NHS England

CCG Pack

Appendix 8 Guidance for Clinical Commissioning Groups (CCGs): Clinical Guidance: Revision Surgery for Complex Obesity

Guidance for commissioning revision surgery

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Contents

1 Introduction

Obesity and being overweight is a global epidemic. The World Health Organisation (WHO) predicts that by 2015 approximately 2.3 billion adults worldwide will be overweight and more than 700 million will be obese [1]. Obesity is a chronic disease which requires treatment over many years. Although dietetic and exercise therapies form the core of treatment programmes, an increasing proportion of individuals (with increasing BMI) will benefit from medical management, drug treatments and psychological therapies. At present the pharmaceutical options are limited and the most effective weight loss treatment or intervention for patients with severe and/or complex obesity is obesity (bariatric) surgery. Best results from surgery are obtained when those patients who meet current guidelines, are well prepared, and the timing of surgery has been optimised within a specialist programme providing pre- and post-operative comprehensive care. This requires a multi-disciplinary weight management service that includes specialist dietetic counselling and education, psychological support, assessment and medical management by a suitably experienced obesity physician. Finally, the decision related to timing of surgery should include consideration of the co-morbidities of obesity which may be serious, severe and risk organ damage or even be life threatening. There are also instances when obesity surgery is requested to reduce weight rapidly prior to carrying out other major surgery (elective or urgent) that a patient may require.

Unprepared or inadequately prepared patients who are unable to engage and comply with a specialist weight management programme are more likely to have poorer outcomes from the surgical obesity procedure, such as weight loss below expected, weight regain, non-resolution/re-emergence of co-morbidities and on-going or emergent psychological morbidity. Hence it is critically important that access to such programmes is matched to a planned follow-up programme.
Surgical management for any chronic disease has its limitations. The concept of failure and the need for revision surgery is well established and accepted in other disciplines such as orthopaedics where for example revision rates for hip arthroplasty are >7% at 5 years [2]. The overall incidence of surgical revision after a primary obesity operation ranges from 5% (Biliary pancreatic diversion (BPD)) up to 50% (Laparoscopic gastric band (LAGB)) with intermediate rates for Roux-en-Y gastric bypass (RYGB) and laparoscopic sleeve gastrectomy (LSG). The different rates may reflect the weight loss efficacy of the three procedures but this is not an absolute truth as there is current National Institute for Health Research (NIHR) funded randomised comparison of LAGB and RYGB to test the hypothesis.
Indications for surgical revision are diverse and can be for weight loss failure or weight regain, re-emergence of co-morbidities as well as other parameters such surgical complications or a combination of these.

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[1] World Health Organisation. Obesity and overweight. Fact sheet N°311. September 2006. http://www.mclveganway.org.uk/Publications/WHO_Obesity_and_overweight.pdf Last accessed 20/6/2014.

[2] Labek G, Thaler M, Janda W, Agreiter M, Stöckl B. Revision rates after total joint replacement: cumulative results from worldwide joint register datasets. J Bone Joint Surg Br 2011;93:293-7.

The rise in obesity operations will inevitably lead to an increasing number of re-operations including revision of the primary obesity operation and/or conversion to a different type of major obesity procedure e.g. LAGB to LSG or RYGB. There is no UK or international consensus regarding the best surgical option in revision surgery. These revisions / re-operations may be performed for heterogeneous indications as highlighted above.

In some cases the need for re-operation will be explicit because of a technical or post-surgical anatomical problem that clearly requires a further surgical procedure to correct. In other cases, the indication will be a perceived failure of the primary surgery to achieve expected weight loss outcomes and satisfactorily resolve pre-operative co-morbidities. This is a more ambiguous area as there is no generally accepted definition of failure in terms of weight loss, weight regain, or inadequate resolution or re-emergence of co-morbidities.
Issues that arise with the provision of revisional surgery, include the indications for a second operation, the effectiveness of revision procedures and the associated morbidity, mortality, and complication rates, the technical expertise of those performing complex revisions and the health service facilities and resource utilisation required for a second operation. Additionally, patients are increasingly presenting to the NHS with either failed operations or with complications following on from surgery carried out in the private sector within the UK or abroad. Such patients may not have previously met NHS England guidance pre- operatively, nor had adequate preparation or follow up.

Current NHS commissioning arrangements require that all patients are initially assessed by a full multidisciplinary team (MDT) prior to surgery and undertake formal follow up for up to 24 months post operation. Surgical patients are required to meet recommended criteria and guidance. Current arrangements are adequate for identifying acute post-operative complications up to 2 years. They are not adequate to detect and/or address any later or long term development of problems of weight re-gain, nutritional deficiencies, re-emergence of co-morbidities and surgical complications that present beyond two years.

This guidance does NOT include:
1. Early re-operation i.e. surgery within 90 days of the index obesity surgical procedure. This should be regarded as a complication of the primary surgical procedure and will be the responsibility of the provider undertaking the primary bariatric operation.
2. Those patients excluded as described in section 7.
3. Those patients who are undergoing planned phased or two-step procedures as agreed at the time of the initial MDT accepting the patient for surgery.

2 Purpose of the document

This guidance aims to describe revision obesity surgery and add clarity to the commissioning issues and reasons behind the current demand for revision surgery. The objectives are to clearly identify the groups of patients to inform commissioning decisions on eligibility for NHS funding.

This document sets out the steps to support devolvement of the responsibility for commissioning specialist Adult Severe and Complex Morbid Obesity services to Clinical Commissioning Groups from 1st April 2016. The aim is to ensure that patient pathways and services are commissioned by the most appropriate organisations that are best placed to contract effectively to improve patient experience and outcomes. This approach embodies the NHS England commitment to a population and patient centred approach to commissioning and supports the work being undertaken by CCGs in ensuring that all clinical pathways meet the needs of patients at a local level.

2.1 Definition of Revision Surgery

The need for revision surgery may be required due to:

1. Surgical complications including technical problems arising from the original obesity surgical procedure. These may present as severe gastrointestinal symptoms such as reflux, nausea, vomiting, dysphagia or inability to tolerate solid foods.
2. Medical complications of the primary procedure including profound macro- and micronutrient deficiencies; anaemia, malnutrition and metabolic abnormalities such as disabling intractable hypoglycaemia.
3. The failure of the primary operation to provide adequate, stable and durable weight loss with adequate resolution of weight related comorbidities, or to address significant weight regain, frequently with re-emergence of pre-operative comorbidities.

Further revision surgery is therefore an additional attempt to maintain or secure further improvements in weight loss, improvement, or resolution of obesity-related co-morbidities, and gains in quality of life. Although at present there is no consensus of what constitutes *adequate* weight loss nor *significant* weight gain (apart from procedure specific average expected excess weight loss at 1 and 2 years or regain to ≥ pre op morbid obesity levels) it is recognised that in some cases revision bariatric surgery is an appropriate strategy for optimal management of the lifelong chronic disease of obesity. Some higher risk patients may have a second bariatric operation as a planned staged procedure according to a risk reduction strategy and they are not considered in this document beyond noting that at present there is insufficient evidence regarding planned one step procedures, or phased or two step procedures or indeed the optimal duration between the two stages. It is also recognised that 'servicing' reoperations are needed for gastric band surgery over time.

3 National context and evidence base

Over the past years there has been a steady increase in the number of obesity procedures in England with 8794 cases performed in NHS hospitals in 2011/12 [3]. In addition, it is estimated that up to 5000 procedures per year are performed for residents of England within the private sector mainly in the UK but also overseas. A

[3] Statistics on Obesity, Physical Activity and Diet: England, 2013. HSCIC 2013

proportion of these cases will progress to a second procedure. It is currently considered (on the basis of United States data) that the overall incidence of surgical revision after a primary obesity operation ranges between 5-50 percent. The lowest rate of revision is associated with duodenal switch at 5%. For gastric bypass it is 10-20%. For gastric banding it is the highest at up to 50% [4] although some centres record a lower rate of 15% for laparoscopic adjustable gastric band (LAGB) revision [5].

The revision rate in England is unknown. However, it is likely that there are significant numbers of cases for the following reasons. Firstly, it is recognised that 40-50% of gastric bands will have complications, or will achieve inadequate weight loss. Secondly, in one NHS England area (population approximately 6.4 million) there were 192 individual funding requests for revisional surgery in 2013. Thirdly, a United States study suggests that 5.3% of all obesity operations are for revisional surgery [6]. Revision surgery is more complex and technically more challenging than the primary obesity surgery and is associated with higher levels of both peri-operative risk and complication rates to the patient [7]. This will require high volume specialist units with greater subspecialty surgical skills and appropriate facilities to optimise results.

3.1 Indications for re-operative and revision surgery

Re-operations are likely for either one or a combination of the following factors.

1: complications relating to their primary procedure;
2: post-surgical failure to lose weight or significant weight regain following initial success;
3: failure to improve or re-emergence of a co-morbidity;
4: a combination of these factors.
5: rarely reversal is required for excessive weight loss, malnutrition, or intractable diarrhoea etc.

The evidence appears to suggest that a second obesity operation confers a greater risk of adverse outcomes such as peri-operative complications, conversion from a laparoscopic to an open procedure, longer lengths of hospital stay, higher intensive care unit utilisation and increased re-admissions than a primary obesity operation. Reasons for the higher morbidity appear to be technical and operative complexity, more technically complex procedures, decreased quality of tissues, presence of adhesions etc. Major complications include a reported higher frequency of leaks, surgical-site infections, intra-abdominal abscesses etc. As the complexity of the revision procedure and number of prior surgeries increases, so does the peri-operative morbidity. Previous fundoplication operations represent the highest risk group. It follows that, for patient safety reasons, revision surgery should be performed in a high volume, tertiary referral obesity centre (Tier 4 bariatric medical

4 Kellogg TA. Revisional bariatric surgery. Surg Clin N Am 2011;91;1353-71.
5 O'Brien PE et al. Long-term outcomes after bariatric surgery: fifteen-year follow-up of adjustable gastric banding and a systematic review of the bariatric surgical literature. Ann Surg 2013;257:87-94.
6 Shimizu H et al. Revisional bariatric surgery for unsuccessful weight loss and complications. Obes Surg 2013;23:1766
7 Hallowell PT et al. Should bariatric revisional surgery be avoided secondary to increased morbidity and mortality? Am J Surg 2009;197:391-6.

and surgical service) with advanced investigative, endoscopic and surgical skills and obesity medical and revision surgery subspecialty expertise.

3.2 Evidence base

Efficacy: Case series of revision surgery demonstrate effective weight loss after second surgeries. The weight loss in carefully selected subjects is of the same order as that seen after primary surgery [8] and it has even been proposed that the metabolic benefits are more pronounced than the weight loss irrespective of whether the primary procedure had been a vertical banded gastroplasty (VGB) or roux-en y gastric bypass (RYGB) [9].

Safety: Revision obesity surgery is more complex than primary surgery and is accompanied by a higher complication rate, longer in-hospital and intensive therapy unit stay but carries the same low mortality risk as primary surgery [10].

Impact on quality of life: There is good evidence for improved quality of life after bariatric surgery. This includes increased employment, reduction in sick leave and reduction in requirement for social security support [11 12].

Cost effectiveness studies: The evidence base for performing obesity surgery by National Institute for Health and Care Excellence (NICE) (2006) was based on first time procedures and short/medium term follow-up. The cost benefit analysis may be different for revision surgery. To date, there have been no cost effectiveness studies for revision surgery. It is recognised that the operative costs are higher due to the higher complication rate [13] but since resolution of co-morbidities occurs, the effectiveness might be expected to be similar to that for primary surgery. However this assumption may be dependent, as in primary bariatric surgery on careful patient preparation, selection and follow up.

It is expected that there will be a limited number of experienced centres performing revision surgery which will ensure that the complication rate is minimised.

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[8] Jennings NA et al. Revisional laparoscopic Roux-en-Y gastric bypass following failed laparoscopic adjustable gastric banding. Obes Surg 2013;23:947-52.

[9] McKenna D et al. Revisional bariatric surgery is more effective for improving obesity-related co-morbidities than it is for reinducing major weight loss. Surg Obes Relat Dis 2013 EPub Dec 18

[10] Hallowell PT et al. Should bariatric revisional surgery be avoided secondary to increased morbidity and mortality? Am J Surg 2009;197:391-6.

[11] Narbro K et al. Sick leave and disability pension before and after treatment for obesity: a report from the Swedish Obese Subjects (SOS) study. Int J Obes Relat Metab Disord 1999;23:619–24.

[12] Hawkins SC et al. Paid work increases and state benefit claims decrease after bariatric surgery. Obes Surg 2007;17:434-437.

[13] Sheppard CE et al. The economic impact of weight regain. Gastroenterol Res Pract 2013, Article ID 379564, http://dx.doi.org/10.1155/2013/379564

4 Rationale

Revision surgery is clinically indicated to treat complications arising > 90 days after the index obesity procedure.
A revision procedure is considered clinically necessary when there is documentation of a secondary surgical complication related to the original obesity operation or there is evidence of metabolic complications of obesity surgery (see below).

4.1 Gastric bypass complications after 90 days for complications of the primary obesity procedure

Marginal ulceration (dyspepsia, bleeding, perforation)
Anastomotic stenoses
Gastro-gastric fistula formation
Enteric fistula formation (rare)
Obstruction (adhesions or internal hernias)
Small bowel intussusception
Chronic abdominal pain (often merits diagnostic laparoscopy)
Staple or suture line leak can occur after 90 days and is likely to result in intra-abdominal Abscess formation requiring drainage

4.2 Band malfunction requiring further operation after 90 days

Band slippage
Gastric pouch enlargement
Band erosion
Band or port site infection
Tube disconnection
Band unbuckling
Band intolerance
Severe reflux oesophagitis

4.3 Sleeve gastrectomy complications requiring further operation after 90 days

Severe gastro-oesophageal reflux
Staple line leak can occur after 90 days and is likely to result in intra-abdominal abscess formation requiring drainage or fistula formation
Late stricture formation

4.4 Duodenal switch (with sleeve gastrectomy)

Rarely performed in UK but late complications include
Anastomotic leaks
Strictures
Obstruction
Protein-calorie malnutrition
Sleeve gastrectomy complications

4.5 Revision for medical complications of primary obesity procedures

Severe adverse and intractable symptoms e.g. dysphagia
functional disorders e.g. dumping syndrome
Persistent vomiting
Disabling post prandial hypoglycaemia
Protein and fat malnutrition
Diarrhoea
Intestinal failure
Severe anaemia
Bacterial overgrowth
Recalcitrant hypocalcaemia (with associated hyperparathyroidism)
Other micronutrient/nutritional deficiencies
Severe weight loss (undesirably low BMI)
Recurrent nephrolithiasis
Note: in elderly patients BMI may poorly reflect lean body mass and mask sarcopaenia (so-called sarcopaenic obesity

4.6 Failure of weight reduction and/or resolution of severe co-morbidities

Repeat surgery for failure of a primary obesity procedure may be due to failure to achieve sufficient or expected weight loss; the latter may be accompanied by failure of co-morbidities to resolve e.g. diabetes, obstructive sleep apnoea. This is a contentious topic as there is no definition (or even debate) of what constitutes weight loss failure. Should failure be defined in terms of weight loss ± resolution of co-morbidities? Many publications reporting on revision surgery do not even describe the patient cohort further other than to say they had inadequate weight loss. In addition to weight loss and co-morbidities, a further classification of failure might be patient symptoms e.g. intractable reflux symptoms, breathlessness, musculoskeletal pain and poor quality of life etc. Revision surgery may be performed, to achieve weight loss that was not realised by the initial (index) procedure. Long-term studies of obesity surgery show a gradual tendency, sometimes even as early (within/soon after) 1–2 years to regain weight that was lost in the first few months after the operation or a failure to attain the expected average percentage of excess weight loss[14]. There may also be a failure of co-morbidities to either resolve fully/partially or there may be a re-emergence with time or weight regain. It should be noted that co-morbidity resolution does not always occur, especially for blood pressure, but also for obstructive sleep apnoea [15] and type 2 diabetes where there has been a long pre-operative duration (> 5 years) or severity (requirement for insulin; poor glycaemic control) [16].

Following surgery, patients will be expected to have engaged and have been compliant with an appropriate follow up programme.

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[14] Sjöström L et al. Bariatric surgery and long-term cardiovascular events. JAMA 2012;307:56-65.

15 Dixon JB et al. Surgical vs Conventional Therapy for Weight Loss Treatment of Obstructive Sleep Apnea: A Randomized Controlled Trial. JAMA 2012;308-:1142-1149.

16 Arterburn DE et al A Multisite Study of Long-term Remission and Relapse of Type 2 Diabetes Mellitus Following Gastric Bypass. Obesity Surgery 2013 epub

This post-operative period should have included a prescribed behavioural, nutritional and exercise programme which will have been administered, assessed and supervised by a physician. There will have been regular monitoring and recording of the clinical progress, weight, nutritional status, co-morbidities, surgical complications as well as engagement with the programme.
The typical patient gradually gains weight after surgery – there is a need to distinguish what can be expected from the natural history and what is due to non-engagement with a healthy life-style and prescribed follow-up plan.

Weight loss failure – patient factors
Some patients manifestly fail to maintain weight loss due to non-engagement with a comprehensive and high quality post-operative programme. Some consider that stretching of a stomach pouch formed by a previous gastric band/bypass/sleeve gastrectomy due to the patient's persistent poor dietary behaviour, should not constitute a surgical complication and the appropriate modality of treatment for these patients is not surgical. However if the procedure has failed to address the patients desire to eat, inability to control portion or meal size, consideration can be given to revision surgery if it is thought that such revisional surgery would address these needs. There may be grounds to consider surgery on the basis of exceptionality through the IFR process.

Weight loss failure – operation factors
Where there has been poor patient preparation and selection for primary obesity surgery in accordance with the NHS recommended pre surgical pathway or lack of adequate follow-up, it could be regarded that failure to lose weight does not merit further surgery. It is recommended that these individuals should be considered for re-engagement with a specialist non-surgical service for the appropriate interventions, before being reconsidered for a revision procedure.
It is recognised that there may be biological factors which make some patients more likely to fail to lose weight or to regain weight but there are no current biomarkers that can be used to define this subgroup of patients.

5 Guidance on criteria for commissioning

NHS Funded Patients*

Group 1
Patients presenting with a clinical history, symptoms and/or signs that suggest acute / acute on chronic / worsening medical and/or surgical complications - related to their primary obesity operation:
Patients must be triaged and treated immediately if classified as **"emergency"**
Patients are triaged by an MDT and may be assessed as **'Clinically Urgent'** if they are judged to have a subsequent risk of developing emergency complications if they remain untreated. This category will include patients with adverse anatomical complications of the primary surgery but exclude loss of restriction due to dilatations of the gastric pouch and/ or the gastro-jejunal junction.
This corrective surgery, or in rare cases reversal surgery, would be as per routine and considered as good clinical practice. Trusts (providers) should triage referral letters from GPs, hospital consultants on this basis.

Examples would include:
1: If there is a band complication ie slippage then the band can be repositioned/ replaced. Conversion can be considered if the criteria as stipulated in the recommended guidance on severe and complex morbid obesity are met, the patient is compliant, on regular follow up and MDT review agrees.
2: If there is a band erosion then band removal can be followed up by a bypass after 6 months if the criteria as stipulated in the recommended policy on severe and complex morbid obesity are met, the patient is on regular follow up, compliant and MDT review agrees.
3: If there is severe band intolerance with gastro-oesophageal reflux, esophageal dysmotility, or persistent vomiting then the same as 1, 2 above.

However if recommended criteria are not met and/ or there has been poor response to primary bariatric surgery (insufficient weight loss or weight regain in the absence of surgical complication), then CCGs should will only fund for band removal.
Medical emergencies might include profound macro and micronutrient deficiencies; anaemia; malnutrition and metabolic abnormalities such as disabling intractable hypoglycaemia: and intractable diarrhoea.
If a band is removed for one of the indications above, then the patients may be considered for conversion to another operation following thorough assessment and counselling regarding treatment options by a Tier 4 service. Ideally the patient should be required to attend the Tier 4 specialist weight management service for at least six months prior to revision surgery, during which period compliance, improvement in weight and co-morbidities is demonstrated.

Group 2
The patient has failed to achieve expected average weight loss targets for the primary obesity procedure performed or regained their pre-operative weight. This category will include patients who following a Gastric Bypass develop a dilated gastric pouch or gastro-jejunal anastomotic dilatation. This category will not include patients who have previously had vertical banded gastroplasty. These patients should not be offered further obesity surgery unless they fall within Group 3 below.

Group 3
The patient has multiple, severe and life threatening co-morbidities which have persisted or re-emerged following primary obesity surgery despite strong evidence that the patient has both attended and engaged with the follow up programme and multidisciplinary assessment has determined and agreed:

- The co-morbidities are potentially life threatening or represent a significant risk to health and well-being that is both severe and serious (in the short to medium term)
- The presence of clear grounds of clinical exceptionality

Groups 2 and 3 will not be routinely funded. If the treating clinician feels strongly that there are clinically exceptional reasons that are relevant to a particular case such as technical failure or other special circumstances in patients who have complied with planned follow up, then an application for funding may be appropriate through the Individual Funding Request (IFR) panel.

Group 4 (Private Patients)

- Some patients may have had their primary obesity surgery outside of NHS contracts at independent/private providers (in Europe, or within the United Kingdom) but subsequently present at NHS facilities as clinical emergencies. The NHS has a duty of care for these patients and will fund emergency and clinically urgent treatment on a similar basis as Group 1 patients.

- These patients may not have previously completed the recommended pre-surgical pathway or have met the NHS guidance for their primary obesity surgery and may not have been adequately followed up. These patients should be referred to the Tier 2 and/or 3 weight management services.

Any request for further (up to two years only) band filling and/or routine outpatient follow-up care (not associated with an acute, non-elective episode for these patients) will require the agreement of the appropriate commissioner and will need to demonstrate that the patient has met recommended eligibility criteria for obesity surgery.

The patient's GP and Private Provider will therefore be required to collaborate to provide evidence on:

1. Weight Management Service attendance including Tier 3
2. Recommended criteria and Guidance fulfillment
3. Primary obesity operation
4. Follow-up attendance
5. Response to primary operation defined by progress with reduction of excess weight at 1 and 2 years including impact on co-morbidities

If these factors are not completely fulfilled, patient must go through tier 2 and/or 3 weight management services in order to comply with recommended criteria.
Codes of good practice for Obesity Surgery have been published by BOMMS [17]. These should be adopted by commissioners.

6 Audit Requirements

For revision surgery applications, if the patient meets the above requirements, the provider should be prepared to submit the following information to the relevant Commissioner:

- Referral source and reason for application
- Previous obesity procedure and provider
- Fulfilment of recommended criteria and guidance, pre-op
- Classification of admission (urgent, emergency, planned, elective)
- Current procedure undertaken and indications
- Discharge plan.
- Patient has engaged and complied with post-op follow-up

[17] BOMMS Professional Standards Document and Standards for Clinical Services & Guidance on Commissioning. http://www.bomss.org.uk/ accessed 9 May 2014

*This is on the basis that NHS Contract Providers are accredited and required to accept patients who meet recommended criteria and current specifications.

7 Patient Pathway

7.1 Management of Failure and Patient Pathway

Current commissioning arrangement in England only prescribes a period of 2 years follow up by the Tier 4 service. Although patients who have had primary obesity surgery should be followed up for life within a specialist programme, such programmes may include 'shared care' with appropriately qualified primary care teams within a structured pathway. At present, there is no guidance on the format of such subsequent follow up. However, appropriate professionally-led lifelong follow up will allow early detection of complications and morbidities following weight loss surgery, including weight loss failure. Early detection may enable non-surgical interventions (e.g. intensified dietary advice and physical activity and supervision) to succeed in the first instance.

Initial assessment of failure should ideally be conducted within the local follow up service. If there is no appropriately constituted follow up service available that can meet the needs of these patients, then they should be referred to a specialist Obesity Centre with both medical and surgical bariatric (Tier 4 service) that can provide this service even if it is not at the original surgery centre. It should be mandatory for obesity surgery providers to develop these services to provide the complete patient pathway for continuity of care and long-term follow-up.

Before considering whether a particular individual is a candidate for a revision of the primary obesity operation, it is important to determine whether the operation failed the patient e.g. an anatomic /technical cause for the complication or weight regain or whether patient factors were responsible. The latter would include weight regain caused primarily as a result of patients' eating behaviour in relation to intake, dietary choices, large portion sizes, snacking, binge eating, alcohol consumption and lack of sufficient physical exercise or where there is a combination of reasons including poor follow-up and persistent psychosocial issues causing emotional eating. It is imperative that these issues be recognised, investigated, diagnosed and resolved before considering revision surgery or there will be repeated operative failure to provide weight loss or to control weight regain.

Failure must therefore be managed according to the cause(s) and revision patients triaged through an appropriately constituted specialist MDT. The need for revision should be based on the suspected cause underlying the patients' problems and requires careful preoperative work up. Clinical evaluation should include a detailed, surgical, medical, dietetic and psychological assessment with appropriate radiological and endoscopic investigations and imaging. There should also be a review of the previous clinical and operative reports, in addition to other documentation from members of the specialist weight management team, (psychologists, physicians or psychiatrists and dieticians).

Full Specialist MDT re-assessment
Patient re-assessment should be conducted by an MDT with a full range of expertise. The composition of the team should include:

- Medical and surgical assessment by specialist obesity physician and surgeon with appropriate knowledge, training and experience, based on large caseload of both primary and revision procedures.
- Dietetic assessment from an experienced obesity dietician, usually at senior grade
- Formal psychological assessment or case review by a psychologist experienced in obesity and obesity surgery.
- Analysis and documentation of reason(s) for failure, which may include the following

Procedure Failure: There is documented evidence of procedure failure such as technical band complications, or persistent marginal ulcer. There is documented evidence of severe and disabling metabolic complications resulting from the original procedure such as malnutrition or intractable hypoglycaemia, or micronutrient deficiencies.

Patient Factors: Patient has failed to adhere to post – operative advice given by the Tier 4 obesity team based on dietary, nutritional or physical activity guidance or complied with regular attendance for follow up.

Service failure: The patient may have been failed by lack of service arrangements i.e. inadequate/absent specialist weight management programmes (Tier 3 and/or Tier 4) and/or follow up arrangements that have either not been prescribed or commissioned. The latter often happens in the private sector, where the focus is on the obesity operation and short-term follow up.
One or more of the above factors may co-exist in the same patient

There should be a physical and not virtual MDT meeting. At these meetings, the presence of the specialist team members as outlined above is mandatory, their attendance, discussion and decision should be recorded. Where possible there should be an agreement between the patient and MDT of the reason(s) for failure.

A comprehensive management plan should be drawn up for each patient which may involve some or all of the following components; further dietetic/psychological support, further clinical investigation /imaging, input from specialist teams such as gastroenterologists (e.g. for parenteral feeding), revision of the primary obesity procedure. Some patients will be deemed unsuitable for re-operation and may require further multidisciplinary specialist weight management by either tier 3 or non-surgical tier 4.

Data should be collected on a database which will allow audit and benchmarking against other such services.

Specialist Surgical Centre role
Patients should only undergo revision or re-operative surgery in appropriately experienced and centres, which may or may not be the original surgical centre. Credentialed centres will provide the following:

- Surgical Providers for Revision Surgery should meet the service specification for primary obesity surgery. In addition they should include Tier 4 bariatric medical and specialist weight management services.
- Facilities as for obesity surgery specification
- A greater breadth of tertiary specialist professional expertise will be required for example cardiology, respiratory physicians, neurology, ophthalmology, with an active interest in weight related disease management.
- Radiology specialists with an active interest in altered anatomy following obesity surgery.
- Nutritional teams with experience of managing severely malnourished patients as this may occur after complicated obesity surgery.
- Specialist psychological assessment provided by psychologists who have experience of working with post-bariatric surgery complications
- 24/7 emergency access to A&E, critical care, OT, imaging ,endoscopy, diagnostic assessment including investigations, bariatric/upper GI surgical rota.

- **National Bariatric Surgery Registry Compliance:**

Data submission to NBSR by surgical centres performing revision surgery is mandatory

8 Governance arrangements

Specialist Surgical Centre role

Basic revisional surgery: removal of repositioning of a gastric band may be performed by any surgeon and unit that fulfils the criteria for obesity surgery that is, annual case load of 100 per unit and 50 per individual surgeon.

Complex revisional surgery: Surgical providers should demonstrate a cumulative activity for obesity surgery at a rate of 100 cases per year for 5 years and each surgeon should have personal lifetime experience of 500 cases within the NHS or which have been documented on the NBSR.

Non-surgical and intensive management

Non-surgical specialist therapy at Tier 4 level will be required for a heterogeneous group of patients who are unwilling or unfit to be considered for obesity surgery.

Non-surgical therapies at Tier 4 level (even if provided within secondary care) will involve physician input and one-to-one dietetic input, with additional one-to-one psychological input and specialist exercise/physiotherapy input as required. Obesity physicians should be able to take the lead role in collating and coordinating care of

multiple pathologies that may exist, changing medication to optimise weight reduction (e.g. low and very low energy diets, pharmacotherapy, reviewing and where possible withdrawing drugs associated with weight gain), optimising diabetes and cardiovascular risk/disease management (appropriate hypoglycaemic treatment including use of weight-neutral or weight-losing drugs such as GLP-1 agonists, DPP4 and SGLT2 inhibitors) and optimising therapy of co-morbidities (e.g. ensuring optimal treatment for joint problems, cancer, benign intracranial hypertension, sleep disordered breathing or heart failure) especially where such co-morbidities are limiting physical activity.

The patterns of care for the heterogeneous group of patients receiving non-surgical care for severe & complex obesity will depend on the cause of the obesity and on the pattern of co-morbidities and will need to be personalised. For some patients eg those with genetic disorders or hypothalamic problems it will be appropriate for life-long care to be provided. Other patients may have severe obesity-related Type 2 diabetes or such severe obesity or psychotic illness with severe obesity that a limited period with the Tier 4 non-surgical service will be required to assess and optimise the issues which might then be followed by referral back to primary care/Tier 3 although a second surgical referral could be contemplated at a later date. Some patients may require a single advisory consultation.

Follow up

All patients who undergo revision obesity surgery should be followed up for life; although it is recommended that CCGs only commission follow-up for 2 years. The surgical revision centre will demonstrate follow up with a minimum 75% compliance at 2 years.

9 Mechanism for funding

Revision surgery undertaken by specialist centres should be considered for funding by CCGs. This includes the longer term follow up when this occurs within the specialist service.

10 Key Service Outcomes

Commissioning data and minimum datasets

Outcome measures for revision surgery:

- Primary obesity surgery: operation type and location, duration / time interval since primary obesity operation, clinical presentation and reason requiring consideration of revision re- intervention, pre and post-surgery: BMI, % EWL, actual weight loss, co-morbidities, psychological morbidity, Tier 3 attendance.

- Current MDT decision (further surgery or referral to specialist weight management programme), type of revision procedure proposed and data on:

post-operative BMI, % Excess Weight Loss, actual weight loss, co- morbidities at 6 months, 1 year, 2 years.

- Patterns (reasons, type) of primary obesity surgical failure (overall and by procedure) for individual specialist obesity centres (NHS and private organisations) should be monitored locally and at a national level.

- The rate of obesity surgery revisions should be less than 25% for LAGB, 10% for sleeve gastrectomy and 5% for RYGB.

11 Documents which have informed this guidance

National Institute for Health and Clinical Excellence: Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. CG189, 2015.
Available from: http://guidance.nice.org.uk/CG189