# Gastroelectrical stimulation (GES) for severe gastroparesis

**Produced by:**  
Dr Mahmoud Ahmed, Fy2 Doctor  
Dr Shamsher Diu, Consultant in Public Health Medicine  
Suzanne Meredith, Consultant in Public Health  
Public Health, Norfolk County Council

**Approved by:**  
Clinical Policy Development Group of the Independent Funding Requests Panel, Norfolk and Waveney

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**Enquiries to:**  
Shamsher.Diu@norfolk.gov.uk  
07798 572345
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<td>2.4</td>
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<td>Removal of words diabetic or idiopathic from first criterion following feedback from CPDG and addition of wording to clarify currently only one specialist centre has been identified.</td>
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1.0 Criteria for Commissioning

1.1 Plain Language Summary

Gastroparesis is a disorder where the stomach empties more slowly than normal (delayed gastric emptying). This can be a complication related to Type 1 and Type 2 diabetes or where people have suffered nerve damage to their stomach after surgery, but often the reason cannot be found.

Gastroparesis can have a highly negative impact on a person’s quality of life. Symptoms include nausea, prolonged vomiting, abdominal bloating and in severe cases, malnutrition and dehydration severe enough to cause hospital admissions. There is no known cure. Current treatment aims to reduce the associated symptoms. This may involve medication, being fed via a tube or stomach surgery.

Gastro-electrical stimulation (GES) is a potential option for treating nausea and vomiting associated with gastroparesis. It involves delivering electrical impulses to the muscles in the stomach via electrodes. An operation is required to attach electrodes to the stomach.

However, some people with gastroparesis do not experience any benefit from GES and there are risks of complications, which can involve needing to remove the device.

NICE guidance\(^1\) on the safety and effectiveness of GES was issued in 2014, which has prompted a review of the commissioning policy for this treatment.

GES for gastroparesis is not routinely funded by CCGs in Norfolk. However, in exceptional cases, a request for funding may be made to the Individual Funding Request (IFR) Panel.
1.2 Policy Statement

Gastro-electrical stimulation for gastroparesis is not routinely funded.

In exceptional cases, the Individual Funding Request panel will consider requests for funding where the patient fulfils all of the following criteria 1-6 or where clinical exceptionality can be demonstrated:

1. Patients suffer from gastroparesis (defined by gastric emptying studies and assessed as part of an MDT) AND
2. The symptoms of gastroparesis are chronic, severe and debilitating (i.e. Grade 3) with evidence of impact affecting quality of life (e.g. poor diabetic control) AND
3. Symptoms are refractory to all previous treatments including dietary modifications, drug treatment (prokinetics and antiemetics) AND
4. Patients require additional nutritional support (feeding tube or total parenteral nutrition (TPN) AND
5. The only remaining treatment option would be irreversible surgery (gastrectomy, jejunostomy, pyloroplasty) AND
6. The Provider is a specialist centre for gastrointestinal motility disorders and able to fulfil NICE IPG 489 recommendations, including MDT assessment*.

7. During the consent process, the patient should be made aware that some patients do not get any benefit from GES. They should also be made aware and given written information regarding the risk of complications, including the need to remove the device (NICE IPG 489 section 1.2).

8. The Provider must agree to provide information to the Commissioner regarding the effectiveness of the intervention and the outcomes of the patient.

*Only one specialist centre was identified during the development of this policy where this treatment is available.

Acknowledgement: Hull CCG, July 2014

1.4 Equality Statement

The Clinical Policy Development Group is committed to ensuring equality of access and non-discrimination as enshrined in the Health and Social Care act 2010. In carrying out its functions, the CPDG will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998.
1.5 Clinical Governance Statement

It is important that the implementation of this policy is seen as an opportunity to encourage team working and cooperation between commissioners, primary, secondary care providers and at the interface between them. Providers should consider the resources needed for successful implementation, tailoring support to suit local circumstances, taking into account any potential barriers. It is expected that implementation of this policy will be monitored through a professionally-led clinical review and audit cycle. Providers should discuss this with their clinical effectiveness lead in the first instance. For guidance in conducting an audit or review you may also contact the Public Health team at Norfolk County Council at hphprojects@Norfolk.gov.uk.

2.0 Background

2.1 Definition of Gastroparesis

Gastroparesis is a chronic disorder in which the stomach empties more slowly than normal (delayed gastric emptying) in the absence of any mechanical obstruction. Common symptoms are nausea, protracted vomiting, abdominal bloating and in severe cases, malnutrition and dehydration severe enough to cause hospital admissions.

It is estimated that no detectable primary underlying abnormality is found in approximately one-half of patients with delayed gastric emptying. Diabetes mellitus is the most frequently recognised systemic disease associated with gastroparesis. Previous gastric and thoracic surgery can result in gastric stasis due to intended or accidental injury to the vagus nerves. Other rare causes include viral, medication induced, neurological disease (e.g. MS, brainstem stroke, amyloid neuropathy) and mesenteric ischemia.

Patients with severe gastroparesis have frequent hospital admissions and experience a poor quality of life.

2.2 Current Management

There is currently no cure for gastroparesis. Treatment is aimed at symptom relief.

Management of gastroparesis consists of modification of dietary intake, supportive measures (e.g. hydration and nutrition), optimising glycaemic control in patients with diabetes mellitus and prokinetic and anti-emetic medication.

Supportive nutrition in the form of a J-tube that feeds directly into the jejunum or even Total Parenteral Nutrition (TPN) may be needed.
2.3 Gastro-electrical Stimulation (GES)

Gastro-electrical stimulation is an option for treating chronic, intractable nausea and vomiting secondary to gastroparesis for patients with diabetes or unknown causes.

A device is implanted in the abdomen to send mild electrical impulses to the nerves and muscle in the lower stomach.

Figures 1: GES hand held controller and electrodes

Figure 2: GES inserted into the stomach

The neuro-stimulator is fitted under general anaesthetic. Electrodes that stimulate the gastric muscle are attached to the stomach and connected via a lead to the neurostimulator which is put in the pocket of the abdominal wall. The neurostimulator can then deliver electrical impulses via the electrodes and this is controlled wirelessly via a hand held external programmer. The rate and amplitude of stimulation may need to be adjusted at future hospital visits to optimise the effect on gastric emptying.

3.0 Epidemiology

It is difficult to estimate the prevalence of gastroparesis, and harder still to estimate the prevalence of severe gastroparesis which is refractory to medication.

Prevalence rates for delayed gastric emptying have been estimated as 25-55% of patients with Type 1 Diabetes and 30% of Type 2 patients\(^3\). However, the development of Gastroparesis is not inevitable and only a minority will experience adverse symptoms associated with severe gastroparesis\(^4\).

One small study in the USA\(^5\), found the age-adjusted prevalence of definite gastroparesis per 100,000 was 37.8 (95% CI, 23.3-52.4) for women and 9.6 (95% CI, 1.8-17.4) for men. However, it is unclear how many of these experienced severe symptoms that were refractory to medication.
A Canadian Health Technology Appraisal\(^1\) reported inconsistencies in the reported prevalence rates for severe Gastroparesis. Medtronic Inc. (the manufacturer of the gastro-electrical stimulation technology) reported prevalence estimates of 0.035% for severe gastroparesis in the US population, with one third of these refractory to medication in 2000. A second study\(^6\) estimated the prevalence of severe, symptomatic, and medically refractory gastroparesis in the United States population as 0.017%.

Applying these US estimates to the Norfolk and Waveney CCG population\(^7\) produces a crude estimated prevalence of between 115-345 people who could have severe gastroparesis which is refractory to medication. Local incidence estimates from local clinical experts suggest approximately 5 cases per annum in Norfolk. No local clinical referrals for gastro-electrical stimulation for severe gastroparesis have been recorded.

### 4.0 Summary of Evidence Review

#### 4.1 Clinical Effectiveness

**4.1.1 NICE Interventional Procedure Guidance (IPG) 489 (2014)**

NICE IPG 489\(^1\) provides guidance on the safety and the efficacy of GES. It does not provide guidance regarding cost effectiveness or whether GES should be funded. That is the local decision of the CCG where the patient is registered.

NICE reviewed the available evidence in 2013\(^8\) and published IPG 489 in 2014. This replaced the previous IPG 103 of 2004. NICE (2014) states there is “adequate evidence to support the use of the procedure as a treatment option for chronic intractable (drug refractory) gastroparesis secondary to diabetic, post-surgical or idiopathic aetiology”.

It must be noted that the treatment did not work in approximately 1 in 4 patients (NICE IPG 489).

<table>
<thead>
<tr>
<th>Summary of NICE IPG 489 recommendations:</th>
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<td>NICE interventional procedures guidance [IPG489] (May 2014)</td>
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<table>
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<tr>
<th>1.1 Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit.</th>
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<td>1.2 During the consent process, clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device.</td>
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<tr>
<td>1.3 Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure</td>
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should only be performed by surgeons working in these units.

1.4 Further publications providing data about the effects of the procedure on symptoms in the long term and on device durability would be useful.

### 4.1.1.1 The evidence behind NICE IPG 489

NICE IPG 489 was based on the evidence provided in two systematic reviews, two RCTs and five case series studies (see Appendix 1).

> “The Committee concluded that the evidence of efficacy was adequate only after prolonged debate about the design of the available randomised trials”

> “The Committee recognised that gastroparesis can be a very debilitating condition with very few treatment options, and it noted patient commentaries describing substantial improvements in quality of life with gastroelectrical stimulation”. NICE, 2014

A local review of the evidence used by NICE found that the two systematic reviews\(^9\),\(^10\) contained mostly case series studies and had four studies which were used in both reviews. The case studies were relatively small and considered poor quality evidence. NICE reviewers debated the quality of the design of one of the RCTs and noted a risk of placebo effect.

Three additional case studies considered by NICE were by the same author\(^11\),\(^12\),\(^13\). It is unclear whether these papers contained results for new patients or just repeat results for existing patients. These studies were also sponsored by the manufacturer that makes the GES technology.

There is a high possibility that the results for some patients in smaller studies have been taken into account more than once in the NICE review.

Taking the quality of the evidence into account, the results of the studies reviewed (listed in Appendix A) indicated:

- Symptoms generally improved (including weekly vomiting frequency) in patients with diabetes, in those with gastroparesis of an unknown cause, and in those who had abdominal surgery, and patients spent less time in hospital after 1 year.

- Gastric emptying was improved after 4 hours in people with diabetes and gastroparesis without an obvious cause, but not in people who had had abdominal surgery. Normal gastric emptying was not restored in most patients.
Patients' weight didn't change.

Fewer patients needed nutritional support after having the procedure.

Patients recorded their Quality of life improved.

4.1.2 American College of Gastroenterology Clinical Guideline 2013

The American College of Gastroenterology Clinical Guideline\(^\text{14}\) concluded that gastric electrical stimulation ‘may’ relieve symptoms, including weekly vomiting frequency, and the need for nutritional supplementation, based on open-label studies.

The guideline recommended that gastric electrical stimulation ‘may’ be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with diabetic gastroparesis, but not in patients with idiopathic gastroparesis or post-surgical gastroparesis. (Conditional recommendation, moderate level of evidence).

4.2 Safety

NICE (2014) recommend that the current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit.

This is an invasive procedure and patients need to be informed of the risks involved. The evidence indicated that there are a number of potential complications associated with this treatment, including:

- A hole in the gut occurred after vomiting in 1 patient out of 17, 2 months after the procedure.

- The device needed to be removed in about 1 in 10 patients, for reasons including infection, blockage in the bowel, the device or its wires moving, the device wearing away through the skin, and symptoms not improving.

- The battery failed and the device had to be replaced in about 1 in 50 patients.

- Wires from the device wore away some tissue around them in fewer than 1 in 100 patients.

- The treatment didn't work in about 1 in 4 patients. Reasons included symptoms not improving, and the, device malfunctioning or stopping working.
• In one study, 2 out of 72 patients died after having the procedure, because of blood supply to the bowel being cut off, and heart failure.

• NICE was also told about some other possible risks: pain where the device is inserted, and a feeling of pins and needles when the device is turned on.

The safety and efficacy of the system has not been evaluated for patients under the age 18 years or over the age of 70.

Although symptoms may be resolved in some patients (such as those with idiopathic GP) after a relatively short period of time, the majority of patients with GP would remain dependent on the device. Another surgery intervention for the replacement of the neurostimulator at appropriate time intervals would be required in the group of patients with persistent symptoms.

4.3 Cost effectiveness

No studies reviewed for NICE IPG 489 reported the cost effectiveness of the treatment.

The costs of the procedure include the cost of purchasing the device and its consumables, the operation costs to implant the device, including pre-op preparation and diagnostics and on-going support to adjust the device to perform at optimum levels. There is also the likelihood that further operations may be required in the future when the device or the battery needs replacing. It is also possible that further operations may be required to remove the device if it is not effective or there is infection or another complication.

In 2004 the cost of implanting the Enterra gastroelectrical device in the USA was estimated at $30k\textsuperscript{15}. In 2006 the UK cost was estimated as £15-16k\textsuperscript{16}. A UK specialist centre has quoted £17,198 for the initial operation (including 5 days stay) and £8,442 for battery replacement\textsuperscript{17}.

If successful, there may be the potential for these costs to be offset against some existing treatment costs, costs of feeding and existing need for hospitalisation relating to severe gastroparesis. A Canadian HTA report in 2006 reported that the cost of treating severe GP in the US was $6972 per month per patient, attributed to hospitalisation, use of parenteral nutrition, diagnostic tests, significant costs re endoscopy and gastric emptying tests.

The HTA concluded that
“Patients with severe GP (not related to mechanical obstructions) of diabetic, post surgery (gastric resection and vagotomy), or idiopathic causes, whose symptoms cannot be controlled by conventional therapy, are considered to be candidates for GES as a last resort treatment after all conventional treatment regimes have failed”.

4.4 On-going trials/ reviews

It is widely acknowledged that further research regarding the cost effectiveness, effects of the procedure in the long term and device durability would be useful. The quality of the existing evidence regarding efficacy and safety could also be more robust.

There are two trials due to complete in 2015 which may add to the evidence base:

- ‘Medico-economic Evaluation of ENTERRA Therapy: The clinical efficacy and efficiency of gastric electrical stimulation (Enterra) for refractory nausea and/or vomiting’. Type: randomised controlled trial (device activated or not); location: France; estimated enrolment: 220; study start date: June 2009; estimated study completion date: November 2015 (on-going but not recruiting participants).18

- ‘Gastric pacemaker implantation for gastroparesis (HUD) Gastric electric stimulation-Enterra Therapy for the treatment of chronic intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. Type: case series; location: USA; estimated enrolment: 40; study start date: June 2007; estimated study completion date: December 2015.

5.0 Conclusions

NICE IPG 489 supports the efficacy and safety of GES for gastroparesis. However, the evidence base is mainly from non-comparative studies, which are limited by potential bias and confounding. GES may be effective to improve symptoms of nausea and vomiting but this effect is not seen in all patients. There is no evidence regarding longer term benefits and there is not sufficient evidence for adequate analysis in terms of cost/benefit. There are also still a number of risks involved with the procedure.

GES for gastroparesis will not be routinely funded by CCGs in Norfolk. However, in exceptional circumstances, a request for funding may be considered by the Individual Funding Request (IFR) Panel.
References

4 A. Patrick, O. Epstein, Review Article: Gastroparesis, Alimentary Pharmacology & Therapeutics, 2008;27(9):724-740
7 Based on mid-year population estimates source: Norfolk Insight http://www.norfolkinsight.org.uk/profiles/profile?profileId=18
17 Correspondence between CSU and specialist centre
18 http://clinicaltrials.gov/ct2/show/NCT00903799
### Appendix 1: Studies reviewed by NICE to produce IPG 489

The summary of the findings of each paper is available at: NICE Interventional procedure overview of gastro electrical stimulation for gastroparesis IP 231/2 (IPG489), May 2013. [http://www.nice.org.uk/guidance/ipg489/resources/ip2312-gastroelectrical-stimulation-for-gastroparesis-overview2](http://www.nice.org.uk/guidance/ipg489/resources/ip2312-gastroelectrical-stimulation-for-gastroparesis-overview2)

<table>
<thead>
<tr>
<th>Study Description</th>
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Search period 1992-2008  
13 studies (1 RCT, 12 case series) n=364 |
Search period 1995-2011  
10 studies (2 crossover RCTs, 8 case series) n=601 |
Phase 1: 3 months prospective case series (device “on” in all patients)  
Phase 2: Randomised crossover trial 6 months  
Phase 3: 4.5 months Prospective case series (device “on” in all patients) |
It is unclear how this study relates to the 2010 study above. |
| McCallum RW, Lin, Forster J et al (2011) Gastric electrical stimulation improves outcomes of patients with gastroparesis for up to 10 years. Clinical Gastroenterology and Hepatology 9(4):314-9 | Case series n=221 USA |
Recruitment period 2003-12 n=103 |
Recruitment period 2001-11 n=113 |
Appendix 2

Individuals consulted in the development of this policy

Many thanks to the following individuals who were consulted in the development of this policy:

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<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>CCG/Acute provider</th>
</tr>
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<tbody>
<tr>
<td>Prof Alastair Watson</td>
<td>Professor of Translational Medicine</td>
<td>University of East Anglia</td>
</tr>
<tr>
<td><strong>CCG clinicians</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr Hitesh Kumar</td>
<td>GP representative</td>
<td>NHS Great Yarmouth and Waveney CCG</td>
</tr>
<tr>
<td>Prof David Scott</td>
<td>Clinical Advisor</td>
<td>NHS Great Yarmouth and Waveney CCG</td>
</tr>
<tr>
<td>Dr Paul Berry</td>
<td>GP</td>
<td>NHS Great Yarmouth &amp; Waveney CCG</td>
</tr>
<tr>
<td>Dr Alasdair Lennox</td>
<td>GP representative</td>
<td>NHS North Norfolk CCG</td>
</tr>
<tr>
<td>Dr Brian Cole</td>
<td>GP representative</td>
<td>NHS Norwich CCG</td>
</tr>
<tr>
<td>Dr Anthony Lister</td>
<td>GP</td>
<td>NHS Norwich CCG</td>
</tr>
<tr>
<td>Dr Les Cooper</td>
<td>GP representative</td>
<td>NHS South Norfolk CCG</td>
</tr>
<tr>
<td>Dr Keeva Rogers</td>
<td>GP</td>
<td>NHS South Norfolk CCG</td>
</tr>
<tr>
<td>Dr Dustyn Saint</td>
<td>GP</td>
<td>NHS South Norfolk CCG</td>
</tr>
<tr>
<td>Louise Stevens</td>
<td>CCG representative</td>
<td>NHS West Norfolk CCG</td>
</tr>
<tr>
<td>Dr Paul Williams</td>
<td>GP</td>
<td>NHS West Norfolk CCG</td>
</tr>
<tr>
<td>Dr Mark Funnell</td>
<td>GP</td>
<td>NHS West Norfolk CCG</td>
</tr>
<tr>
<td>Dr Anthony Burgess</td>
<td>GP and CCG Governing member</td>
<td>NHS West Norfolk CCG</td>
</tr>
<tr>
<td>Dr Pallavi Devulapalli</td>
<td>GP</td>
<td>NHS West Norfolk CCG</td>
</tr>
<tr>
<td>Dr Ian Mack</td>
<td>Chair</td>
<td>NHS West Norfolk CCG</td>
</tr>
<tr>
<td>Dr Maggie Carter</td>
<td>Clinical Governance Lead</td>
<td>NHS West Norfolk CCG</td>
</tr>
<tr>
<td><strong>CCG Colleagues</strong></td>
<td><strong>Position</strong></td>
<td><strong>Organisation</strong></td>
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</tr>
<tr>
<td>Michael Dennis</td>
<td>Prescribing Advisor</td>
<td>NHS Great Yarmouth and Waveney CCG</td>
</tr>
<tr>
<td>Kerry Dos Anjos</td>
<td>Commissioning Manager</td>
<td>NHS Great Yarmouth and Waveney CCG</td>
</tr>
<tr>
<td>Kathryn Griffiths</td>
<td>Project Management Specialist</td>
<td>(representing) NHS Great Yarmouth and Waveney CCG</td>
</tr>
<tr>
<td>Rachel Leeds</td>
<td>Commissioning Manager</td>
<td>NHS Great Yarmouth and Waveney CCG</td>
</tr>
<tr>
<td>Sally Nye</td>
<td>Commissioning Manager</td>
<td>NHS Great Yarmouth and Waveney CCG</td>
</tr>
<tr>
<td>Ellis Layward</td>
<td>Commissioning Manager</td>
<td>NHS North Norfolk CCG</td>
</tr>
<tr>
<td>Lindsay Springall</td>
<td>Commissioning Manager</td>
<td>NHS Norwich CCG</td>
</tr>
<tr>
<td>Ben Hogston</td>
<td>Programme Manager</td>
<td>NHS Norwich CCG</td>
</tr>
<tr>
<td>Jim Barker</td>
<td>Assistant Director, Acute Commissioning</td>
<td>NHS South Norfolk CCG</td>
</tr>
<tr>
<td>Louise Browning</td>
<td>Independent Consultant</td>
<td>(representing) NHS South Norfolk CCG</td>
</tr>
<tr>
<td>Anne Moates</td>
<td>Lead Commissioner</td>
<td>NHS South Norfolk CCG</td>
</tr>
<tr>
<td>Debbie Oades</td>
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</tr>
<tr>
<td>Jan Sanders</td>
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<tr>
<td><strong>Public Health</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr Mahmoud Ahmed</td>
<td>FY2 Doctor</td>
<td>Norfolk County Council</td>
</tr>
<tr>
<td>Dr Shamsher Diu</td>
<td>Consultant in Public Health Medicine</td>
<td>Norfolk County Council</td>
</tr>
<tr>
<td>Suzanne Meredith</td>
<td>Consultant in Public Health</td>
<td>Norfolk County Council</td>
</tr>
<tr>
<td>Joanne Creaser</td>
<td>Clinical Audit Officer</td>
<td>Norfolk County Council</td>
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