenocarcinoma. Cancer risk is higher for patients with HGD (some of whom may already have developed early-stage cancer) and lower for patients with LGD or no dysplasia.

2.1.2 Patients with HGD are usually offered oesophagectomy, or frequent endoscopic surveillance and re-biopsy (with the aim of detecting neoplastic changes early). Endoscopic treatments that aim to remove or ablate abnormal epithelium have also been developed, including endoscopic mucosal resection and photodynamic therapy.

Interventional procedure guidance 344

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Appendix 3 cont'd.

2.1.3 Patients with LGD or no dysplasia are usually offered regular endoscopic surveillance and re-biopsy (with the aim of detecting potential progression to HGD or cancer).

2.2 Outline of the procedure

2.2.1 The aim of RFA is to destroy the Barrett's epithelium in order to allow re-epithelialisation with squamous epithelium.

2.2.2 The procedure is carried out with the patient under conscious sedation, usually in an outpatient setting. Using endoscopic visualisation, an appropriately sized RFA probe is inserted into the oesophagus and advanced to the target area. Controlled pulses of RF energy are delivered to thermally ablate a thin epithelial layer in the affected areas. RFA is sometimes used after previous endoscopic mucosal resection.

2.2.3 If follow-up endoscopy and re-biopsy show residual Barrett's changes, repeat treatment sessions may be necessary.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at www.nice.org.uk/IP397aoverview

2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 127 patients (63 with HGD and 64 with LGD) treated by RFA or a sham procedure reported complete eradication of Barrett's oesophagus in 77% (65/84) and 2% (1/43) of patients respectively at 12-month follow-up ($p < 0.001$).

2.3.2 In the same RCT, among patients with HGD, fewer RFA-treated patients progressed to cancer at 12-month follow-up (2% [1/42]) compared with those in the sham group (19% [4/21]) ($p = 0.04$).

2.3.3 A register of 142 patients with HGD reported efficacy data on 92 patients with at least 1 follow-up endoscopy. At a median 1-year follow-up, HGD resolution had occurred in 90% (83/92) of patients; 80% (74/92) had no dysplasia (HGD or LGD) and 54% (50/92) had no Barrett's at all.

2.3.4 The Specialist Advisers listed key efficacy outcomes as eradication of metaplasia and dysplasia, relapse rate and reduction in development of cancer.

2.4 Safety

2.4.1 Oesophageal stricture was reported in 6% (5/84) of patients treated by RFA in the RCT of 127 patients (successfully treated by endoscopic dilatation) and 8 patients (denominator not stated) from a register of 106 patients treated by RFA (timing of events and management not stated).

2.4.2 Buried glandular mucosa detected on surveillance biopsy was reported in 15% (4/27) of patients 6–12 weeks after RFA (precise timing of detection not stated) in a case series of 27 patients. All were treated with additional RFA. One buried glandular mucosa was reported in neosquamous epithelium among 1475 biopsies (less than 1%) in a case series of 44 patients (subsequent treatment not described).

2.4.3 In the RCT of 127 patients, 1 patient developed new-onset chest pain and 1 patient developed chest discomfort and nausea. Both patients required overnight admission to hospital.

2.4.4 The Specialist Advisers listed anecdotal adverse events as dysphagia, minor bleeding, oesophageal perforation and pain (such as retrosternal pain).

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure in patients with LGD or no dysphagia make special arrangements for audit. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion), available from www.nice.org.uk/guidance/IPG344

3.2 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/guidance/IPG344/publicinfo