# Clinical Commissioning Policy Proposition: Gastroelectrical stimulation for gastroparesis

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# Clinical Commissioning Policy Proposition: Gastroelectrical stimulation for gastroparesis

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# 1 Executive Summary

## Policy Statement

NHS England proposes to not routinely commission gastroelectrical stimulation (GES) for the treatment of gastroparesis in accordance with the criteria outlined in this document.

In creating this policy proposition NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

## Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England 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. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

## Plain Language Summary

The policy proposition aims to confirm NHS England's commissioning approach to the use of gastroelectrical stimulation (GES) for the treatment of gastroparesis.

Gastroparesis is a long-term (chronic) condition in which the stomach cannot empty itself in the normal way. It means food passes through the stomach more slowly than usual, leading to symptoms such as:

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- feeling full very quickly when eating;
- nausea (feeling sick) and vomiting;
- loss of appetite;
- weight loss;
- bloating;
- abdominal pain or discomfort; and
- heartburn.

These symptoms can be mild or severe, and tend to come and go. In severe cases, patients may suffer dehydration from repeated vomiting and malnutrition, with diabetics also suffering from poor glycaemic (i.e., blood sugar) control. Such consequences of severe gastroparesis may result in hospital admission.

It is difficult to estimate the number of people living with gastroparesis (i.e., prevalence) because of difficulties in diagnosing the condition and inconsistency between different definitions of the condition. However, women appear to be more likely to develop the condition.

Conventional management of gastroparesis includes a change in diet together with anti-emetic medications. In cases of extremely severe gastroparesis, i.e., that are not improved with dietary changes and medication, patients may benefit from a feeding tube. There are many different types of feeding tube available, some which are temporary, and others which are permanent.

In addition to the use of feeding tubes, there are a number of other surgical procedures which can be used to release gas, relieve bloating and /or create a new opening between the stomach and small intestine or to connect your stomach directly to the second part of the small intestine. These procedures may reduce symptoms by allowing food to move through your stomach more easily.

Gastroelectrical stimulation (GES) is a relatively new treatment option for individuals with severe gastroparesis. The procedure is supported by NICE Interventional Procedure Guidance (IPG 489, 2014), which recognised that gastroparesis can be a

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very debilitating condition with very few treatment options and specifically noted patient stories describing substantial improvements in quality of life following treatment with GES.

The GES procedure is carried out under a general anaesthetic and can be performed through either a cut in the abdomen, or by keyhole surgery. A device designed to stimulate the stomach (similar to heart pacemaker) is placed into a small pocket made under the skin of the abdomen. When the stimulating device is turned on, it sends electrical impulses to the stomach muscles in order to help them to work more normally. The amount of stimulation can be adjusted to suit the patient, though this adjustment may be required to be undertaken in hospital.

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of gastroelectrical stimulation (GES) for the treatment of gastroparesis.

## 2 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission Gastroelectrical Stimulation (GES) for gastroparesis.

Gastroparesis is a chronic disorder characterised by delayed emptying of the stomach in the absence of mechanical obstruction. Symptoms include nausea and protracted vomiting. In severe cases, patients may suffer dehydration, poor nutritional status, and poor glycaemic control (in diabetics) which may require hospitalisation.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final commissioning decision on gastroparesis is planned to be made by NHS England by May 2016 following a recommendation from the Clinical Priorities Advisory Group.

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## 3 The proposed intervention and clinical indication

Gastroparesis is a stomach disorder in which food is digested more slowly than normal. In a healthy digestive system, strong muscular contractions move food from the stomach through the digestive tract. With gastroparesis, however, the stomach muscles work poorly (or not at all), thus preventing the stomach from emptying properly.

Gastroelectrical stimulation (GES) is a treatment option for individuals with intractable gastroparesis. The treatment involves the insertion of electrodes, which are fixed to the muscle of the distal stomach. The connector end of each lead is then attached to the neurostimulator. When the neurostimulator is turned on, electrical impulses are delivered via the electrodes. The aim of GES is to reduce symptoms and enhance gastric emptying.

Conventional management of gastroparesis includes dietary modification and prokinetic/anti-emetic medications together with a range of surgical techniques. However, a proportion of patients will be refractory to these measures.

The difficulty in clinical practice is that gastroparesis can be debilitating and without alternative treatment options, such as GES, some patients may be nutritionally crippled by the disease and may progress through ever-more invasive and costly surgical treatments. Examples of this are artificial feeding and stomach surgery including gastrectomy (removal of the stomach).

It is acknowledged that the GES procedure may benefit some individual patients, however at this point the evidence-base is not sufficiently developed to enable the identification of specific patient populations, or well-defined clinical criteria, enabling the procedure to be routinely commissioned.

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## 4 Definitions

**Gastroparesis:** Delayed emptying of the stomach leading to a series of symptoms including:

- Nausea

- Vomiting
- Abdominal bloating
- Abdominal pain
- Weight-loss

**Gastroelectrical stimulation (GES):** Electrical stimulation of the stomach to increase emptying of the stomach.

## 5 Aim and objectives

This policy proposition considered: GES for the treatment of gastroparesis.

The objectives were to: Establish whether there is sufficient robust evidence of clinical and cost- effectiveness and safety to support the use of GES to treat gastroparesis.

## 6 Epidemiology and needs assessment

The prevalence of gastroparesis is difficult to estimate due to diagnostic difficulties and inconsistencies between definitions. Women appear to be disproportionately susceptible to gastroparesis from any cause. Some commentators speculate that this may be because of higher levels of progesterone in women, which can affect smooth muscle motility (Chu et al, 2012). No studies were found of the prevalence of gastroparesis in children (Waseem et al, 2012).

A high prevalence of gastroparesis has been reported in patients with diabetes, and the number of cases appears to be increasing due in part to the rise in the incidence of diabetes (O'Grady et al, 2009). Studies suggest that diabetic gastroparesis affects about 20% to 50% of patients with type 1 diabetes and up to 30% of patients with type 2 diabetes, especially those with long-standing disease (Alberta Heritage Foundation for Medical Research, 2006). However, these studies were from tertiary academic medical centres where the prevalence is expected to be higher than the general population. In one community study, the prevalence was estimated to be about 5% among type 1 diabetics, 1% among type 2 diabetics and 0.2% in non-

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diabetics (Choung et al, 2012). More community-based data are required to confirm or enhance the published figures.

The prevalence of severe, refractory gastroparesis is seldom reported in the literature. In 2002, the prevalence of severe, symptomatic and medically refractory gastroparesis in the United States population was estimated at 0.017% or 17 per 100,000 people (Alberta Heritage Foundation for Medical Research, 2006).

## 7 Evidence base

O'Grady (O'Grady et al, 2009) conducted a systematic and meta-analysis to examine the evidence for the effectiveness of GES, primarily in patients with medically refractory gastroparesis of diabetic or idiopathic origin. The review included 13 studies. Only one of these was a randomised comparison (n=33) (Abell et al, 2003). There were nine prospective case series and three retrospective case series.

This review reported that GES was associated with statistically significant improvements from baseline in total symptom severity score (3/13 studies, mean difference 6.52 [CI: 1.32, 11.73], p=0.01), vomiting severity score (4/13, 1.45 [CI: 0.99, 1.91], p<0.0001), nausea severity score (4/13, 1.69 [CI: 1.26, 2.12], p<0.0001) and the need for enteral or parenteral nutritional support (8/13, OR 5.53 [CI: 2.75, 11.13], p<0.001). There were also statistically significant improvements in SF-36 physical composite and mental composite quality of life scores.

Chu (Chu et al, 2012) carried out a systematic review and meta-analysis to assess the effects of GES on symptoms and gastric emptying in patients with gastroparesis, and the effects of GES on the three subgroups of gastroparesis (diabetic gastroparesis (DG), idiopathic gastroparesis (IG) and postsurgical gastroparesis (PSG)). This study included ten studies (n = 601); only two of which were randomised, double-blind trials (MaCallam et al, 2010, Abell et al, 2003), the others being uncontrolled observational studies.

The review reported that GES significantly improved symptoms and gastric emptying overall. However both total symptom severity score (TSS) (P < 0.00001)

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and gastric retention at 2 h (P = 0.003) and 4 h (P < 0.0001) significantly improved in patients with DG, while gastric retention at 2 h (P = 0.18) in IG patients, and gastric retention at 4 h (P = 0.23) in PSG patients, did not reach significance. The results from the RCT were not significant on their own. The authors concluded that GES is an effective and safe method for treating refractory gastroparesis. DG patients seem the most responsive to GES, both subjectively and objectively, while the IG and PSG subgroups are less responsive and need further research.

The two systematic reviews were well conducted; the questions were well defined and eligibility criteria were clear. However, they were limited by the lack of high-quality studies available. Most of the studies were uncontrolled case series, so the results may be affected by changes in the symptoms attributable to other factors, such as the natural history of the condition or the placebo effect.

McCallum (McCullum et al, 2013) carried out an RCT of 32 patients with gastroparesis of idiopathic origin. The primary objective of their study was to test for an improvement in weekly vomiting frequency (WVF) when the device was turned on, compared to when the device was turned off, during blinded, three-month, crossover phases. The secondary goal was to demonstrate a reduction in symptom scores and to assess changes in quality of life, gastric emptying, number of days in hospital, and body mass index (BMI) in the idiopathic gastroparesis cohort when receiving active stimulation for up to 12 months.

They reported that during the unblinded on period, there was a significant reduction in WVF from baseline (61.2%, P <0.001). At one year after the blinded phase, the mean WVF was 87% lower, (P < 0.001). This was accompanied by improvements in gastroparesis symptoms, gastric emptying and days of hospitalisation (P < 0.05).

The study had a number of limitations. The question was well defined and eligibility criteria were clear. However, the study only included a small number of patients. The authors pointed out that the lack of wash-out period between the on and off periods may have masked the effect of GES. The carry-over effect induced by GES for first 1½ months in all participants, and 4½ months in half of them, may have biased the study.

Zehetner (Zehetner et al, 2013) carried out a retrospective chart review of 103

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patients who had surgical treatment for medically refractory gastroparesis. 72 patients had GES implanted and 31 had either subtotal or total gastrectomy. Of the GES group, 63% of the patients rated their symptoms as improved versus 87% in the primary gastrectomy group (p=0.02). There was no significant difference in mortality rates. Some patients who did not respond to GES had subtotal gastrectomy. The authors concluded that GES is an effective treatment for medically refractory gastroparesis but that subtotal gastrectomy should also be considered. The study only included a small number of patients from one center and the data were collected retrospectively.

GES for gastroparesis has been supported by NICE Interventional Procedure Guidance (IPG 489, 2014). The IPG committee recognised that gastroparesis can be a very debilitating condition with very few treatment options specifically noting patient stories describing substantial improvements in quality of life following treatment with GES.

**Evidence of effectiveness in children**

Islam (Islam et al, 2008) reported on an uncontrolled study of nine consecutive patients younger than 18 years old with gastroparesis who underwent temporary and/or permanent GES.

At baseline, all the patients were symptomatic. The authors reported significant improvements in combined symptoms score (p=0.04), nausea (p=0.039), and vomiting (p=0.0016) at follow-up (8 to 42 months). However there was no change in the rates of gastric emptying. The authors concluded that GES can be successfully applied to adolescents with intractable nausea and gastroparesis symptoms who fail to respond to medical therapy.

Teich (Teich et al, 2013) carried out a retrospective review of 16 consecutive children with functional dyspepsia and gastroparesis refractory to medical therapy implanted with the Enterra™ system to assess the feasibility and clinical outcomes of the intervention.

The authors found that, after permanent GES, there was significant improvement in symptom score compared to baseline for severity of vomiting 2.57 vs. 0.46, frequency of vomiting 2.42 vs. 0.39, frequency of nausea 3.79 vs. 1.57 and severity

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of nausea 3.29 vs. 1.07. They conclude that GES improves health in children with functional dyspepsia and gastroparesis who did not respond to medical therapy.

These studies suggest that GES is effective in children with gastroparesis. However, the results should be interpreted with caution because both studies were very small, uncontrolled and carried out at single centres. Therefore the findings reported may not be valid and/or generalisable to a larger population of patients.

### Safety

Adverse effects and other post-operative treatment sequelae were not consistently reported in the studies. The reported complications relate to the insertion of the device. The most common adverse event associated with GES appears to be infection at the site of device implantation. Other complications related to the device include erosion, migration and stomach wall perforations.

The frequency of device removal reported in the literature was around 10% (O'Grady et al, 2009, Alberta Heritage Foundation for Medical Research, 2006, Chu et al, 2012, Macallum et al, 2013). Infection was reported to occur in about 5% to 10% of cases, (Alberta Heritage Foundation for Medical Research, 2006), skin and lead erosion in 1% (Keller et al, 2013), and one study reported a case of gastric perforation. One study (Zehetner et al 2013) reported two cases of death due to small bowel infarction and heart failure.

No adverse effects were reported in the studies of GES in children.

### Cost effectiveness

No studies assessing cost effectiveness were identified. However, the North East Treatment Advisory Group (Horsley, 2010) produced a costing report on GES for gastroparesis for the North East Specialised Commissioning Team in 2010. Their report estimated that the cost for implantation of an Enterra™ device is between £16,000 and £18,000 per patient. This included all pre-, peri- and postoperative care and hardware costs, although noting additional costs may arise where there are complications. This estimate was calculated based on the HRG tariff price in 2010 and the cost of the device.

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## 8 Proposed criteria for commissioning

Not applicable.

## 9 Proposed patient pathway

There is no change to the patient pathway as a result of this policy proposition.

## 10 Proposed governance arrangements

Not applicable.

## 11 Proposed mechanism for funding

Not applicable.

## 12 Proposed audit requirements

Not applicable.

## 13 Documents which have informed this policy proposition

None.

## 14 Date of review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by May 2016).

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