

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Professional Expert questionnaire

Before completing this questionnaire, please read [Conflicts of Interest for Specialist Advisers](#).

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Insertion of biodegradable balloon for obesity

Name of Professional Expert: Mary O’Kane

Job title:

Professional Regulatory Body: Other (specify) HCPC

Registration number: DT03029

Specialist Society: British Dietetic Association

Nominated by (if applicable):

1 About you and your speciality’s involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

Comments:

1.2 Is this procedure relevant to your specialty?

Yes.

Comments:

1.3 Is this procedure performed by clinicians in specialities other than your own?

Yes – please comment Performed by surgeons

Comments:

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

I do this procedure regularly. I have supported patients with nutritional advice in the private sector who have had this procedure

Comments:

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

I have taken part in patient selection or referred a patient for this procedure at least once.

Comments: Patients have usually read about this procedure in social media /newspapers and made an appointment to see the surgeon regarding the procedure. On receipt of the referral from the surgeon, I make contact with the patient and go through the nutrition and behaviour changes required. We discuss expectations

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

I have done bibliographic research on this procedure.

Most papers I have seen are from single centres and in Obesity Surgery which I subscribe too. I have not done an extensive literature search

Comments:

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

Fewer than 10% of specialists engaged in this area of work.

Comments:

This is in the private sector only as not NICE approved and a short-term procedure.

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

Yes

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Comments:

2.2 Which of the following best describes the procedure (choose one):

.

Definitely novel and of uncertain safety and efficacy.

Comments:

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

I am not aware of any. The nearest procedure will be the intragastric balloon which is usually now in place for one year

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

I am not aware

- 2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or 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.**

IFSO 2019 conference abstracts attached

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

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

Adverse events reported in the literature (if possible please cite literature)

Bowel obstruction, Early deflation. Abdominal pain - Mohammad H. Jamal The Safety and Efficacy of Procedureless Gastric Balloon: a Study Examining the Effect of Elipse Intra-gastric Balloon Safety, Short and Medium Term Effects on Weight Loss with 1-Year Follow-Up Post-removal Obesity Surgery (2019) 29:1236–1241
<https://doi.org/10.1007/s11695-018-03671-w>

Initially nausea, vomiting, cramping, abdominal pain, regurgitation, satiety, difficulty in swallowing liquid, and solid foods. One patient needed iv fluids - A. Genco -Safety and Efficacy of a New Swallowable Intra-gastric Balloon Not Needing Endoscopy: Early Italian Experience OBES SURG (2018) 28:405–409 DOI 10.1007/s11695-017-2877-1

From IFSO 2019 Abstracts (pdf attached)

O-003 ELIPSE PROCEDURELESS GASTRIC BALLOON FOR WEIGHT LOSS: MULTI-CENTER EXPERIENCE IN 1623 CONSECUTIVE PATIENTS “41 (2.5%) patients had intolerance requiring endoscopic balloon removal. One (0.06%) patient developed esophagitis. One (0.06%) had gastric perforation requiring surgery. There were no small bowel obstructions or any other serious complications.

O-077 MULTICENTER EXPERIENCE WITH THE ELIPSE PROCEDURELESS GASTRIC BALLOON IN OBESE ADOLESCENTS 3(6%) patients required endoscopic removal for intolerance

O-106 12 MONTHS EXPERIENCE AND RESULTS WITH THE NEW SWALLOWABLE INTRA-GASTRIC BALLOON – intolerance and dehydration reported

PO-136 SWALLOWABLE INTRAGASTRIC BALLOON (ELIPSE®). FEASIBILITY, RESULTS AND ENDOSCOPIC REQUIREMENTS. INITIAL EXPERIENCE Adverse effects: 1 balloon vomited, 1 intolerance (extraction by gastroscopy) and 1 ileal occlusion (extraction by ileoscopy)

I have attached the abstract book as there may be others

Anecdotal adverse events (known from experience)

Some patients have reported distress when the balloon is placed. Many report extreme nausea, sickness and stomach cramps in the first few days. Some have reported that the balloon has deflated early. One struggled to eat properly through out but declined balloon removal. Weight loss expectations not met

Theoretical adverse events

3.2 Please list the key efficacy outcomes for this procedure?

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

In the small number of patients I have supported, most were disappointed with results

3.4 What clinician training is required to do this procedure safely?

I am unable to comment on surgical training. Dietitian should be skilled in supporting patients post bariatric surgery. Although this is not an operation, many of the issues with diet are similar to when patients have surgery

3.5 What clinical facilities are needed to do this procedure safely?

This is for surgeons to comment

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

The original video on the Allurion website appeared to suggest that a woman had the procedure in her lunch break and would then return to work. This video seems to have been replaced. Most patients feel very nauseous afterwards and need to take time off work

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This 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:

Weight loss over time balloon in place
Quality of diet
Behavioural changes
Maintenance of weight loss 3 and 6 months after balloon deflated
Patient satisfaction
Impact on satiety whilst balloon in place

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

Symptoms – nausea, vomiting, abdominal pain – how long they last for
Medication to control symptoms
Hospital admission and reason whilst band in place
Early deflation
Any issues arising during deflation (apparently some patients may vomit parts of the balloon back

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

- Rapidly (within a year or two).
- Slowly (over decades)
- I do not think the NHS will adopt this procedure

Comments:

I do not think this will be adopted by NHS as it is a short-term procedure with variable results

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

- 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.

Comments:

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

- Major.
- Moderate.
- Minor.

Comments:

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

7 Data protection and conflicts of interest

7.1 Data Protection

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I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our [privacy notice](#)

7.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the “Conflicts of Interest for Specialist Advisers” policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures. [Conflicts of Interest for Specialist Advisers](#)

Declarations of interest form			
Mary O’Kane, Specialist advisor			
Type of interest	Description of interest	Relevant dates	
		Interest arose	Interest ceased
<i>Financial?</i>	<i>I supported patients in the private sector who had this procedure. I am employed as a bank member of staff by Nuffield Hospital</i>	<i>Approximately from August 2018</i>	May 2019 as Nuffield stopped the procedure following

	<i>Leeds to see patients who have bariatric surgery</i>		complaints from patients about the procedure
<i>International federation of surgery for obesity and metabolic diseases</i>	I sit on IFSO Exec Board and am chair of IFSO Integrated Health Committee (This procedure has never been discussed)	Exec Board since 2017 Vice chair of IH committee since 2017 and chair since Sept 2019	
<i>British Obesity and Metabolic Surgery Society Committee</i>	BOMSS committee member since 2012 (This procedure has never been discussed)		

* Guidance notes for completion of the Declarations of interest form

Name and role	Insert your name and your position in relation to your role within NICE
Description of interest	<p>Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest.</p> <p>Types of interest:</p> <p>Direct interests</p> <p>Financial interests - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. <i>For examples of financial interests please refer to the policy on declaring and managing interests.</i></p> <p>Non-financial professional and personal interests - Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. <i>For examples of non-financial interests please refer to the policy on declaring and managing interests.</i></p> <p>Indirect interests - Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in</p>

	<p>question to benefit.</p> <p>A benefit may arise from both a gain or avoidance of a loss.</p>
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair **Mirella Marlow Programme Director**

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Interventional Procedures Programme

Professional Expert questionnaire

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Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name:	Insertion of biodegradable balloon for obesity	
Name of Professional Expert:	Richard Welbourn	
Job title:	Consultant UGI and Bariatric Surgeon	
Professional Regulatory Body:	GMC	<input checked="" type="checkbox"/>
	Other (specify)	<input type="checkbox"/>
Registration number:	2839903	
Specialist Society:	BOMSS/AUGIS	
Nominated by (if applicable):	NICE	

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

No – please answer no more questions and return the form

Comments:

I do this procedure.

1.2 Is this procedure relevant to your speciality?

Yes.

No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

Bariatric procedure.

1.3 Is this procedure performed by clinicians in specialities other than your own?

Yes – please comment

No

Comments:

Only done by bariatric surgeons

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

I have never done this procedure.

I have done this procedure at least once.

I do this procedure regularly.

Comments:

I have done it throughout 2019

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

I have never taken part in the selection or referral of a patient for this procedure.

I have taken part in patient selection or referred a patient for this procedure at least once.

I take part in patient selection or refer patients for this procedure regularly.

Comments:

Please see above.

1.6 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 had no involvement in research on this procedure.
- Other (please comment)

Comments:

I took part in a training programme provided by the manufacturer before starting the procedure.

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

- Yes
- No - If no, please suggest alternative titles.

Comments:

2.2 Which of the following best describes the procedure (choose one):

- 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.

Comments:

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

Existing endoscopically placed balloons.

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

Not to my knowledge.

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or 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.

I'm sure the manufacturers would be happy to supply a recent list.

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

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

Adverse events reported in the literature (if possible please cite literature)

Misplacement into the trachea; small bowel obstruction due to passage of a partially deflated balloon requiring operation or percutaneous drainage.

Anecdotal adverse events (known from experience)

Very early deflation within 2-3 weeks, and passage of balloon per rectum. Also: intolerance and requirement for early removal (no different from other balloons).

Theoretical adverse events

As above.

3.2 Please list the key efficacy outcomes for this procedure?

Weight loss, tolerance of it being in the stomach.

3.3 Please list any uncertainties or concerns about the efficacy of this procedure?

Weight loss seems equivalent to other intragastric balloons, but this needs checking via a literature search.

3.4 What clinician training is required to do this procedure safely?

The manufacturers mandate a 3-hour interactive lecture (via Skype or similar) and their representative to be present for the first 20 placements.

3.5 What clinical facilities are needed to do this procedure safely?

Done in Xray under fluoroscopy.

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Not to my knowledge.

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This 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:

Weight loss, improvement in comorbidities, quality of life

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

Small bowel obstruction; failure to be able to swallow / place balloon. From time zero to 6 months, or when balloon has passed.

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

- Rapidly (within a year or two).
- Slowly (over decades)
- I do not think the NHS will adopt this procedure

Comments:

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

- 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.

Comments:

No reason why it wouldn't be done in every bariatric unit in the NHS – currently over 40 to my knowledge of these.

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

- Major.
- Moderate.
- Minor.

Comments:

Balloons are currently only used to my knowledge within the NHS to reduce the weight of very severely obese patients to make them fitter for surgery and many centres don't use them. They could take over from the existing balloons as they require less resource to place them (endoscopy / theatre time for placement / removal).

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

Please see above; no reason why it shouldn't be used in the NHS.

7 Data protection and conflicts of interest

7.1 Data Protection

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Declarations of interest form			
Type of interest	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Private practice	<i>I insert these balloons in my bariatric practice and already have approval to place them in my NHS hospital (but have not placed any</i>	<i>Jan 2019 – started placing this particular balloon in addition to existing balloon.</i>	Current

	<i>there yet as we haven't found a suitable patient or one who wishes this over a different type of balloon) – however I do not see this as a COI. In the NHS and privately I have placed balloons for >10 years.</i>		

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Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It

	should include the rationale for this action, and the name and role of the person who reviewed the declaration.
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Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair **Mirella Marlow Programme Director**

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Interventional Procedures Programme

Professional Expert questionnaire

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Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Insertion of biodegradable balloon for obesity

Name of Professional Expert: Dr Simon Cork, PhD

Job title: Teaching Fellow in Medical Education

Professional Regulatory Body: GMC

Other (specify)

Registration number:

Specialist Society: The Physiological Society

Nominated by (if applicable):

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

Yes.

No – please answer no more questions and return the form

Comments:

1.2 Is this procedure relevant to your speciality?

- Yes.
- No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

1.3 Is this procedure performed by clinicians in specialities other than your own?

- Yes – please comment
- No

Comments:

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

- I have never done this procedure.
- I have done this procedure at least once.
- I do this procedure regularly.

Comments:

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

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

Comments:

1.6 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 had no involvement in research on this procedure.
- Other (please comment)

Comments:

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

Comments:

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

- Yes
- No - If no, please suggest alternative titles.

Comments:

2.2 Which of the following best describes the procedure (choose one):

- 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.

Comments:

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

Insertion of gastric balloon under general anaesthetic

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

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or 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.

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3.1 What are the potential harms of the procedure?

Please list any adverse events and major 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

3.2 Please list the key efficacy outcomes for this procedure?

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

This procedure is likely to provide a similar level of efficacy as current gastric balloons in terms of weight loss, with the added benefit that patients do not need to undergo anaesthesia for the balloon to be inserted. As with current gastric balloons, this device will not lead to long term weight loss, but will only lead to modest weight loss whilst the balloon is inflated. Once the balloon disintegrates, the lost weight will likely be regained.

3.4 What clinician training is required to do this procedure safely?

3.5 What clinical facilities are needed to do this procedure safely?

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This 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:

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

- Rapidly (within a year or two).
- Slowly (over decades)
- I do not think the NHS will adopt this procedure

Comments:

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

- Most or all district general hospitals.
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- Cannot predict at present.

Comments:

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

- Major.
- Moderate.
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Comments:

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Declarations of interest form			
Type of interest	Description of interest	Relevant dates	
		Interest arose	Interest ceased

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Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair **Mirella Marlow Programme Director**