NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1970 Endoscopic gastric plication for severe obesity**

Your information

Name:	Mr Jamie Kelly
Job title:	Upper GI lead consultant surgeon
Organisation:	University Hospital Southampton
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BOMSS, AUGIS
Nominated/ratified by (if applicable):	BOMSS
Registration number (e.g. GMC, NMC, HCPC)	GMC 4258632

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Yes ☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

Yes ☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	I have performed over 400 ESG procedures. I teach/proctor the procedure within Europe and am published on the procedure. I currently use the device in the NHS for Fistula closure, Stomal outlet reduction for type 2 dumping post gastric bypass surgery, stent fixation and plication to facilitate gastric drainage. As such the Overstitch device can be used by gastroenterologists and surgeons as an endoscopic suturing device where appropriate. Within the NHS I understand there has been agreed funding for 20 procedures at Kings (Lon) and I am aware of at least 5 Centres in the NHS currently preforming the procedure. Within Bariatrics all my ESG cases go through MDT approval.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients. I have published this research.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Endoscopic Sleeve Gastroplasty is used for the treatment of obesity. It was first reported in 2013 by the Mayo Clinic and it was first performed in the UK in 2015 by me. Its mechanism of action is well established but varies from traditional bariatric surgery[1]. Meta-analysis data consistently demonstrates a SAE risk of around 2% - this is lower than traditional bariatric surgery[2]. It is the second in a new class of “endo-bariatric” suturing procedures with over 50,000 cases completed worldwide. However, most of the data comes from case series although there are now two randomised trials available. 1.ESG is thought to be the safest and most viable approach for bariatric intervention with lower morbidity and shorter stay in hospital.*(Novikov, A. A., Afaneh, C., Saumoy, M.,et al. (2018). Endoscopic sleeve gastroplasty, laparoscopic sleeve gastrectomy, and laparoscopic band for weight loss: how do they compare? J. Gastrointest. Surg. 22, 267–273. doi: 10.1007/s11605-017-3615-7).* *2.Hedjoudje A, Abu Dayyeh BK et al. Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis, Clinical Gastroenterology and Hepatology, Volume 18, Issue 5, 2020.)*
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	An addition to existing standard of care
5	Have there been any substantial modifications to the procedure technique or,	There is some variation in technique, but outcome data is equivalent.

	if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	The initial GEN2 Overstitch device required double channel gastroscope from Olympus. The newer SX device is used with single channel gastroscopes that are routinely available within all NHS hospitals performing endoscopy. The safety of the procedure has led to consensus documents from South America and Saudi Arabia lowering the BMI threshold for the procedure to 27.5. These have been published in the last few years[3]. 3.Neto MG, Silva LB, de Quadros LG, Grecco E, Filho AC, de Amorim AMB, de Santana MF, Dos Santos NT, de Lima JHF, de Souza TF, de Morais HWP, Vieira FM, Moon R, Teixeira AF; Brazilian Endoscopic Sleeve Gastroplasty Collaborative. Brazilian Consensus on Endoscopic Sleeve Gastroplasty. Obes Surg. 2021 Jan;31(1):70-78. doi: 10.1007/s11695-020-04915-4. Epub 2020 Aug 20. PMID: 32815105.

Current management

6	Please describe the current standard of care that is used in the NHS.	Patients for NHS obesity management must complete Tier 1,2 and 3 weight loss management courses prior to being eligible for tier 4 surgical management.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	POSE 2 is a similar procedure but so far outcome data is not as good, and longevity of FU data is shorter.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Less risk, earlier intervention to avoid end stage obesity related disease, maintained GI tract with minimal risk of nutritional deficiencies, more acceptable to patients without the “stigma of surgery”.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Three groups 1. Patients with hostile abdomen from previous surgical intervention 2. Patients who will not accept more formal surgical intervention. 3. Patients with lower BMI to act more as a preventative measure avoiding metabolic comorbidities.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Its less invasive, earlier return to work, would not require lifelong blood tests and more acceptable to patients. ESG has demonstrated reduced OR time and associated length of stay compared to bariatric surgery. However, UK specific studies are required to demonstrate this from the perspective of the NHS.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Endoscopy is usually freely available in theatres so very little if any facility changes.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Apollo (company that produces Overstitch) teach users how to use device and provide proctors for first cases and ongoing support where required. The company has now been acquired by Boston Scientific and the support remains unchanged.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology?	Like many abdominal procedure risks are intrabdominal infection, bleed, risk of damaging surrounding structures, leak. The literature describes a Clavien-Dindo complication of II and above running at around 2%

	Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	However more serious complications requiring intervention (3b and above) seems to run at less that 0.2%. No deaths have been reported in the literature.
14	Please list the key efficacy outcomes for this procedure/technology?	Minimum safety and effectiveness thresholds for endoscopic bariatric therapies have been defined by a joint task force convened through the American Society for Gastrointestinal Endoscopy and the American Society for Metabolic and Bariatric Surgery. These have been met and exceeded by ESG trials and in particular the Randomised MERIT trial[4]. 4.Abu Dayyeh BK, Bazerbachi F, Vargas EJ, Sharaiha RZ, Thompson CC, Thaemert BC, Teixeira AF, Chapman CG, Kumbhari V, Ujiki MB, Ahrens J, Day C; MERIT Study Group; Galvao Neto M, Zundel N, Wilson EB. Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. Lancet. 2022 Aug 6;400(10350):441-451. doi: 10.1016/S0140-6736(22)01280-6. Epub 2022 Jul 28. PMID: 35908555.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long term 5year FU data is currently weak due to lack of published data
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above the longevity of the procedure is not fully established but there is now increasing 3- and 4-year FU data but only one 5-year fu study. This argument is often countered by evidence that the procedure is repeatable if required and does not prevent any other bariatric surgery or medical therapy in the future.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Pertinent to this discussion I recently had the following accepted by DDW for oral presentation - abstract is available online

DDW 2023

View Abstract

CONTROL ID: 3848717
CURRENT CATEGORY: Bariatric Endoscopy
CURRENT SUBCATEGORY/DESCRIPTORS: Endoscopy: Endoscopic Therapy for Metabolic Conditions (DM, NAFLD, NASH)
PRESENTATION TYPE: ASGE Oral or Poster
APPLICANT: Jamie Kelly
APPLICANT (EMAIL ONLY): jamiekelly@doctors.org.uk

Abstract

TITLE: UK COST-EFFECTIVENESS ANALYSIS OF ENDOSCOPIC SLEEVE GASTROPLASTY VERSUS LIFESTYLE MODIFICATION ALONE FOR ADULTS WITH CLASS II OBESITY

AUTHORS (LAST NAME, FIRST NAME): Kelly, Jamie[1]; Menon, Vinod[2, 3]; O'Neill, Frank[4]; Elliot, Laura[5]; Combe, Emily[5]; Drinkwater, Will[5]; Hayee, Bu'Hussain[6]
INSTITUTIONS (ALL): 1. University Hospital Southampton NHS Foundation Trust, Southampton, Southampton, United Kingdom.
2. University Hospitals Coventry and Warwickshire NHS Trust, Coventry, United Kingdom.
3. University of Warwick, Coventry, West Midlands, United Kingdom.
4. Apollo Endosurgery UK Ltd., Knaresborough, Yorkshire, United Kingdom.
5. Fiecon, Saint Albans, Hertfordshire, United Kingdom.
6. King's College London, London, London, United Kingdom.

ABSTRACT BODY:

Abstract Body : Background: The UK has one of the highest obesity rates in Europe affecting more than one-quarter of adults in England. Obesity is a risk factor for many chronic diseases and is associated with reduced quality of life and premature mortality. Lifestyle modification (LM) is the first-line treatment for obesity, but bariatric intervention is recommended in contemporary international guidelines for adults with class II obesity (body mass index [BMI] 35.0-39.9 kg/m^2). Endoscopic sleeve gastroplasty (ESG) is a minimally invasive procedure with robust evidence demonstrating its effectiveness and safety. The MERIT randomized controlled trial (RCT) showed that ESG with concomitant LM ('ESG') led to significant and durable additional excess weight loss versus LM alone ('LM') in adults with class I obesity (BMI 30.0-34.9 kg/m^2) and class II obesity, as well as improvements in obesity-related comorbidities. This is the first cost-utility analysis comparing ESG with LM for adults with class II obesity, incorporating evidence from the MERIT RCT.
Methods: A 6-state Markov model was developed comprising 5 BMI-based health states and an absorbing death state (Figure 1). A UK healthcare payer perspective was adopted and methods were aligned with NICE guidance. Baseline characteristics, utilities, and transition probabilities were informed by patient-level data from the subset of patients with class II obesity in MERIT. Adverse events (AEs) were based on the MERIT safety population. Mortality was estimated by applying BMI-specific hazard ratios from the literature to UK general population mortality rates. Utilities for the healthy weight and overweight states were informed from the literature; disutility associated with increasing BMI in obesity I-III states was estimated using MERIT utility data. Disutilities due to AEs and the prevalence of obesity-related comorbidities were based on the literature. Costs included intervention costs, AE costs, and comorbidity costs.
Results: ESG resulted in higher overall costs than LM, but led to an increase in life years and quality-adjusted life years (QALYs) (Table 1). The incremental cost-effectiveness ratio (ICER) for ESG vs LM was £1,887/QALY gained. One-way sensitivity analysis showed that results were most sensitive to utility estimates, though ESG was consistently cost effective across all sensitivity analyses with no ICER estimate exceeding £4,000/QALY gained. In the probabilistic sensitivity analysis, ESG remained cost effective in 98.6% of iterations at a willingness-to-pay threshold of £20,000/QALY gained.
Conclusion: Our analysis suggests that compared with LM alone, ESG is a highly cost-effective treatment option for adults with class II obesity in the UK. Further research is needed to validate findings of this study and to compare the clinical and cost effectiveness of ESG with other bariatric obesity interventions.

19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	A randomised trial is being arranged and funded by the French (this will be independent of industry financial input)
20	Please list any other data (published and/or unpublished) that you would like to share.	Nil currently

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	It will depend on government funding/support for bariatric intervention but currently 25.9% of UK population has a BMI over 30
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Excess weight loss/Total body weight loss - 1, 2, and 5 years Resolution of comorbidities - 1, 2 and 5 years QUALY 1, 2 and 5 years Adverse outcome measures: SAE rate of less than 5% at 3 months It would be useful to understand longevity of intact procedure with radiology and endoscopy findings at 1, 2 and 5 years.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	There is a very good paper from the Strasbourg group demonstrating the learning curve of the procedure – If ESG becomes available to NHS patients' careful consideration to training will need to be given to avoid early procedure failure for the first cohort of patients[5]. 5..Pizzicannella M, Lapergola A, Fiorillo C, Spota A, Mascagni P, Vix M, Mutter D, Costamagna G, Marescaux J, Swanström L, Perretta S. Does endoscopic sleeve gastroplasty stand the test of time? Objective assessment of endoscopic ESG appearance and its relation to weight loss in a large group of consecutive patients. Surg Endosc. 2020 Aug;34(8):3696-3705. doi: 10.1007/s00464-019-07329-1. Epub 2020 Jan 13. PMID: 31932925.

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Renumeration from Apollo to teach and proctor on the overstitch device	**2018**	**ongoing**
Non-financial professional	Equipment support to help two-day ESG course run at University Hospital Southampton.	**2022**	**2023**
Choose an item.			

yes ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Jamie Kelly**
Dated:	**12/03/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1970 Endoscopic gastric plication for severe obesity**

Your information

Name:	Dr Devinder Bansi
Job title:	Consultant Gastroenterologist and Interventional Endoscopist/Honorary Senior lecturer
Organisation:	Imperial College, London
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 3278886

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

x☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

I give consent

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have been using the OverStitch device since 2017 and have performed a large number of endoscopic stent fixations and gastric defect closures. I have also published the largest series of endoscopic revisions of gastric bypass surgery in the UK *(Prades LP, Ahmed A, Marta m. Lopes M, Kaur V, **Bansi D**. Use of the Overstitch Device For Endoscopic Revision of Roux-EN-Y Gastric Bypass: An Update from the Largest UK Series [Abstract]. Gastrointestinal Endoscopy. Volume 91, No. 6S: 2020.)* I perform ESG in the private sector and routinely teach/proctor internationally on these procedures.
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own?	The OverStitch system is widely adopted by a number of NHS hospitals for a many applications (GI & Bariatric). I am aware of a number of NHS hospitals currently preforming ESG, with many others either having completed, or going through the approval process. The speed of uptake could be relatively quick based on the well-established technique. OverStitch is routinely used by surgeons and gastroenterologists across a number of NHS trusts. Therefore, ESG could be performed by both specialities, with the support of a bariatric MDT. All patients referred for ESG would go through the full bariatric MDT process of which I am part.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I am a member of the BOMSS endoscopy advisory group and have contributed to the guidelines on bariatric endoscopy (2021) I have also published on endoscopic revisions (see reference in Q1 above)
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?	Endoscopic Sleeve Gastroplasty is indicated for the treatment of obesity This indication is appropriate, there has been ~50,000 procedures preformed globally to date with good clinical efficacy and well conducted systematic reviews demonstrate positive safety profile (2.2%) in the reported data. (*Hedjoudje A, Abu Dayyeh BK et al. Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis, Clinical Gastroenterology and Hepatology, Volume 18, Issue 5, 2020.)* ESG is now considered an established procedure and has a better safety profile compared to the current standard of care (bariatric surgery). The procedure is less invasive, incisionless and organ-sparing compared to bariatric surgery. In a recent meta-analysis by Beran et al. the incidence of new-onset gastroesophageal reflux disease (GERD) was significantly lower after ESG compared to bariatric surgery, 1.3% vs. 17.9%, respectively (RR 0.10, 95% CI 0.02-0.53, P = 0.006). *(Currie AC, Glaysher MA, Blencowe NS, Kelly J. Systematic review of innovation reporting in endoscopic sleeve gastroplasty. Obes Surg 2021; 31: 2962–78).* *(Beran A, Matar R, Jaruvongvanich V, Rapaka BB, Alalwan A, Portela R, Ghanem O, Dayyeh BKA. Comparative Effectiveness and Safety Between Endoscopic Sleeve Gastroplasty and Laparoscopic Sleeve Gastrectomy: a Meta-analysis of 6775 Individuals with Obesity. Obes Surg.*

		2022 Nov;32(11):3504-3512. doi: 10.1007/s11695-022-06254-y. Epub 2022 Sep 2. PMID: 36053446.)
	Which of the following best describes the procedure (please choose one):	Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	An addition to existing standard of care
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	Adaptions have been made to the OverStitch device to facilitate service delivery across all NHS hospitals. The current version, OverStitch Sx, is now compatible with single channel gastroscopes from a number of different manufacturers, thus making the device and the associated procedures available to any NHS trust that performs endoscopy.
	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	The MERIT Trial is the first prospective, multi-center, open-label, randomized, controlled clinical study of ESG and was published in The Lancet journal in 2022. The study evaluates the clinical efficacy and safety of ESG compared to lifestyle modification in patients with a BMI of ≥30 and ≤40 kg/m2, and who failed to achieve and maintain weight loss without surgery. ESG performed better than lifestyle modification and induced clinically meaningful weight loss with improvements in obesity-related comorbid conditions of metabolic syndrome, type 2 diabetes, hypertension, quality of life, eating behaviours, and depression, and did not lead to worsening of gastroesophageal reflux disease, while maintaining a high patient satisfaction. *(Abu Dayyeh BK, Bazerbachi F, Vargas EJ, Sharaiha RZ, Thompson CC, Thaemert BC, Teixeira AF, Chapman CG, Kumbhari V, Ujiki MB, Ahrens J, Day C; MERIT Study Group, Galvao Neto M, Zundel N, Wilson EB. Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. Lancet. 2022 Aug 6;400(10350):441-451. doi: 10.1016/S0140-6736(22)01280-6. Epub 2022 Jul 28. PMID: 35908555*.). In addition to the MERIT study there is emerging relevant evidence regarding the efficacy of the procedure. For example, Sakar et al., have demonstrated the procedure can be replicated safely,

		providing sustained clinically significant weight loss and improvement of comorbidities across 6 independent centres. *(Sarkar A, Tawadros A, Andalib I, et al. Safety and efficacy of endoscopic sleeve gastroplasty for obesity management in new bariatric endoscopy programs: a multicenter international study. Therapeutic Advances in Gastrointestinal Endoscopy. 2022;15. doi:10.1177/26317745221093883).* In addition to the aforementioned SLR's (Q3) retrospective analysis demonstrates that ESG is a clinically effective and safe procedure in elderly (>65 year) patients, who may be contraindicated to more invasive surgical approaches. *(Matteo MV, Bove V, Pontecorvi V, De Siena M, Ciasca G, Papi M, Giannetti G, Carlino G, Raffaelli M, Costamagna G, Boškoski I. Outcomes of Endoscopic Sleeve Gastroplasty in the Elder Population. Obes Surg. 2022 Oct;32(10):3390-3397. doi: 10.1007/s11695-022-06232-4. Epub 2022 Aug 2. PMID: 35918595; PMCID: PMC9532333.)*

Current management

6	Please describe the current standard of care that is used in the NHS.	All patients are referred into the bariatric MDT and offered Tier 1-4 interventions (diet/lifestyle/pharmacotherapy/ invasive surgery) depending on clinical need and patient choice
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	The POSE 2 device, manufactured by USGI medical, is another procedure in this space. However, the clinical efficacy and safety data is less favourable and the long term data is shorter than that of ESG. Furthermore, as far as I am aware , no UK centres are performing this currently

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Reduced hospitalisation, earlier discharge, quicker return to work, earlier intervention (lower BMI), ability to treat more patients, particularly those who are unsuitable or unwilling to undergo bariatric surgery. Also, does not preclude the option of surgery later on if still clinically indicated
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients unwilling to have bariatric surgery i.e. fear or risk. Patients where transabdominal surgery may not be possible (scars/burns/trauma) Patients with a lower BMI, to intervene earlier and avoid disease progression
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	ESG is less invasive compared to traditional bariatric surgery. There is potential for it to reduce length of stay, the number of hospital visits and thus to reduce costs Recent systematic reviews have demonstrated a reduced incidence of GERD compared to standard of care (Laparoscopic Sleeve Gastrectomy). *(Beran A, Matar R, Jaruvongvanich V, Rapaka BB, Alalwan A, Portela R, Ghanem O, Dayyeh BKA. Comparative Effectiveness and Safety Between Endoscopic Sleeve Gastroplasty and Laparoscopic Sleeve Gastrectomy: a Meta-analysis of 6775 Individuals with Obesity. Obes Surg. 2022 Nov;32(11):3504-3512. doi: 10.1007/s11695-022-06254-y. Epub 2022 Sep 2. PMID: 36053446.)*
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	ESG can be performed under GA in the endoscopy or operating theatre setting. No specialist equipment, other than a gastroscope and endoscopy tower are required. These are readily available at most NHS sites.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Apollo Endosurgery have a robust training pathway consisting of hands-on porcine model training and support from a network of experienced proctors. Proctors provide support for the initial first cases and this is provided for as long as it is deemed necessary. Ongoing training and support is provided by trained Apollo representatives too.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology?	

	Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	ESG is a safe procedure with a <2% incidence of side effects . These include bleeding, perforation or peri-gastric collections (*Hedjoudje A, Abu Dayyeh BK et al. Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis, Clinical Gastroenterology and Hepatology, Volume 18, Issue 5, 2020.)* Anecdotal adverse events (2 reported cases I am aware of) of gallbladder problems (full thickness suture placed into gallbladder) requiring successful cholecystectomy.
14	Please list the key efficacy outcomes for this procedure/technology?	Minimal thresholds of 25% Excess Body Weight Loss (EBWL) and <5% Severe Adverse Events (SAE) are recommended by the American Society for Gastrointestinal Endoscopy and the American Society for Metabolic and Bariatric Surgery joint task force for proving effective bariatric treatment. ESG with a reported mean SAE rate of 1.5%–2.3% and %EBWL of 59.1%–61.8% could qualify as a safe and primary endoscopic bariatric intervention. *(Yoon JY, Arau RT et al. The Efficacy and Safety of Endoscopic Sleeve Gastroplasty as an Alternative to Laparoscopic Sleeve Gastrectomy. Clin Endosc 2021;54(1):17-24.)*
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	none
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	None. Long term date to 5 years shows good efficacy. 7 year f/u data soon to be published from group in New York
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	As above in various answers (3, 5, 10)
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	None I am aware of
20	Please list any other data (published and/or unpublished) that you would like to share.	N/A

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Approx. 30% of patients between BMI 30-40 who would be eligible for weight loss interventions
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related	Beneficial outcome measures: The MERIT Trial is the first prospective, multi-center, open-label, randomized, controlled clinical study of ESG and was published in The Lancet journal in 2022. The study evaluates the clinical efficacy and safety of ESG compared to lifestyle modification in patients with a BMI of ≥30 and ≤40 kg/m2, and who failed to achieve and maintain weight loss without surgery. ESG performed better than lifestyle modification and induced clinically

	outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	meaningful weight loss with improvements in obesity-related comorbid conditions of metabolic syndrome, type 2 diabetes, hypertension, quality of life, eating behaviours, and depression, and did not lead to worsening of gastroesophageal reflux disease, while maintaining a high patient satisfaction. *(Abu Dayyeh BK, Bazerbachi F, Vargas EJ, Sharaiha RZ, Thompson CC, Thaemert BC, Teixeira AF, Chapman CG, Kumbhari V, Ujiki MB, Ahrens J, Day C; MERIT Study Group, Galvao Neto M, Zundel N, Wilson EB. Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. Lancet. 2022 Aug 6;400(10350):441-451. doi: 10.1016/S0140-6736(22)01280-6. Epub 2022 Jul 28. PMID: 35908555.*). In addition to the MERIT study there is emerging relevant evidence regarding the efficacy of the procedure. For example, Sakar et al., have demonstrated the procedure can be replicated safely, providing sustained clinically significant weight loss and improvement of comorbidities across 6 independent centres. *(Sarkar A, Tawadros A, Andalib I, et al. Safety and efficacy of endoscopic sleeve gastroplasty for obesity management in new bariatric endoscopy programs: a multicenter international study. Therapeutic Advances in Gastrointestinal Endoscopy. 2022;15. doi:10.1177/26317745221093883).* In addition to the aforementioned SLR's (Q3) retrospective analysis demonstrates that ESG is a clinically effective and safe procedure in elderly (>65 year) patients, who may be contraindicated to more invasive surgical approaches. *(Matteo MV, Bove V, Pontecorvi V, De Siena M, Ciasca G, Papi M, Giannetti G, Carlino G, Raffaelli M, Costamagna G, Boškoski I. Outcomes of Endoscopic Sleeve Gastroplasty in the Elder Population. Obes Surg. 2022 Oct;32(10):3390-3397. doi: 10.1007/s11695-022-06232-4. Epub 2022 Aug 2. PMID: 35918595; PMCID: PMC9532333.)*

		Adverse outcome measures:

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	It would be very important to initiate and maintain a national database of cases performed to be able to assess efficacy with outcome data as well as side effect profiles

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	I am a proctor and paid consultant for Apollo Endosurgery and travel nationally and internationally to teach and assist with cases	**Approx. 2018 onwards**	
Choose an item.			
Choose an item.			

x ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Dr Devinder Singh Bansi**
Dated:	**15.03.2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1970 Endoscopic gastric plication for severe obesity**

Your information

Name:	Rehan Haidry
Job title:	Consultant Gastroenterologist
Organisation:	University College London Hospitals / Cleveland Clinic London
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Society of Gastroenterology
Nominated/ratified by (if applicable):	British Society of Gastroenterology
Registration number (e.g. GMC, NMC, HCPC)	6028603

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	Endoscopic remodelling of the stomach has become an attractive target as a primary weight loss intervention. Endoscopic devices that manipulate gastric anatomy offer an effective, quick, and minimally invasive alternative to bariatric surgery that are associated with a lower number of adverse events. There are two CE-marked devices currently on the market: • Apollo OverStitch (Apollo Endosurgery, Austin, TX) • Primary Obesity Surgery Endoluminal (POSE) (USGI Medical, San Clemente, CA). I currently use the Apollo Overstitch in my daily practice. The system and accessories are intended for endoscopic placement of sutures and approximation of soft tissue within the gastrointestinal tract utilising a dual channel endoscope. All components of the system have FDA 510k clearance for use in human subjects. The device will be used within its intended FDA and CE-mark approval. The device allows placement of full thickness sutures to significantly reduce the volume of the stomach. The main indications for the suturing device: • Endoscopic sleeve gastroplasty (treatment for obesity) • Stent fixation (e.g. oesophageal stent) • Closure of defects (e.g. fistula, perforation) • Reduction of Gastro-jejunal anastomosis in RYGB I currently use the device frequently in my daily practice, which includes as a primary obesity treatment. I have a good knowledge of the device, its risk/benefit, and role within obesity management. The POSE procedure is completed with an endoscopic suturing device known as the incisionless operating platform. The delivery catheter (g-Cath EZ) and associated devices are CE-marked and

	procedure/technology, please indicate your experience with it.	510(k) cleared for approximation of soft tissue in minimally invasive gastroenterology procedures. The procedure allows multiple gastric plications by placement of 19-21 suture anchors within the stomach to significantly reduce its size. The device has been used frequently in America and Spain but there is less experience in the UK, including in my own practice. --- The Apollo device is predominantly used by advanced upper GI interventional endoscopists in tertiary centres who are involved in the management of gastrointestinal defects and stent placement. Those using the device need to have advanced endoscopic skills and utilise these in their daily practice. For these individuals, the training curve is small with proficiency in 15-20 cases. I am actively involved in training days relating to the device and its use in practice. The device is also used by bariatric surgeons who can perform a procedure known as 'TORe' to reduce the size of the gastro-jejunal anastomosis following a Roux-en-Y gastric bypass. Myself, as a gastroenterologist, will decide whether to use the device for fixation and defects, but the selection of the device for management of obesity will be aided by referral from the bariatric MDT to ensure that patients are aware of all the possible treatment options available to them and to also get psychological and medical support in weight management. Within the gastroenterology community there is significant interest in the use of the device and this would lead to a rapid uptake across the country, including integration into advanced endoscopy training programmes.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	**I have done bibliographic research on this procedure.** I have done research on this procedure in laboratory settings (e.g. device-related research). **I have done clinical research on this procedure involving patients or healthy volunteers.** I have published this research. I have had no involvement in research on this procedure. Other (please comment) I have been actively involved in research in endoscopic sleeve gastroplasty. I have published literature reviews and acted as a primary supervisor to several doctoral students studying metabolic endoscopy. I am in the process of publishing outcomes on the use of suturing within the

		upper gastrointestinal tract with the Apollo Overstitch device, have set up patient registries for its role in obesity and looking to conduct prospective trials on both devices in the next year.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The two devices that are currently used to remodel the stomach via endoscopy utilise endoscopic suturing. The two processes are known as gastroplasty (Apollo OverStitch) and gastric plication (POSE). Endoscopic Sleeve Gastroplasty is the more widely utilised procedure with the most evidence to support its use. Therefore, I wonder whether endoscopic 'remodelling' of the stomach may be a more encompassing term to account for different suturing techniques. In addition, I would also question the use of the term 'severe' obesity. This generally implies a BMI >40, however, these endoscopic devices are best placed for patients with a BMI 30-40. The Overstitch can be used as a bridge to bariatric surgery in those with a very high BMI, but this is not the standard indication for this device. **Established practice and no longer new.** There is now well-established prospective trials, randomised controlled data, and meta-analyses on the safety and efficacy of the endoscopic sleeve gastroplasty using the Apollo OverStitch. In other countries it is being used widely as an endoscopic treatment of obesity. In addition, it is commonly be used in the private sector as a treatment option for obesity. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. Definitely novel and of uncertain safety and efficacy. The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Obesity is a complex, chronic, disease. There is no one treatment that is the most effective for all patients. New treatments including drugs and endoscopic devices should complement current standards of care and need to take into account the severity of obesity, the side-effects of the procedures, the level of efficacy, and of course, patient preference. We see these new endoscopic devices that remodel the stomach to reduce its size as safe and effective procedures for those with mild-to-moderate obesity who would like a one-off procedure in addition to adjuvant diet and exercise advice. There is no doubt that bariatric surgery is still the most effective treatment for severe obesity, but endoscopic remodelling could be used as an alternative option, not a

		replacement. These devices could also be used in combination with medical therapy in the future, but further trials exploring the efficacy of this need are needed.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	There have been no major modifications to the Apollo OverStitch that is utilised with a double channel endoscope. The predominant changes have been related to the suture pattern used to place the full thickness sutures within the stomach. There is currently no agreement on the most appropriate pattern and this is up to the discretion of the endoscopist. In addition, the use of argon photocoagulation (APC) prior to suture placement is less frequently used. In similar fashion, the POSE procedure uses the same device and associated accessories but there have been changes to the suture pattern. Traditionally, the procedure placed sutures within the fundus of the stomach, due to inadequate weight loss in randomised trials, the new procedure (POSE2.0), targets sutures to the body of the stomach, which has seen more profound weight loss in prospective trials. Apollo Endosurgery are currently assessing the safety and efficacy of a new device known as the Overstitch Sx system, which works in the same principal, but can attach to a single channel endoscope. Clinical trials looking at this device are ongoing.

Current management

6	Please describe the current standard of care that is used in the NHS.	Patients with obesity may be referred to a Tier 3 or 4 weight management service to aid with weight loss. Patients may be offered to enter a clinical trial or discussion around bariatric surgery if they meet specified NICE criteria. In the near future, patients will also be offered new GLP-1 agonists for weight management based on specific criteria. At present, patients who have an indication for bariatric surgery but decline may be offered an endoscopic sleeve gastroplasty (Apollo OverStitch) as an alternative. Therefore, there is currently no primary treatment option for endoscopic procedures.

7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	The only endoscopic, or minimally-invasive, alternative available to patients on the NHS through a weight management service could be an intragastric balloon. These devices show good short-term weight loss (albeit still less than endoscopic remodelling), but the outcomes on long-term weight loss is lacking and safety concerns remain due to spontaneous deflation, and need for early removal.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Endoscopic remodelling of the stomach offers patients a one-off, quick, reliable, and safe alternative to bariatric surgery to promote weight loss with 15-18% weight loss noted in clinical trials and meta-analyses after 1 year with early data suggesting good durability over 5 years. These procedures are associated with serious adverse events around 2-3%, which is similar to any interventional endoscopic procedure in the upper GI tract. We know that early data from the trials on new GLP-1 agonists show that patients often regain weight on drug withdrawal. Therefore, gastric remodelling could be used as an alternative to life-long drug therapy. In addition, these procedures would be more appropriate among patients at lower BMI (30-40) compared to bariatric surgery.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	People living with obesity with a BMI 30-40 kg/m2 and at least 1 obesity-related co-morbidity as an adjunct to diet and exercise advice, and potentially, as an adjunct to drug therapy in the future.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes. Patients could be given an endoscopic option as a primary treatment for obesity as an alternative to bariatric surgery. In addition, this could be an alternative or complement to drug therapy. Compared to bariatric surgery, endoscopic remodelling is safer, quicker, more cost-effective and associated with shorter hospital stay (theoretically patients could be discharged the same day). It would also widen the access to obesity treatments.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The procedure can be completed under general anaesthetic within an endoscopy unit. Existing hospitals pathways that conduct therapeutic endoscopic procedures on an anaesthetic list would be needed to perform the procedure, which is commonly available in tertiary hospitals. This would include the same pre-admission and post-admission protocols.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Endoscopists who perform advanced endoscopist procedures would need to undertake training with the device. Proficiency would be expected after 15-20 procedures to then work independently. The adverse events that can occur in relation to the procedure are the same as those with any advanced endoscopist procedure, so endoscopists would already be trained on how to deal with these scenarios.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Adverse events from endoscopic sleeve gastroplasty or primary obesity surgery endoluminal: - Abdominal tightness - Cramping, pain - Diarrrhoea - Difficulty swallowing - Mucosal injury to gastrointestinal tract - Perforation - Sore throat - Stricture - Transient bleeding - Abscess formation These are similar risks to any advanced endoscopic procedure within the upper GI tract (e.g. duodenoscopy, endoscopic ultrasound, stent placement). Specific risks unique to the device could include: - Allergic reaction to the device materials - Component degradation - Device breakage - Disarticulation of component from the device - Device/component lost in GI tract or wall - Puncture damage to surrounding structures (e.g. liver, pancreas

		Meta-analyses data (ESG) Singh et al (2020): serious adverse events in 2.26% (95% CI: 1.25-4.03). No mortality DOI: 10.1016/j.soard.2019.11.012 Hedjoudje et al (2020): serious adverse events in 2.2% (95% CI: 1.57-3.09). No mortality DOI: 10.1016/j.cgh.2019.08.022 Due-Petersson et al (2020): serious adverse events 1.5%. No mortality Dan Med J 2020 Vol. 67 Issue 11 **RCT data (ESG)** Abu Dayyeh et al (MERIT RCT; 2022): serious adverse events 2%. ESG reversal (malnutrition), intra-abdominal abscess (managed endoscopically), upper GI bleeding DOI: 10.1016/S0140-6736(22)01280-6 **Prospective data (POSE2.0)** US POSE2.0 pilot & Spanish POSE2.0 prospective study – no serious adverse events **RCT data (POSE)** Miller et al (MILEPOST RCT; 2017): no serious adverse events Sullivam et al (ESSENTIAL RCT; 2017): serious adverse events (5%): included one extra-gastric bleed needing laparoscopy, and one hepatic abscess. DOI: 10.1002/oby.21702
14	Please list the key efficacy outcomes for this procedure/technology?	Primary: Total body weight loss percentage (1, 3, 5-years) Secondary: reduction in obesity-related co-morbidities at 1, 3, 5-years (HbA1c, Serum lipids, hepatic steatosis, hepatic fibrosis, systolic BP, diastolic BP)

15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The endoscopic sleeve gastroplasty procedure has been shown to have excellent safety and efficacy data across thousands of patients. The Primary Obesity Surgery Endoluminal 2 procedure has ongoing studies looking into the safety and efficacy of the new suture pattern. However, the technical deployment of the sutures has been well studied in thousands of patients with very minimal adverse events <0.1% across all serious adverse events.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The only set-back is the limited longer-term outcome data for weight loss among patients undergoing gastric remodelling. Sharaiha et al (2021; DOI: 10.1016/j.cgh.2020.09.055) showed good 5-year durability of 15.9% (95% CI, 11.7–20.5) among 38 patients.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. **A minority of hospitals, but at least 10 in the UK.** (any hospital that conducts advanced endoscopic procedures in the upper GI tract (i.e. Endoscopic submucosal dissection, endoscopic ultrasound) could perform the procedure) Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help	n/a

	us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Endoscopic Sleeve Gastroplasty Versus GLP-1 Analogue for Class 1 and 2 Obesity Study (EGG) – not yet recruiting Efficacy and Safety of Endoscopic Sleeve Gastroplasty Versus Laparoscopic Sleeve Gastrectomy in Obese Subjects With NASH (TESLA-NASH) – recruiting Efficacy of the sleeve gastroplasty with the endoscopic system overstitch Sx on weight loss and reduction of co-morbidity of obese patients (SLEEVE) – recruiting (use of the new device for single channel endoscope)
20	Please list any other data (published and/or unpublished) that you would like to share.	n/a

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Any patient with a BMI 30-40 kg/m2 and no contra-indication to the procedure (i.e. significant inflammation of the stomach or oesophagus, upper GI cancer, stricture, history of coagulopathy, large hiatal hernia ≥3cm) could undergo the procedure for weight loss. This would account for a significant proportion of patients currently referred to Tier 2, 3, and 4 weight management services within the UK.
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late	Beneficial outcome measures: - Total Body Weight Loss percentage (weigh patient – 1, 3, 5-years) - Excess Weight Loss percentage (weight patient – 1, 3, 5 years) - Reduction in HbA1c (blood test – 1, 3, 5-years) - Reduction in NAFLD risk scores (e.g. FIB-4; blood tests – 1, 3, 5 years) - Reduction in Hepatic fibrosis (e.g. Fibroscan; transient elastography – 1, 3, 5-years) - Reduction in systolic/diastolic BP (BP reading – 1, 3, 5 years) - Reduction in use of diabetic medications (no. of medications – 1, 3, 5 years) - Reduction in use of blood pressure medications (no. of medications – 1, 3, 5 years)

	complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: - Incidence of peri-procedural and 3-day risk of bleeding, perforation, infection, need for re-intervention (endoscopy), need for surgery, readmission, length of hospital stay, mortality - Incidence of 1-year risk of malnutrition, need for reversal, conversion to bariatric surgery

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	n/a

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Click here to enter text.Rehan Haidry**
Dated:	**Click here to enter text.27-03-23**

View results

Respondent

2 Anonymous

33:02
Time to complete

Your information

1. Name: *

Andrew Currie

2. Job title: *

Consultant in Upper GI and General Surgery

3. Organisation: *

Epsom and St Helier Hospitals NHS Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

British Obesity and Metabolic Surgery Society

6. Nominated/ratified by (if applicable):

BOMSS

7. Registration number (e.g. GMC, NMC, HCPC) *

GMC 6160470

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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8. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

9. Please describe your level of experience with the procedure/technology, for example:

   Are you familiar with the procedure/technology?

   I am very familiar with the technology. I have performed ex-vivo training with the technology as part of a travelling fellowship to Brigham and the Women's Hospital in Boston, USA. I have published research on endoscopic sleeve gastroplasty.

10. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

    - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

    I am aware of the use of endoscopic sleeve gastroplasty (ESG) in the UK. I am part of the National Bariatric Surgery Registry committee, which would be the ideal place for clinical practice to be routinely recorded as part of any prospective roll-out. I am a trained upper GI and bariatric surgeon and would be involved in selection of patients for ESG. It will be upper GI/bariatric surgeons and gastroenterologists performing the procedure.

11. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

13. Is the proposed indication appropriate? If not, please explain

The description includes the nomenclature double channel. I am aware that there are single channel devices too so that could be amended.

14. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Novel approach and concept. Currently, the NHS offers limited interventions between lifestyle advice/medication and bariatric surgery. Endoscopic bariatric therapies may offer an important middle ground.

15. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

16. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Obesity is a chronic disease and like all chronic diseases a multitude of interventions are needed for levels of disease and patient preference. Itwould likely be used as an addition to standard care (accepting that standard of care is only offered to a very small percentage of the eligible population with severe and complex obesity in the UK)

Current management

17. Please describe the current standard of care that is used in the NHS.

current standard of care in obesity is lifestyle management. Patients have to move through a tiered system of weight management in order to access more effective therapies. The most effective therapy for obesity is bariatric-metabolic surgery.

18. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

    The most common comparators would be lifestyle advice and medications and then bariatric surgery. There is significant variation in the access to these therapies currently within the NHS

Potential patient benefits and impact on the health system

19. What do you consider to be the potential benefits to patients from using this procedure/technology?

    this would enable people with obesity to undergo effective therapy without the need for surgery in those patients who currently don't meet the criteria for surgery or do not wish to undergo surgical procedures.

20. Are there any groups of patients who would particularly benefit from using this procedure/technology?

    Any patient with obesity who need weight management assistance and do not wish to undergo surgical procedures.

21. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    This would result in quite significant change - day-case intervention and less invasiveness. These would bring about significant benefits to the healthcare system in addition to the substantial benefits from actively treating obesity and the associated co-morbidities

22. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

Availability of operating theatres to facilitate treatment.

23. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes. There is a learning curve. In addition to being a trained endoscopist, the literature indicates a learning curve of around 10-30 cases. The proceduralist should be working within a Tier 4 MDT to ensure that people with obesity are having this procedure discussed alongside all other NHS approved therapies for severe and complex obesity

Safety and efficacy of the procedure/technology

24. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Nausea, vomiting and abdominal pain. Rarer events including abdominal abscess and gastrointestinal bleeding.

25. Please list the key efficacy outcomes for this procedure/technology?

Total body weight loss (percentage)
Co-morbidity resolution
Health-related quality of life

26. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

The longer term outcomes are less certain in terms of persistent of weight loss (regain). The ability to convert to more effective therapies in the longer term (bariatric surgery) is reported.

27. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

The longer term outcomes. It is complicated to learn and so it may not be applicable to every practitioner

28. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

29. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

30. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

31. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

32. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Using Health Survey for England, Hospital Episode Statistics and other datasets, around 3 million people in England are eligible for bariatric-metabolic surgery. Focussing on class 1 and class 2 obesity, around 5% of the population would be eligible.

33. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Patient acceptability - tool to be defined - pre-intervention
Percentage excess weight loss - 6 and 12 months and 24 months
Health-related quality of life - Eq5D - 3,6, 12 and 24 months

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Complications - 30 and 90 day
Length of stay - primary and total
Need for re-intervention - 30 days

Further comments

35. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

With regards to implementation, I think it should be mandatory to include in a registry. There is a National Bariatric Surgery Registry, currently mandated by NHS England to report NHS bariatric-metabolic surgery as part of an annual Consultant Outcomes Publication.

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

36. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

37. Description of interests, including relevant dates of when the interest arose and ceased. *

n/a

38. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

    Please note, all declarations of interest will be made publicly available on the NICE website. *

    - (●) I agree
    - ( ) I disagree

Signature

39. Name: *

    Andrew Currie

40. Date: *

    28/03/2023

View results

Respondent

3 Anonymous

59:44
Time to complete

Your information

1. Name: *

Dimitrios Pournaras

2. Job title: *

Consultant in Upper GI and Bariatric/Metabolic Surgery

3. Organisation: *

North Bristol NHS Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

British Obesity and Metabolic Surgery Society

6. Nominated/ratified by (if applicable):

British Obesity and Metabolic Surgery Society

7. Registration number (e.g. GMC, NMC, HCPC) *

6109278

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

8. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

9. Please describe your level of experience with the procedure/technology, for example:

   Are you familiar with the procedure/technology?

   Familiar with the procedure. Aware of indications, clinical application and mode of action.

10. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

    - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

    Have no direct experience of using the technology. As part of CMR have received training in courses and conferences. The technology is used by colleagues (bariatric surgeons), but also others (gastroenterologists, endoscopists). The selection process is often by multidisciplinary teams that routinely include bariatric surgeons.

11. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

13. Is the proposed indication appropriate? If not, please explain

Yes.

14. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a novel approach, however the mode of action is based on other treatments targeting the GI tract.

15. Which of the following best describes the procedure:

- (●) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

16. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

As there is an unmet need for obesity care, this procedure will add to the existing standard of care taking a place between bariatric surgery and pharmacotherapy.

Current management

17. Please describe the current standard of care that is used in the NHS.

The standard of care is bariatric surgery. Recently pharmacotherapy is also included in the standard of care. Other endoscopic options include intragastric balloon. Lifestyle modifications with very low energy diets are also part of the standard of care.

18. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

Other modalities for obesity care have a different risk/benefit profile. Due to the heterogeneity of the disease of obesity, multiple options are needed. This procedure will not compete with others, but has the potential to complement some of them, for example pharmacotherapy.

Potential patient benefits and impact on the health system

19. What do you consider to be the potential benefits to patients from using this procedure/technology?

Weight loss and weight loss maintenance.

20. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patients who have not responded to lifestyle interventions (that is the majority of patients) and/or pharmacotherapy.
Patients who are deemed too high risk for bariatric surgery.
Patients for whom bariatric surgery is not an acceptable option.

21. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

People who respond to this treatment as part of obesity care will have fewer appointments/interventions.
As obesity is associated with a large number of conditions and diseases, an improvement mediated via this technology will lead to better outcomes including fewer visits and interventions.

22. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

A multidisciplinary obesity care team and endoscopy facilities allowing endoscopy under general anaesthetic.

23. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Endoscopy skills specific to the procedure (endoscopic suturing) and basic training for the multidisciplinary team (dietetic management).

Safety and efficacy of the procedure/technology

24. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Bleeding, infection, perforation, venous thromboembolism.
1.3% moderate adverse events without any severe or fatal adverse events were reported in the RCT MERIT. https://doi.org/10.1016/S0140-6736(22)01280-6
There is a theoretical risk of future bariatric surgery being more complex, this has not been reported in the literature.

25. Please list the key efficacy outcomes for this procedure/technology?

Weight loss maintenance at different timepoints.
Obesity associated disease improvement/resolution.
Improvement in function and quality of life.

26. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Long term safety and efficacy outcomes are not available yet. Short and mid term are available.

27. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Long term (10 year) efficacy.

28. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) Most or all district general hospitals.
- (•) A minority of hospitals, but at least 10 in the UK.
- ( ) Fewer than 10 specialist centres in the UK.
- ( ) Cannot predict at present.

Abstracts and ongoing studies

29. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

30. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

31. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

32. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Less than 1% of the population with severe and complex obesity access treatment currently. This technology will improve this, but the number of people treated will remain lower than the number of people undergoing bariatric surgery.

33. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Obesity associated disease. (HbA1c, medication usage for type 2 diabetes and hypertension, CPAP use for obstructive sleep apnoea).
Weight loss maintenance (BMI and weight).
Quality of life (EQ-5D).
12, 24 and 60 months for all measurements.

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Perforation, bleeding, surgery, further procedures.

Further comments

35. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

N/A

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

36. Type of interest: *

- [x] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [x] Indirect
- [ ] No interests to declare

37. Description of interests, including relevant dates of when the interest arose and ceased. *

Honoraria for consulting and profesional education: Johnson and Johnson, Medtronic, Novo Nordisk (2020-2023).
Previously board member for Keyron (2019-2022).

38. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

39. Name: *

Dimitri Pournaras

40. Date: *

27/03/2023

View results

Respondent

1 Anonymous

1265:01
Time to complete

Your information

1. Name: *

Ahmed Ahmed

2. Job title: *

Clinical Senior Lecturer

3. Organisation: *

Imperial College London

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

BOMSS

6. Nominated/ratified by (if applicable):

BOMSS

7. Registration number (e.g. GMC, NMC, HCPC) *

GMC 4305462

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

8. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

9. Please describe your level of experience with the procedure/technology, for example:

   Are you familiar with the procedure/technology?

   Yes I am familiar with ESG. Endoscopic sleeve gastroplasty is a minimally invasive weight loss transoral endoscopic procedure that reduces the size of the stomach and limits food intake. The procedure is done as a day case under general anaesthesia. A double channel scope with a procedure specific endoscopic device attached is introduced transorally. A series of endoluminal full-thickness triangular suture plications are done along the greater curvature of the stomach (through the gastric wall, extending from the pre-pyloric antrum to the gastroesophageal junction). This involves folding the stomach in on itself and stitching it together creating a restrictive endoscopic sleeve to reduce the stomach volume/capacity by about 70 to 80%. There is no resection of the stomach and the procedure may be potentially reversible.

10. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

    - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

    Yes this procedure is performed in certain NHS hospital who have the expertise.
    The procedure is performed by endoscopists.
    I refer patients for this ESG

11. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

13. Is the proposed indication appropriate? If not, please explain

Yes

14. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Novel approach

15. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

16. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Addition

Current management

17. Please describe the current standard of care that is used in the NHS.

Bariatric Surgery

18. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

Endoscopic Gastric balloons

Potential patient benefits and impact on the health system

19. What do you consider to be the potential benefits to patients from using this procedure/technology?

weight loss and comorbidity improval

20. Are there any groups of patients who would particularly benefit from using this procedure/technology?

BMI >30

21. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes

22. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

None. You just need endoscopic department, purchase the appropriate kit and have accesss to theatres and anaesthesia

23. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes the manufacturer of the kit provides this

Safety and efficacy of the procedure/technology

24. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

ESG had gained attention for its advertised minimal invasiveness, quicker recovery, and low or nil complications It involves the creation of gastric tube through plication of gastric mucosa using an Overstitch device. It is reported to be a less invasive intervention with equivalent outcomes to surgery for patients with BMI < 35 kg/m2. Some authors reported total body weight loss of up to 20.9% over 24 months

Despite the low risk advertised with ESG, major post-procedure complication rates are reported between 1.1 and 2.4%, and procedure failure ranges between 50 and 90%.

Other studies record with regard to postoperative complaints, 924 patients (92.4%) complained of nausea or abdominal pain that was controlled with medications during the first week after ESG. Twenty-four patients were readmitted: 8 for severe abdominal pain, of whom 3 had ESG reversal; 7 for postprocedure bleeding, 2 of whom received 2 units of packed red blood cells each; 4 for perigastric collection with pleural effusion, 3 of whom underwent percutaneous drainage; and 5 for postprocedure fever with no sequelae. Eight patients were revised to sleeve gastrectomy, and 5 had redo-ESG (Al Qahtani et al 2019)

The Merit study shows ESG-related adverse events are reported for participants who underwent a completed or attempted ESG procedure: 927 events were reported in 138 (92%) of 150 participants in the primary and crossover ESG group. Two-thirds (612 [66%] of 927) of reported adverse events were accommodative gastrointestinal symptoms expected in the post-procedural acclimation period, including pain, heartburn, nausea, and vomiting. Most of these symptoms resolved within 1 week . Three participants (2%) who underwent ESG had a device-related or procedure-related adverse event that met the criteria of grade 3 (requiring surgical, endoscopic, or radiological intervention) or higher on the Clavien-Dindo classification scale. These events included abdominal abscess, managed endoscopically; upper gastrointestinal bleed, managed conservatively without transfusion; and a case of malnutrition requiring endoscopic reversal of the ESG. Six (4%) of 150 participants required subsequent hospital admission for medical management of accommodative symptoms. All participants with serious adverse events fully recovered, and the primary safety objective of 5% or less observed device-related or procedure-related serious adverse events was met.

25. Please list the key efficacy outcomes for this procedure/technology?

1. WEIGHT LOSS

Several systematic reviews and meta-analyses have been published;five recent systematic reviews and meta-analyses evaluated the effectiveness and safety of ESG for the treatment of obesity in the same year First, Hedjoudje et al. included 1,772 patients from eight studies published between 2016 and 2019 and reported a 6-month mean %TBWL of 15.1%, mean percentage of excess body weight loss (%EBWL) of 57.7%, and mean reduction in body mass index (BMI) of 5.65 kg/m2 . Weight loss was sustained at 1 year and at 18–24 months with %TBWL of 16.5% and 17.2%, respectively. Second, in a meta-analysis of 2,170 patients from 11 studies published before October 2019, the pooled mean %TBWL values observed at 6, 12, and 18 months were 15.3%, 16.1%, and 16.8%, respectively. The pooled mean %EBWL values at 6, 12, and 18 months were 55.8%, 60%, and 73%, respectively . Third, Li et al. enrolled a total of 1,542 patients from nine studies published up to February 2019 and reported the pooled %TBWL values of 8.8%, 11.9%, 14.5%, and 16.1%, respectively, at 1, 3, 6, and 12 months . The pooled %EBWL values at 1, 3, 6, and 12 months were 31.2%, 43.6%, 53.1%, and 59.1%, respectively . Fourth, in a meta-analysis by Singh et al. with 1,859 patients from eight studies published before June 2019, the pooled mean %TBWL values at 6, 12, and 24 months were 14.9%, 16.4%, and 20.0%, respectively . The pooled mean %EBWL values at 6, 12, and 24 months were 55.8%, 61.8%, and 60.4%, respectively . Lastly, Due-Petersson et al. included a total of 2,142 patients from 23 studies regardless of publication date and reported a %TBWL of 16.3% at 12 months.

2. IMPROVEMENT IN OBESOTY RELATED CO-MORBIDITIES
Alongside the weight loss, there is evidence to suggest that ESG is associated with reduction in HbA1c level, systolic blood pressure, triglyceride level, and risk of hepatic steatosis and fibrosis; it even improved the quality of life in some studies.

26. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

ESG is a novel procedure that should provide good obesity outcomes with minimal complications in selected patients. However, this procedure, in my view, has comparable complication rates and operative time to LSG (laparoscopic sleeve gastrectomy) with poorer weight loss outcomes than previously reported. It is also a demanding procedure with a steep learning curve. Careful training and patient selection are mandatory to achieve better results

27. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

see answer to 26 above

28. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) Most or all district general hospitals.
- (•) A minority of hospitals, but at least 10 in the UK.
- ( ) Fewer than 10 specialist centres in the UK.
- ( ) Cannot predict at present.

Abstracts and ongoing studies

29. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    none that I know of

30. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    The Mertit study - https://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2822%2901280-6/fulltext

31. Please list any other data (published and/or unpublished) that you would like to share.

None

Other considerations

32. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

So there are around 3.2 million people that meet NICE criteria for obesity surgery. All of these could undergo ESG instead and also in my estimation a further 5-8 million would qualify from BMI 30-35 (although manufacturer allows ESG from BMI 27 onwards)

33. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

1. %weight loss at year 1,5,10
2. Co-morbidity improvement at years 1,5, 10

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

1. Complications and Serious adverse events frequency and nature at 3 months
2. Common side effects after ESG incidence at 3 months
3. Conversion from ESG to standard bariatric surgery frequency at year 1

Further comments

35. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

None

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

36. Type of interest: *

- [ ] Direct: financial
- [x] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [ ] No interests to declare

37. Description of interests, including relevant dates of when the interest arose and ceased. *

I am council member for BOMSS (from 2017 onwards, and Treasurer since 2019)

38. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

39. Name: *

Ahmed Ahmed

40. Date: *

15/03/2023