

Additional Consent Form

This additional consent form is intended to ensure that you fully understand the risks and long term implications of weight loss surgery. Please do not sign this form until you are happy that everything has been clearly explained and your questions have been answered.

Bariatric Surgery is different to many other types of operation in that it is surgery that you don't have to have that carries risks of complications or death. The risks are small, but as it is surgery that you choose to have, it is very important be absolutely clear about the benefits that the surgery will give you and weigh them up with the risks that you would be willing to take. Your individual risk and benefit profile will be discussed with you by the weight management team.

Benefits:

The benefits of weight loss surgery can be divided into three main areas:

1. How much weight will I lose?

The amount and speed of weight lost depends on many factors including the type of operation, your motivation, post-operative eating and exercise behaviours and your weight prior to surgery. On average patients lose 50-70% of their excess weight after surgery.

It is important to be realistic and to be aware that most people are still overweight after surgery (although weigh much less than before). The actual weight loss achieved however is not as important as the beneficial effects on your health and quality of life.

2. What will be the effects on my overall health and longevity?

One of the main reasons to have surgery is for you to be healthier and live longer.

It is well known that weight loss surgery can have huge benefits on a number of different conditions including type 2 diabetes, hypertension, lipid abnormalities, obstructive sleep apnoea, acid reflux and fertility. The risk of developing some cancers related to obesity is also reduced. Patients with a BMI over 40 have a reduced life expectancy and this will be improved with weight loss.

3. How will surgery improve my Quality of Life?

In general, patients' quality of life is improved after surgery. Weight loss has beneficial effects on functional status and mobility and many people find this surgery transformative. How much this improves depends on the individual, how active they are before surgery and how motivated they are to change.

What will surgery not improve?

- Many of our patients have had mental health and emotional issues in the past. It is known that weight loss surgery doesn't always help with this and can sometimes increase stress. Depression, anxiety and eating disorders can be made worse, not better after surgery. Addictive habits, including over-reliance on emotional eating, can be transferred from food to other substances such as alcohol or drugs (illegal or prescription medication).
- Significant weight loss may result in loose skin. This can lead to distress and dissatisfaction with body image post-operatively. Surgical correction is possible but is unlikely to be funded on the NHS.
- Long term chronic pain issues (e.g. fibromyalgia) will not be resolved with surgery and can be made worse. Sometimes patients need to increase their pain medications postoperatively.

What can I do to reduce the risks of surgery?

- Follow the liver shrinking diet. Technically bariatric surgery can be very challenging. The lighter you are, the easier the operation for your surgeon. This has the benefit of making it more likely to be successful, as well as lowering the risks.
- Be as active as possible. Physical activity is good before surgery and being fitter means that the chances of a complication are lower. You are also more likely to be active after surgery and therefore lose more weight.

- Have your other health problems optimised before surgery. Many of our patients are on medications for chronic conditions. Having a medicines check and making sure high blood pressure, asthma, sleep apnoea and diabetes are optimised by your GP will help in the recovery period.
- Stop smoking. Surgical risks are significantly higher in smokers. It is a requirement that you stop smoking before the operation.
- Smokers are more likely to develop post-operative chest problems, thrombosis and ulcers.

Patients who don't fall into these categories in general have an overall 5% (1 in 20) chance of complications within the first 30 days after surgery and a 1:500-1:1000 chance of death (which is similar to surgery for gallstones).

The operation:

- Bariatric surgery is performed using the laparoscopic (keyhole) method. More recently robotic techniques (advanced laparoscopy) are being introduced.
- Surgery involves five small incisions each approximately 2cm long being made across the upper abdomen. With any laparoscopic surgery it is important to be aware that occasionally it is not possible to safely complete the operation using the keyhole technique and a larger open incision will need to be made.
- Surgery takes between 30-90 minutes and most people are able to be discharged home the following day.

Risks:

The risks of Bariatric Surgery are generally low although there are some groups of patients who have higher risks of complications or death. These include:

- Age over 60 yrs
- Patients whose BMI is over 60
- Patients with other health problems (e.g. respiratory or cardiac issues, patients on anticoagulants or who have had previous blood clots or thrombosis).
- Patients who have had previous surgery in the upper abdomen – especially bariatric surgery.
- Patients with poor mobility are more likely to suffer with complications and lose less weight overall.
- All operations are started via the laparoscopic (keyhole technique) however there is a risk of conversion to a larger open incision should there be technical difficulties encountered. Occasionally patients with internal bleeding or difficult and unusual anatomy may need an open operation.
- All abdominal surgery has an inherent risk of damage to nearby abdominal structures during the operation (risk: 1 in 1000). This can happen either at the start of the surgery on insertion of the ports, or during dissection, and is higher if you have had previous surgery. Nearby structures that can be inadvertently injured include the Spleen, Liver, Small and Large Bowel, Pancreas, Stomach and Oesophagus. Blood vessels may also be injured. This is a rare occurrence and will be dealt with at the time of operation if noticed. Occasionally the initial injury can present later in the recovery period (about 1 in 3 of these injuries) in which case further surgery may be necessary.
- Occasionally patients will need to return to theatre for further surgery should there be a post-operative complication. This may be to investigate or treat an anastomotic leak, bleed or obstruction. This is usually completed with laparoscopy but could require an open incision.
- Laparoscopic wounds generally heal very well with only minimal scarring. Occasionally patients may have a wound infection, bruising or bleeding. This usually requires no treatment but may need a course of antibiotics.
- A port site hernia can occur where a section of fat or bowel can bulge underneath the scar (risk: 1 in 100). This may require further surgery to repair and bowel resection may be necessary if the bowel is strangulated.

- Heart problems such as arrhythmia or heart attack can happen after any operation and bariatric surgery is no different.
- Respiratory (breathing) issues can occur after bariatric surgery. Causes for this can include pain, chest infection or thrombosis and may need investigation with chest Xray or CT scan. These issues are more frequent in smokers.
- Thrombosis in the legs (DVT) is a recognised complication after bariatric surgery. The clot can dislodge and get stuck in the lung (Pulmonary Embolus). This is a serious and life threatening complication and is more common in obese patients. The risk is reduced by using compression (TED) stockings, calf compressors during the operation and blood thinning injections of Low Molecular Weight Heparin (Clexane or Fragmin). This risk doesn't stop when you leave hospital so you will need to keep the stockings on and self-administer LMWH injections at home for 14 days post operatively. We also need you to be mobile and active soon after surgery.

Longer term risks of all operations:

- Inadequate weight loss or weight regain if you don't eat and exercise properly.
- Nutritional, vitamin and mineral deficiencies if you don't take regular supplements and have regular monitoring blood tests.
- Gallstone formation. Weight loss is associated with the development of gallstones. Occasionally patients present with upper abdominal pain, jaundice or pancreatitis after surgery. This could be due to gallstones and is investigated with ultrasound or MRI scanning. Should symptoms be significant, then gallbladder removal surgery (cholecystectomy) is often recommended.
- All of the operations have a small re-operation rate in the long term as detailed below.

Post-operative symptoms:

- Gastrointestinal symptoms such as diarrhoea and constipation are frequently encountered. This usually settles within a few weeks but can persist.

Ongoing troublesome symptoms can be investigated with colonoscopy and biopsies, bile acid malabsorption or breath tests to look for rarer causes.

- Long term pain can be an issue for patients. It is common for chronic pain issues present before surgery not to be improved and occasionally made worse.
- All cases of acute pain are taken seriously and investigated – no matter how long after surgery. Investigations for this may include Endoscopy, Ultrasound, CT or MRI scans, Barium Swallow Xray or reoperation via laparoscopy.
- Dumping symptoms are related to hypoglycaemia and are commonly seen after gastric bypass surgery. This can cause light headedness and fainting symptoms. Your dietician will be able to assist with nutritional strategies to help with this.

Gastric Band Risks:

Gastric banding involves the placement of a soft silicone band around the top of the stomach which is connected to a port that is placed underneath the abdominal skin. This is adjustable and slows down the passage of food into the stomach. Specific risks of gastric banding include:

- Overall complication rate 1%, Death rate 1:2000.
- Injury to the stomach, liver, spleen or oesophagus during placement.
- Band slippage: the stomach can slip up through the band and cause pain or obstruction. Very rarely the blood supply to the stomach can be obstructed and cause stomach necrosis. This is a serious and life-threatening complication.
- Band erosion: the band can wear away at the stomach and erode inside. This can cause pain, gastric bleeding or infection of the port.
- Fibrous capsule formation: the band causes irritation of the wall of the stomach, scarring and overtightness even if the band is deflated.
- Over-restriction (overly tight band): can damage the oesophagus and cause it to be dilated and poorly functioning. This can lead to permanent oesophageal damage and difficulties swallowing.

- Intolerance: some patients do not tolerate the band and have significant symptoms of pain or swallowing issues even if the band is well placed and adjusted.
- Port issues: the access port can move or flip over making adjustments difficult to perform, the tube can break or leak.
- Band Removal: These complications may require the band to be removed and sometimes this needs to be done as an emergency. It is estimated that 30% of patients with gastric bands placed will need them to be taken out. This is a further laparoscopic operation usually performed as a day case. The stomach anatomy is restored to as close to normal as possible.
- It is important to be aware that the scarring may mean that a further revisional operation such as a gastric bypass may not be possible.
- Weight is generally regained after band removal.

Gastric Bypass Risks:

In gastric bypass surgery, a small pouch is created at the top of the stomach and a limb of small intestine joined (anastomosed) to it. There is a further join lower down the bowel to allow mixing of bile and digestive juices. Specific risks of gastric bypass include:

- Overall complication rate 5% (1 in 20), Death rate 1:500-1:1000.
- Injury to the stomach, liver, spleen or oesophagus during dissection.
- Staple line leak or bleed (risk: 1 in 50). A stapling device is used to seal and cut the stomach and small intestine. The two internal joins are checked for bleeding and leaks during the operation and problems dealt with at the time. Occasionally leaks and bleeds can happen later in the recovery period. This will be identified when you are in hospital but should you be unwell at home you would need to attend hospital urgently. Treatment may require further surgery and blood transfusion.
- Bleeding from within the bowel. Minor bleeding with vomiting after surgery is common and does not need treatment. Rarely more significant bleeding can give

black tarry stools and a drop in blood count. This could require CT scanning or endoscopy to resolve.

- Obstruction (blockage) of the bowel can occur after gastric bypass. This can be due to an overtight join (anastomosis) in either the upper or lower joins (risk: 1 in 50), or a twist around scar tissue. This presents with bloating, nausea and pain and is diagnosed with a CT scan. Treatment usually requires further surgery and may need drainage or feeding tubes.
- Anastomotic tightness or stricture of the upper join can usually be treated with endoscopy and stretching with a balloon device.
- Internal Herniation is a recognised complication of gastric bypass (risk: 1 in 100). Here the bowel twists through gaps in the fat. These gaps are closed during the operation but can reopen with weight loss. This presents with abdominal pain and needs a further laparoscopy to repair. Very rarely the internal hernia can strangulate. This is a serious and life-threatening complication.
- Ulceration: The upper join from the stomach pouch to the intestine can ulcerate and cause pain or bleeding. This typically is sore after eating and is more common in smokers. It is investigated with endoscopy and managed with antacids. Very rarely the anastomosis needs to be re-operated.
- Revisional operations (when patients have had previous bariatric procedures) are higher risk especially of staple line leak or bleeding due to the dense scar tissue.
- Occasionally a gastric bypass is not technically possible. This may be due to lack of space inside, a large liver or that the small intestine does not stretch up to the stomach pouch. In these cases a sleeve gastrectomy could be considered.
- Rarely no surgery can be performed. Whether or not you may be suitable for a further attempt at surgery depends on the reasons for abandoning.

Sleeve Gastrectomy Risks:

With sleeve gastrectomy surgery, approximately 80% of the stomach is removed using a stapling device leaving a thin tube (sleeve). Specific risks of sleeve gastrectomy include:

- Overall complication rate 5% (1 in 20), Death rate 1:500-1:1000.
- Injury to the stomach, liver, spleen or oesophagus during dissection.
- Staple line leak or bleed (risk: 1 in 100). A stapling device is used to seal and cut the stomach. The sleeve is checked for leakage at the time of the operation. Occasionally leaks and bleeds can happen later in the recovery period. This will be identified when you are in hospital but should you be unwell at home you would need to attend hospital urgently. Treatment may require further surgery and blood transfusion.
- Post sleeve gastrectomy leakage is a serious and life threatening complication and may take a long time to heal. This may require endoscopic or laparoscopic procedures with drains and feeding tubes with a prolonged hospital stay.
- Bleeding from within the bowel. Minor bleeding with vomiting after surgery is common and does not need treatment. Rarely more significant bleeding can give black tarry stools and a drop in blood count. This could require CT scanning or endoscopy to resolve.
- Difficulty swallowing can be encountered due to narrowing or twisting of the sleeve (risk: 1 in 100). This may require endoscopy or further surgery.
- Acid reflux is a common complication after surgery (risk: 5 in 100). This is especially seen in patients with pre-existing reflux or hiatus hernias and sleeve gastrectomy is generally not recommended in these patients. If the reflux is debilitating then conversion to a gastric bypass may be necessary.
- Long term acid reflux damage to the lower oesophagus can lead to cell changes (Barrett's Oesophagus) and very rarely predispose to oesophageal cancer.
- Current recommendations are for follow up endoscopies every three years after surgery to check for reflux.
- Revisional operations (when patients have had previous bariatric procedures) are higher risk especially of staple line leak or bleeding due to the dense scar tissue.
- Occasionally a sleeve gastrectomy is not technically possible. This may be due to lack of space inside, large liver or dilated blood vessels causing a high risk of bleeding.
- Occasionally surgery will need to be abandoned. Whether or not you may be suitable for a further attempt at surgery depends on the reasons for abandoning.

Post-operative considerations:

Generally patients recover very well and quickly after surgery.

- Post-operative pain is common and is due to pain from the incisions and abdominal surgery as well as from the gas inflation (CO₂) of the abdomen that can give bloating and shoulder discomfort. The body will absorb this gas over 24 hours or so. Mostly patients require only simple painkillers such as paracetamol and codeine as well as small doses of morphine.
- Nausea is also common after surgery and is treated with antisickness medication. This usually settles quickly. Occasionally patients vomit and it is not unusual to see streaks of blood within the vomit. This is nothing to worry about in small volumes and is due to the stapling of the stomach.
- Oral fluids can be introduced straight away after surgery as tolerated. We encourage early mobilisation and for you to be as active as you can be. Most patients are discharged after one night in hospital although some patients need to stay longer depending on their recovery.
- Post-op medications to take home will be provided and include painkillers (paracetamol and codeine), blood thinning injections and antacids.
- You will be given dietary instructions by the team to follow at home.

Should there be a problem:

You need to be aware of the following symptoms as they may show that you have a serious complication:

- Pain that is worsening or severe
- High temperature or fever
- Dizziness, feeling faint or shortness of breath
- Vomiting and unable to keep fluids down

It is very important to inform the team if there are any issues with your recovery. During normal working hours please contact the team for advice. Out of hours or if you are significantly unwell please attend the Emergency Department at Southmead Hospital.

Data collection:

Bariatric surgeons and multidisciplinary teams are mandated to enter some information about your surgery and hospital care into the National Bariatric Surgery Registry which is stored in an encrypted form on UK data servers. The Registry needs to collect a few personal details about you - your NHS number, name, date of birth and postcode to help healthcare professionals link surgical information to other national health databases. This allows healthcare professionals to measure and evaluate long-term surgical outcomes.

Your information will be stored in a secure environment and will only be available to appropriate staff. The Registry conforms to the strict confidentiality rules defined by the Data Protection Act 1998, the NHS Act 2006, the Health and Social Care Act 2008 and the General Data Protection Regulation Act 2018. Your personal details will not be shared with anyone outside the NHS. Data may be shared for research, but only after the data have been made anonymous (people cannot be identified).

We need your permission to hold information (e.g. NHS number) that can identify you. Please tick the appropriate boxes below to show whether or not you consent to the collection of your personal information, and sign this form.

I confirm that I understood the above statement. I have had the chance to ask questions and received satisfactory answers.

I consent to my specialist providing information to the National Bariatric Surgery Registry that can identify me for the purposes of monitoring and improving patient care. I understand I can withdraw my consent at any time without giving any reasons.

I do not consent to my specialist providing information to the National Bariatric Surgery Registry that identifies me in person.

Signature

Date

I AM HAPPY THAT I UNDERSTAND ALL OF THE ABOVE POINTS. I HAVE NO UNANSWERED QUESTIONS OR CONCERNS AND WISH TO PROCEED WITH SURGERY. I AM FREE TO CHANGE MY MIND AT ANY TIME, EVEN AFTER SIGNING THIS FORM AND WILL LET MY SURGEON KNOW IF I NO LONGER WISH TO GO AHEAD.

Signature

Print name

Date:

Healthcare Professional:

Print name:

Date: