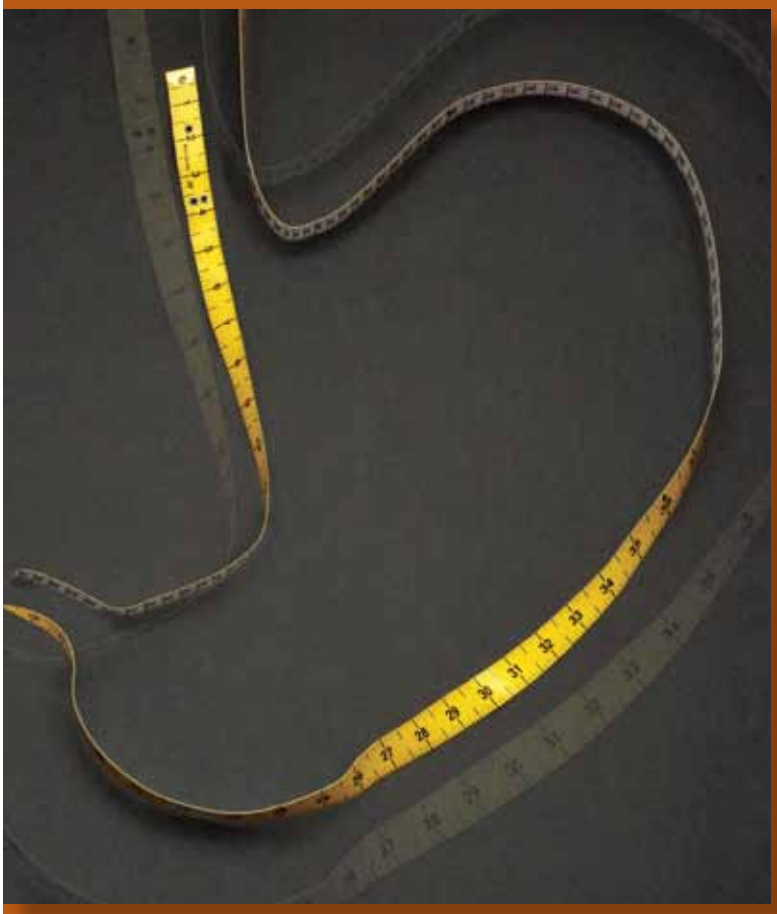
Too Lean a Service?

A review of the care of patients who underwent bariatric surgery



NCEPOD

Too Lean a Service?

A review of the care of patients who underwent bariatric surgery

A report by the National Confidential Enquiry into Patient Outcome and Death (2012)

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Foreword

The abiding message of this report is that those responsible for commissioning and delivering health care are struggling to resolve issues inherent in a surgical solution to a complex metabolic, social and behavioural problem. It is well-established that bariatric surgery works. Indeed it is hardly counter-intuitive that a mechanical interference with the ability of the gut to absorb food is likely to have a useful place in the armamentarium for managing obesity. However the mechanisms by which surgical procedures lead to weight loss involve more complex changes in the controls of metabolism and satiety. It is not surprising that surgical solutions have become more widely available both in the NHS and in the private sector as the severity of the problems have become clearer.

During the last 20 years obesity has reached epidemic proportions in the UK and we are now told that excessive adiposity is associated with most of the ills that flesh is heir to. These are not confined to the cardiovascular diseases about which the physicians of the 1960s counselled their over-weight patients: now they add cancer, stroke and dementia to a list that includes diseases of the heart, liver, and kidneys. Even eyesight is vulnerable through Type 2 diabetes. Today they also tell us that many of these prognoses are improved where the obesity is reduced. So far, so good for those who can offer a simple and effective solution that may not depend upon changes in behaviour that history suggests will be uncongenial to the patients.

The problem is that surgery can only ever be part of the solution. Surgery is not a panacea, nor will it be the treatment of choice for every case. However, this point is likely to be less apparent to the isolated peripatetic surgeon than a properly constituted multi-disciplinary team which cares for patients over a long period of time. We have seldom published a study that more graphically called to mind the old saw, that to a man with a hammer most things look like a nail.

For me the first lesson from this study is that it reinforces one of the findings of *'A Mixed Bag'* - our 2009 study on parenteral nutrition, namely that the value of dietitians and nutritionists is not sufficiently recognised by the modern health service. It is extraordinary that both the private sector and the NHS should offer a surgical solution to people suffering from an extreme disorder of diet without involving the dietitian. If changes in eating behaviour are to be sustained, the advice of the dietician will be invaluable. If surgery is to be sufficiently radical to resolve problems of extreme obesity in isolation, the dangers of malnutrition cannot be avoided with confidence.

Similar issues arise from the failure to involve psychologists and psychiatrists. Extreme obesity may be associated with psychological problems. A doctor who is seeking to treat the problems of their patient needs to understand them at an individual level. Treatment of one presenting symptom is neither safe nor reliable unless it is undertaken in the context of a confident assessment of the whole problem faced by the patient.

Lastly in this group of messages are those involved in marketing. It is disgraceful that doctors should allow their services to be marketed in the fashion described in Chapter 8, where complex surgery is presented in optimistic "quick-fix" terms rather than presenting balanced information about the risks and disadvantages inherent in the procedure. These are problems we have previously highlighted in our study of cosmetic surgery, *'On the face of it'*, and they are no more acceptable with this equally vulnerable group of morbidly obese patients.

Moving to the substance of the surgery, I looked forward to this study because in my work as a malpractice lawyer

FOREWORD

I have seen too many cases of doctors being caught out by the significant surgical challenges posed by patients with obesity. I have seen cases of patients with an unsuspected bowel injury being discharged by a doctor who failed to recognise adverse signs that were muffled by the insulation of a massive abdominal apron. These cases often present with complex co-morbidities that many young surgeons are too inexperienced to handle on their own. My firm has handled cases in which surgical treatment of obesity, whilst an apparently appropriate response to the burden of adipose tissue, was followed by extreme malnutrition. And there is some support for that view in our Advisors' findings. Despite what we read about the dangers of health care few studies, of an unselected patient cohort, reveal a 10% incidence of complications and adverse incidents of elective surgery. These are very difficult patients and it is all too easy for those of us outside the medical profession to fail to understand the extent of the problems they pose to their health care providers.

Doctors used to advise their patients that excessive weight was a sort of nuisance, a burden on other parts of the body, but it is now well recognised that obesity presents difficulties in managing most aspects of health care. To take one illustration, it has been appreciated for many years that very overweight women could have problems in pregnancy and giving birth. Today there is a specific Royal College and CMACE Guideline[1] for the management of what is seen as one of the most common risk factors in obstetric practice. This has led to dedicated high risk clinics to assess these patients and in most hospitals specialist equipment and instruments such as wider beds, hoists and long epidural needles are routinely available on the labour ward.

Most hospitals now have to be able to cater for people who are barely able to walk onto the premises by reason of their weight. This involves specially reinforced operating tables and trolleys, as well as large capacity MRI machines. This challenge of increasing obesity to the NHS is second only to the advancing age of the patients, and the surgical teams who are now an important part of the response should command our gratitude and admiration.

However that response does need to be improved. The core problems are generic to the rest of the NHS and familiar to readers of our reports. A lack of thoughtful pre-operative assessment. A failure to do the simple things methodically and well, such as careful post operative follow-up. If ever there was an extreme illustration of Paré's dictum that the surgeon closes the wound before God heals the patient, it is when the surgeon fits a gastric band to a day case patient. In one visit a patient whose habitus would pose a challenge to any surgical operation has undergone a procedure that is likely to be associated with changes in nutritional habit that will ultimately affect the function of every body system. Furthermore, that surgery is still comparatively novel, having been offered widely for less than 10 years. Yet our Advisors found that one third of these patients had inadequate follow-up (See Table 6.5). If a gastric band is going to resolve a long-standing eating disorder safely, it should be in the context of careful supportive follow-up.

We must also recognise that any young and rapidly expanding field of surgery will pose novel and challenging problems. As such it is vital to assemble audit results at a national level. Yet less than half of the cases we assessed had their data reported to the National Bariatric Surgery Register. The profession will not learn from experience unless it collects and shares the data produced by that experience.

We also found many cases where the experience of the team appeared to be scanty in the extreme. Far too many teams were practicing occasional surgery in a fashion reminiscent of the cosmetic surgical practices that we reported in *'On the face of it'*, and this time it is not only in the private sector that many centres reported they were doing procedures less than 10 times a year. Again, our authors acknowledge that the leader of the team who undertook sleeve gastrectomy less than once a month may also be performing similar procedures at

other hospitals, but the advantage of other members of the team having specialist skills is clear in the case of patients who may pose anaesthetic problems, or need special instruments or specific fluid management regimens. Since there are now about 12,000 of these operations a year in the NHS alone, a figure which reflects the rapid spread of a comparatively novel modality in recent years, this is a timely report that will be of value to health care providers.

On behalf of the Trustees, I would like to thank the team who have made it possible – the Expert Group who devised the study and guided it, the Local Reporters and Ambassadors who assembled the data, the Advisors and Co-ordinators who formulated the assessments and the Authors who reduced the data to a coherent narrative.

Last and by no means least, our thanks are due as always to the clinicians who co-operated and willingly subjected their work to this level of scrutiny. All these people have come together for one reason only, because they want to make things better for patients. The report contains an abundance of suggestions as to how things can be improved and I hope these will be absorbed and put to such use as may be appropriate.

Bertie Leigh
NCEPOD Chairman

1 *Management of women with obesity in pregnancy*
http://www.rcog.org.uk/files/rcog-corp/CMACERCOGJointGuidelineManagementWomenObesityPregnancya.pdf

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Principal Recommendations

In common with other types of specialist surgery, bariatric surgery is not for the occasional operator. The Specialist Associations involved with bariatric surgery should provide guidance regarding the numbers of procedures which both independent operators and institutions should achieve in order to optimise outcomes. *(Specialist Associations)*

All patients must have access to the full range of specialist professionals appropriate for their needs in line with NICE guidelines. *(Clinical Directors and Medical Directors)*

There should be a greater emphasis on psychological assessment and support and this should occur at an earlier stage in the care pathway for obese patients. Psychological screening tools are available and may be of value in identifying those patients requiring formal psychological intervention. *(Consultants)*

As for all elective surgery, a deferred two-stage consent process with sufficient time lapse should be utilised, and details of benefits and risks should be clearly described, and supported with written information. The consent process should not be undertaken in one stage on the day of operation for elective bariatric surgery. *(Medical Directors [*policy*]* and *Consultants [implementation])*

Given the potential for significant metabolic change (and its dietary dimension) after bariatric surgery, good quality care is supported if patients have clear post-operative dietary guidance and a timely and complete discharge summary, with full clinical detail and post discharge plan to ensure safe and seamless care. This must be provided to the GP as soon as possible following discharge, preferably within 24 hours. *(Consultants and Dietitians)*

A clear, continuous long-term follow-up plan must be made for every patient undergoing bariatric surgery. This must include appropriate levels of informed surgical, dietitian, GP and nursing input. An assessment for the requirement of physician and psychology/psychiatric input must be made and provided should the patient require it. *(Consultants)*

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Introduction

Bariatric surgery is surgical treatment to promote health in people who suffer from severe or complex obesity, by aiding the reduction in calorie intake and assisting in weight loss. It is indicated for patients who have a body mass index (BMI) >40 kg/m^2, sometimes known as "morbid obesity", in its own right, or who have a BMI between 35 kg/m^2 and 40 kg/m^2 with other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight[1].

Obesity rates in the UK are amongst the highest in Europe, and medical intervention has proved largely ineffective in reversing obesity once present. Estimates for the UK suggest that the end consequences of obesity cost the health economy £5 billion per year, and that this is forecast on the present trajectory to double by 2050[2]. Surgery has proved to be both clinically and cost effective and, as such, has been endorsed by the National Institute for Health and Clinical Excellence (NICE).

In England in 2009 the prevalence of overweight or obese (BMI >25) people aged 16 and over was 61%. In Wales in 2007, 57% of adults were classified as overweight or obese, including 21% obese[3]. The prevalence of obesity (BMI >30) among adults in England and Wales is increasing. In 2010 reported obesity prevalence in England was 26% for both men and women. The increase is apparent when the 2010 figures are compared with those for 1998 which were 17.3% for men and 21.2% for women[4].

The 2006 prevalence of morbid obesity (BMI >40) in England was 2.1% (just under 863,000 people) with women being more likely to be morbidly obese than men (2.7% of women versus 1.5% of men)[5]. In comparison, the 1998 figures for morbid obesity were 1.9% for women and 0.6% for men. For a standard primary care trust (PCT) population of 250,000, there would be 5,250 cases of morbid obesity (based on the overall 2006 population value for England of 2.1% morbid obesity).

The number of recorded hospital admissions in the NHS in England alone related to obesity rose by more than 30 per cent in one year, from nearly 8,000 in 2008/09 to nearly 10,600 in 2009/10 and rising again by almost 10% in 2010/11 to 11,600[6].

The number of prescription items dispensed in the community in England specifically to treat obesity also increased from 1.28 million in 2008 to 1.45 million in 2009 – a rise of 13 per cent, however this figure fell in 2010 to 1.1 million.

The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) conducted in 2009[7] concluded that bariatric surgery appeared to be a clinically effective and cost-effective intervention for moderately to severely obese people compared with non-surgical interventions. However the report concluded that uncertainties remain regarding:

a) *the relationship between surgeon experience and outcome,* i.e. what is the optimum level of experience and ideal volume of procedures which should be undertaken by surgeons and teams to ensure best outcome?
b) *long term morbidity,* i.e. are there complications following surgery which do not become apparent until several years following the procedure?
c) *duration of comorbidity remission,* i.e. are the initial improvements in comorbidities which usually occur in the early aftermath of surgery maintained in the long term?

Three main types of bariatric procedure were considered in the HTA assessment, namely sleeve gastrectomy, gastric bypass and gastric bands, and in this study these procedures represent almost all of the procedures undertaken. (see Appendix 2)

The number of recorded bariatric weight loss hospital procedures carried out on obese people in England rose by 70 per cent from just over 4,200 in 2008/09 to just over 7,200 in 2009/10, and again rose in 2010/11by a further 10% to just over 8000.

Hospital coding for bariatric weight loss procedures has been historically unreliable, because of a lack of unique codes for some of the standard procedures available. However the codes were updated in 2009/10, which means it is now possible to identify how many of them were for maintenance of an existing gastric band. Of the 7,200 bariatric procedures in 2009/10 - 1,400 of these were for maintenance.

Of bariatric weight loss operations carried out on obese people (including maintenance of gastric bands in 2009/2010):

- Four fifths were carried out on women.
- More weight loss procedures were carried out in the East Midlands and London Strategic Health Authorities (SHAs) for every 100,000 of the population than any other regions.
- Data from 2010/11 indicates that this pattern of practice has been maintained.

The reason for different rates of bariatric surgical episodes between SHA regions is unclear. There is no obvious correlation with the prevalence of obesity, and so this is likely to be a reflection of either variations in availability of surgical services, or commissioning variations between PCTs.

In 2008, a collaboration between The Association of Laparoscopic Surgeons (ALS), The Association of Upper Gastrointestinal Surgeons (AUGIS) and The British Obesity and Metabolic Surgery Society (BOMSS) led to the establishment of The National Bariatric Surgery Registry (NBSR)[8]. The key objective of the registry is to accumulate sufficient data to allow the measurement of outcomes following bariatric surgery, including weight loss, improvement or reversal of comorbidities and improvement of quality of life. The NBSR collects data from the point of acceptance for surgery, and includes data from follow-up appointments. Whilst it will provide a rich, continuous source of data, there are aspects of the overall patient journey and organisational structure of care for bariatric surgical patients that the NBSR data will not address. Therefore whilst this evolving specialty is at an early stage in its development, it seemed timely for NCEPOD to undertake a qualitative study, to complement the work of the NBSR.

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1 – Method and Data Returns

Study aim

To describe variability and identify remediable factors in the process of care (from referral to follow-up) for patients undergoing bariatric surgery.

Objectives

The Expert Group identified eight main objectives that would address the primary aim of the study, and these will be covered in the following chapters:

- Referral process,
- Availability of multi-disciplinary team (MDT) meetings,
- Management of comorbidities
- Pre intra and post-operative care
- Prolonged critical care stays
- Surgical and medical complications
- Discharge and follow-up/readmissions (within 6 months)
- Organisational factors

Hospital participation

National Health Service (NHS) and independent hospitals in England, Wales and Northern Ireland were expected to participate, as well as hospitals in the Isle of Man, Guernsey and Jersey.

Within each hospital, a named contact, referred to as the NCEPOD Local Reporter, acted as a link between NCEPOD and the hospital staff, facilitating case identification, dissemination of questionnaires and data collation.

Expert group

The Expert Group comprised a multi-disciplinary group of: consultants in bariatric surgery, anaesthesia and bariatric medicine; a dietitian, a specialist nurse and a general practitioner.

Study population

All adult patients (>16 years old) who underwent bariatric surgery between 1st June 2010 to 31st August 2010 inclusive were eligable to be included. Cases were limited to a maximum of three per surgeon per hospital. Limiting the number of questionnaires that any one surgeon received meant that the proportion of patients in the study sample that came from lower volume sites was higher than that of the whole bariatric surgery population.

Case ascertainment

Patients were identified retrospectively using operating procedure codes (OPCS coding).

Questionnaires and case notes

Two questionnaires were used to collect data for this study. A clinician questionnaire for each patient and an organisational questionnaire for each hospital participating in the study.

Clinician questionnaire

A short questionnaire was sent to the surgeon responsible for each patient's weight loss surgery. Information was requested on the referral and pre-assessment, operation and inpatient episode, follow-up and audit of each patient included in the study.

Organisational questionnaire

The data requested included information on types and number of bariatric procedures performed, pre-operative assessment facilities, availability and structure of MDTs, training, patient information and follow-up clinics. The final section of the questionnaire focussed on facilities and equipment for morbidly obese patients and was for completion by hospitals that admit patients as an emergency, in addition to those that carried out weight loss surgery at the time of the study.

The organisational questionnaire was sent to the Local Reporter for completion in collaboration with relevant specialty input. A letter outlining our request, was also sent to the Medical Director.

Case notes

Photocopied case note extracts were requested for each case that was to be peer reviewed:

- Outpatient annotations including referral and pre-assessment clinics
- Referral letters and other relevant correspondence
- Notes from MDT meetings
- Inpatient annotations/medical notes for the surgical episode
  - Nursing notes
  - Nutrition/Dietitian notes
  - Consent forms
  - Operation notes
  - Anaesthetic charts
  - Observation charts
  - Haematology/biochemistry charts
  - Fluid balance charts
  - Discharge summary/letter
- Outpatient annotations for follow-up clinics
- Inpatient annotations/medical notes for any post-surgical readmissions

These were anonymised upon receipt at NCEPOD.

Advisor group

A multi-disciplinary group of Advisors was recruited to review the case notes and associated clinician questionnaires. The group of Advisors comprised consultants, associate specialists, nurses and trainees, from the following specialties: bariatric surgery, anaesthesia, intensive care medicine, metabolic medicine, dietetics, specialist bariatric nursing and physiotherapy.

Questionnaires and case notes were anonymised by the non-clinical staff at NCEPOD. All patient, clinician and hospital identifiers were removed. Neither the clinical co-ordinators at NCEPOD, nor the Advisors, had access to identifiable information.

After being anonymised, each case was reviewed by at least one Advisor within a multi-disciplinary group. At regular intervals throughout the meeting, the Chair allowed a period of discussion for each Advisor to summarise their cases and ask for opinions from other specialties or raise aspects of the case for discussion.

Advisors answered a number of specific questions by direct entry into a database, and were also encouraged to enter free text commentary at various points.

The grading system below was used by the Advisors to grade the overall care each patient received:

Good practice: A standard that you would accept from yourself, your trainees and your institution.
Room for improvement: Aspects of **clinical** care that could have been better.
Room for improvement: Aspects of **organisational** care that could have been better.
Room for improvement: Aspects of both **clinical and organisational** care that could have been better.
Less than satisfactory: Several aspects of clinical and/or organisational care that were well below that you would accept from yourself, your trainees and your institution.
Insufficient information submitted to NCEPOD to assess the quality of care.

Quality and confidentiality

Each case was given a unique NCEPOD number so that cases could not easily be linked to a hospital.

The data from all questionnaires received were electronically scanned into a preset database. Prior to any analysis taking place, the data were cleaned to ensure that there were no duplicate records and that erroneous data had not been entered during scanning. Any fields that contained spurious data that could not be validated were removed.

Data analysis

Following cleaning of the quantitative data, descriptive data summaries were produced.

The qualitative data collected from the Advisors' opinions and free text answers in the clinician questionnaires were coded, where applicable, according to content to allow quantitative analysis. The data were reviewed by NCEPOD Clinical Co-ordinators, a Researcher, and a Clinical Researcher, to identify the nature and frequency of recurring themes.

Adapted case studies have been used throughout this report to illustrate particular themes.

All data were analysed using Microsoft Access and Excel by the research staff at NCEPOD and the findings of the report were reviewed by the Expert Group, Advisors and the NCEPOD Steering Group prior to publication.

Data returns

In total, 397 clinician questionnaires were returned and 381 cases were assessed by the Advisors. The remainder of the returned case note extracts were either too incomplete for assessment or were returned after the final deadline and last Advisor meeting. There were 105 organisational questionnaires from hospitals which undertook bariatric surgery and a further 138 questionnaires from hospitals which although they did not undertake bariatric surgery, did admit patients as emergencies.

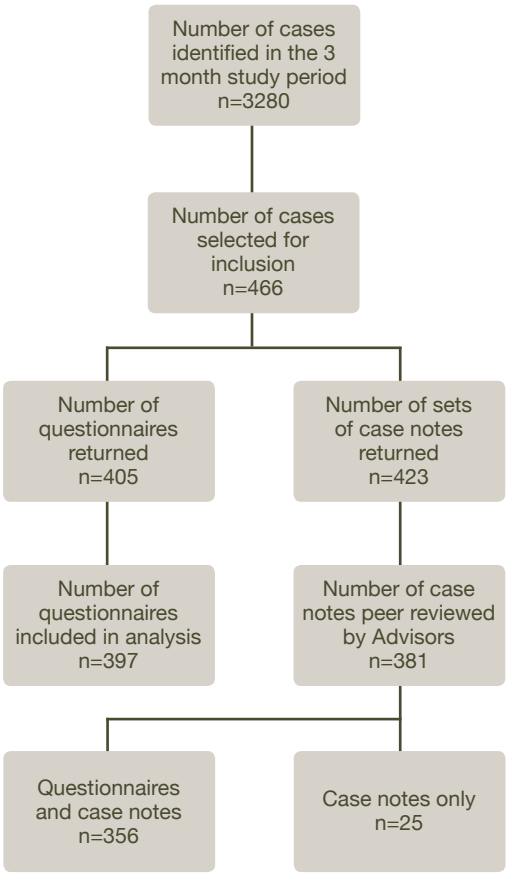

Figure 1. Data returns

Study sample denominator by chapter

Within this report the denominator will change for each chapter and occasionally within each chapter. This is because data have been taken from different sources depending on the analysis required. For example in some cases the data presented will be a total from a question taken from the clinician questionnaire only, whereas some analysis may have required the clinician questionnaire and the Advisors' view taken from the case notes.

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2 – Demographics

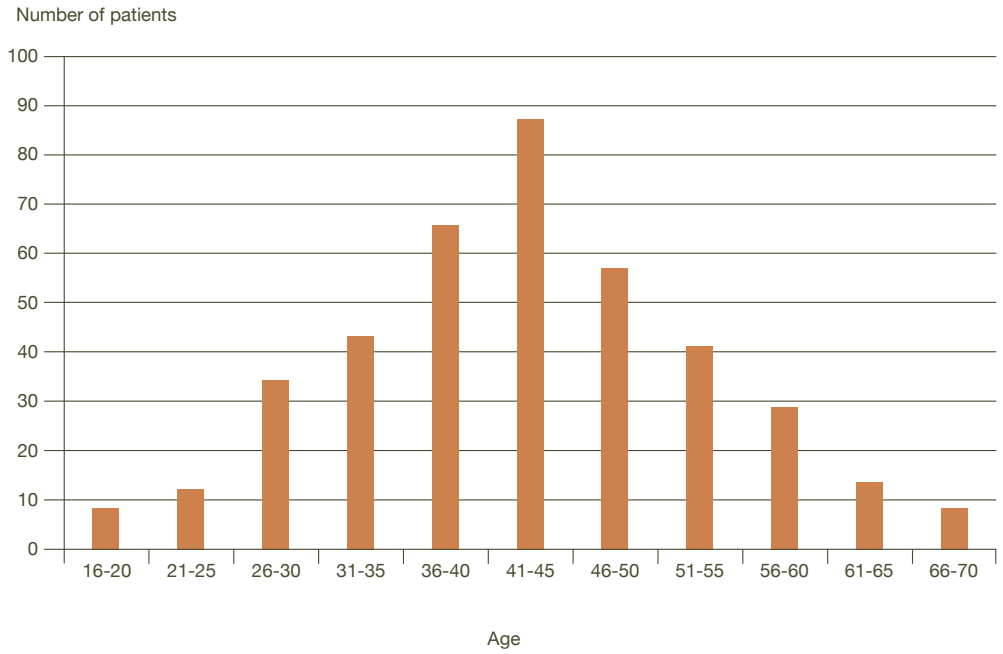

Figure 2.1 Age in years of the study population

The age range of the study population was 18 – 69 years, with a median of 43 years (Figure 2.1). Approximately 80% (325/397) of the patients were female, which is consistent with data published in the NBSR[8].

Weight loss surgery is an elective procedure and whilst there are NICE guidelines that identify the patients that may benefit from this type of surgery, limitations on resources has meant that NHS commissioning bodies apply varying criteria, many of which at a higher threshold than those set by NICE, meaning that many patients do not have access to bariatric surgery funded by the NHS[9]. In the current study, 56% (223/396) of patients had their surgery funded by the NHS, the remainder were privately funded (Table 2.1).

There are three main sources of referral for bariatric surgery, general practitioner, self and secondary care referral, such as diabetic and obesity clinics. Figure 2.2 illustrates the source of referral for the study population. The majority of patients 236/340 (60%) were referred for surgery by their GP, 101/390 (26%) were self referrals and the remainder 53/390 (14%) were referred by a secondary care clinic.

Table 2.1 Type of patient funding

Patient funding	Number of patients	%
NHS	223	56.3
Private	173	43.7
Subtotal	**396**	
Not answered	1	
Total	**397**	

Although only 26% (101/390) of patients in the study group were self referrals, many more (44%; 173/396) ultimately paid for their weight loss surgery. Figure 2.3 shows the source of referral by type of funding.

Figure 2.3 Source of referral by type of patient funding
Data were collected on patients' body mass index (BMI) at the time of surgery and this is shown in Figure 2.4.

A proportion of patients had a BMI below that of 35, the lowest BMI which falls into NICE guidance for weight loss surgery (albeit at the time of referral), and only then if the patient has specific comorbidities. In fact the Advisors peer reviewing the case notes and completed questionnaires judged that 50 patients in the study population did not meet NICE guidelines (see pages 35-37).

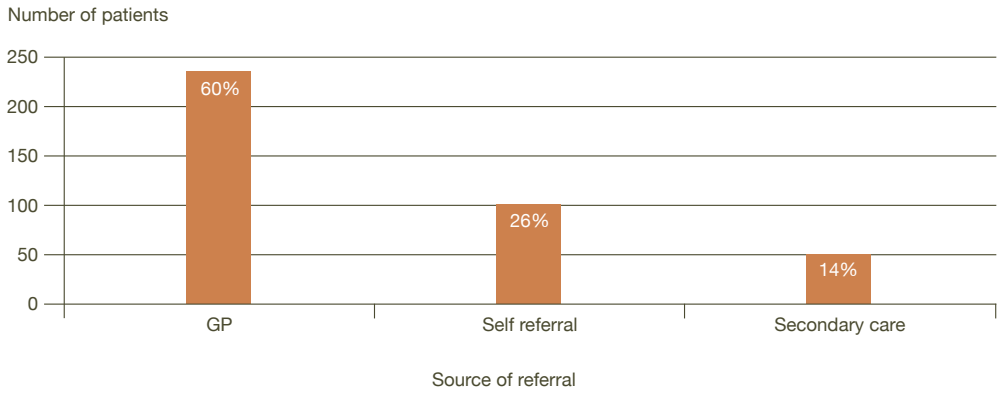

Figure 2.2 Source of referral

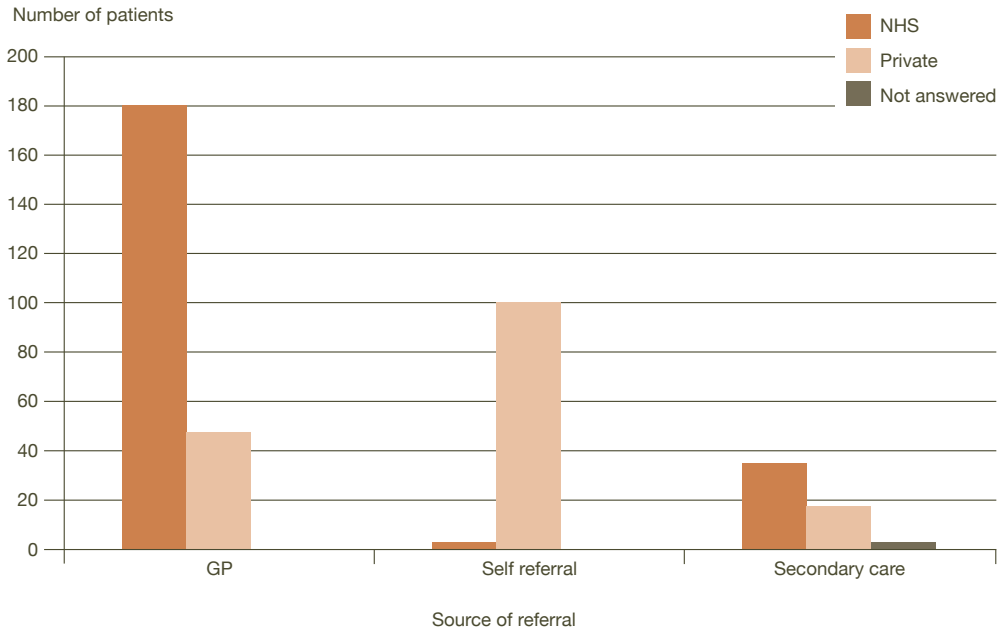

Figure 2.3 Source of referral by type of patient funding

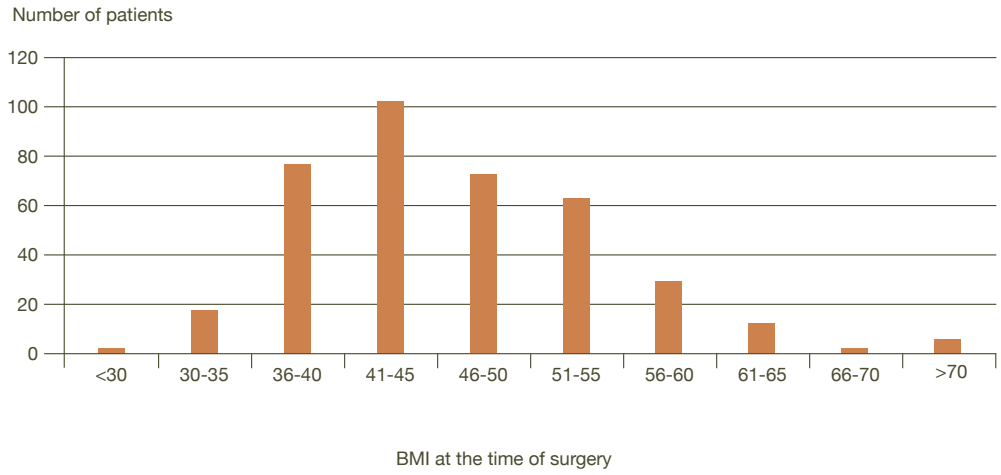

Figure 2.4 BMI of the study population

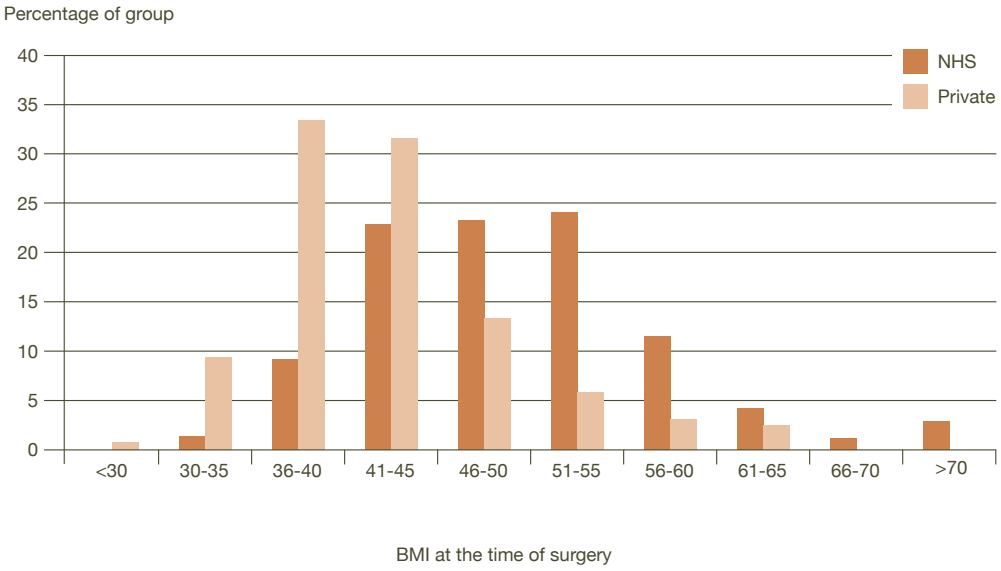

Figure 2.5 BMI of the study population by type of patient funding

Figure 2.5 shows the BMI data by type of funding, expressed as a percentage of the funding group. The BMI range for the NHS funded group was 32 – 78 compared to 28 – 62 for privately funded patients. The median BMI was higher in the group of patients whose surgery was funded by the NHS (49 vs 42). This probably reflects the shortfall in NHS funding for bariatric surgery and the fact that commissioners have raised the bar for eligibility for surgery from that recommended by NICE (particularly with regard to a patient's BMI).

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3 – Organisational Data

The first part of this chapter focuses on the hospitals where bariatric surgery for weight loss took place during the study period. A completed organisational questionnaire was returned from 105 hospitals in which weight loss surgery was performed.

Types of facility and patients

Table 3.1 shows the types of hospital in which bariatric surgery was carried out and Table 3.2 the types of patient (NHS or privately funded weight loss surgery patients) that were operated on within each hospital.

Table 3.1 Types of hospital providing bariatric surgery for weight loss

Type of hospital	Number of hospitals
Private	62
University Teaching Hospital	25
District General Hospital > 500 beds	12
District General Hospital ≤ 500 beds	6
Total	**105**

Table 3.2 Types of patient operated on

Types of patients	Number of hospitals
Privately funded	48
NHS funded and privately funded	33
NHS funded	24
Total	**105**

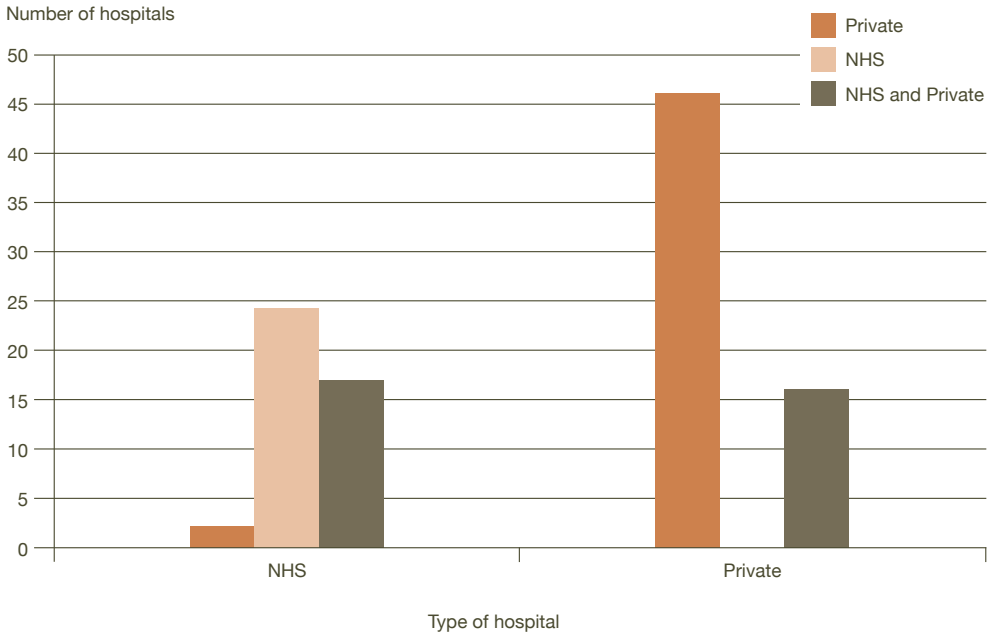

Figure 3.1 Type of hospital providing bariatric surgery by type of patient funding

Seventeen of the 43 NHS hospitals operated on private as well as NHS patients. Two NHS hospitals just operated on private patients during the study period whilst the remaining 24 hospitals, operated on NHS patients only. In addition to private patients, 16 of the 62 private hospitals also operated on NHS patients (Figure 3.1).

The NICE guidelines on the prevention, identification, assessment and management of overweight and obesity in adults and children devoted a section to surgical procedures for weight loss and clear patient criteria are defined for indication for consideration for surgery.

Table 3.3 Adherence to NICE guidance

Outside NICE guidance	Number of hospitals
Yes	13
No	83
Subtotal	**96**
Not answered	9
Total	**105**

Thirteen of the hospitals (Table 3.3) that undertook bariatric surgery responded that they operated on patients outside of NICE guidance, 10 of these were private hospitals and the other three were NHS hospitals.

Types of procedures

The most widely available procedure in NHS and private hospitals was gastric banding (Table 3.4), followed by gastric bypass and sleeve gastrectomy.

A large number of private hospitals (26/60) only offered gastric banding as a surgical procedure for weight loss (Figure 3.2). Thirty three of the 43 NHS hospitals undertook all three of the most commonly used types of weight loss surgery and four NHS hospitals just undertook banding.

Table 3.4 Types of weight loss surgery

	Type of hospital		
Type of operation	**NHS**	**Private**	**Total**
Gastric band	42	60	**102**
Roux-en-Y gastric bypass	37	28	**65**
Sleeve gastrectomy	34	27	**61**
Gastric balloon placement/retrieval	19	30	**49**
Revisional gastric band	25	13	**38**
Duodenal switch	3	5	**8**
Bilio-pancreatic diversion	1	3	**4**
Duodenal switch with sleeve	0	4	**4**

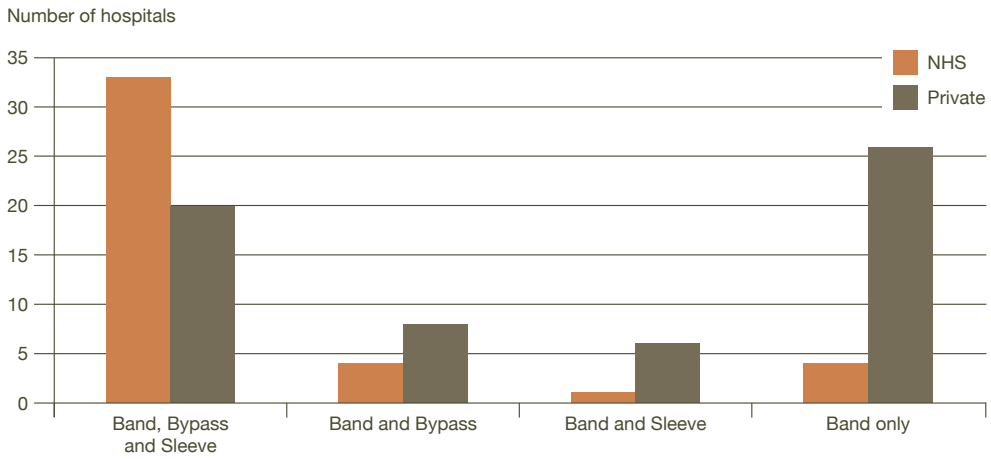

Figure 3.2 Types of weight loss surgery performed by type of hospital

Tables 3.5, 3.6 and 3.7 show the number of gastric bands, bypasses and sleeve gastrectomies performed by each hospital in the 2010-2011 financial year. Forty of the 84 (48%) hospitals that performed gastric banding carried out 10 or less operations in the 2010-2011 financial year.

Furthermore, 16 of the 84 hospitals (19%) only performed gastric banding and nine other hospitals were low volume sites (≤10 procedures/year) for all weight loss surgical procedures. Eighteen hospitals did not provide details on the number of gastric bands that were performed.

Table 3.5 Number of gastric bands performed in the 2010 – 2011 financial year

	Type of hospital		
Gastric bands	**NHS**	**Private**	**Total**
1 – 10	13	27	**40**
11 – 20	4	11	**15**
21 – 30	2	3	**5**
31 – 40	1	0	**1**
41 – 50	4	4	**8**
> 50	8	7	**15**
Subtotal	**32**	**52**	**84**
Not answered	10	8	**18**
Procedure not performed	1	2	**3**
Total	**43**	**62**	**105**

Table 3.6 Number of Roux-en-Y gastric bypasses performed in the 2010 – 2011 financial year

	Type of hospital		
Roux-en-Y gastric bypass	**NHS**	**Private**	**Total**
1 – 10	5	7	**12**
11 – 20	3	6	**9**
21 – 30	3	3	**6**
31 – 40	0	0	**0**
41 – 50	3	1	**4**
> 50	15	8	**23**
Subtotal	**29**	**25**	**54**
Not answered	8	3	**11**
Procedure not performed	6	34	**40**
Total	**43**	**62**	**105**

Table 3.7 Number sleeve gastrectomies performed in the 2010 – 2011 financial year

	Type of hospital		
Sleeve gastrectomy	**NHS**	**Private**	**Total**
1 – 10	9	10	**19**
11 – 20	6	7	**13**
21 – 30	4	0	**4**
31 – 40	1	0	**1**
41 – 50	1	2	**3**
> 50	3	3	**6**
Subtotal	**24**	**22**	**46**
Not answered	10	5	**15**
Procedure not performed	9	35	**44**
Total	**43**	**62**	**105**

Although fewer hospitals undertook Roux-en-Y gastric bypass and/or sleeve gastrectomy (65 and 61 hospitals respectively), there were still a significant number of hospitals (12/54 and 19/46) that carried out 10 or less procedures per year (Tables 3.6 and 3.7).

Whilst these data may not reflect the number of procedures performed by a particular surgeon (who may carry out weight loss surgery at more than one site), they do demonstrate that a large number of hospitals are performing very low numbers of weight loss surgery.

Although the current study does not look at institutional work load and outcome/complications, it is worth considering that there is published literature showing that outcome is associated with workload at both the institutional and surgeon level[10-13]. However, the NIHR Technology Assessment conducted in 2009 was less conclusive stating that uncertainties remain regarding the relationship between surgeon experience and outcome[8].

Assessment for bariatric surgery

The decision on whether or not a patient is suitable/ready for weight loss surgery should be made with the input of a number of different health care professionals. One, but not the only way of achieving this is with the use of MDT meetings. Just over half (57/104) of the hospitals in the study ran MDT meetings for bariatric surgical patients (Table 3.8).

Table 3.8 Utilisation of MDT meetings onsite

MDT meetings	Number of hospitals
Yes	57
No	47
Subtotal	**104**
Not answered	1
Total	**105**

In Figure 3.3 the MDT data are split by type of hospital. Eighteen out of the 61 private hospitals that completed an organisational questionnaire held MDT meetings onsite, 10 of which operated on NHS, as well as privately funded patients. The greater use of MDTs with NHS funded patients is reflected in the patient level data and discussed in detail in Chapter 4.

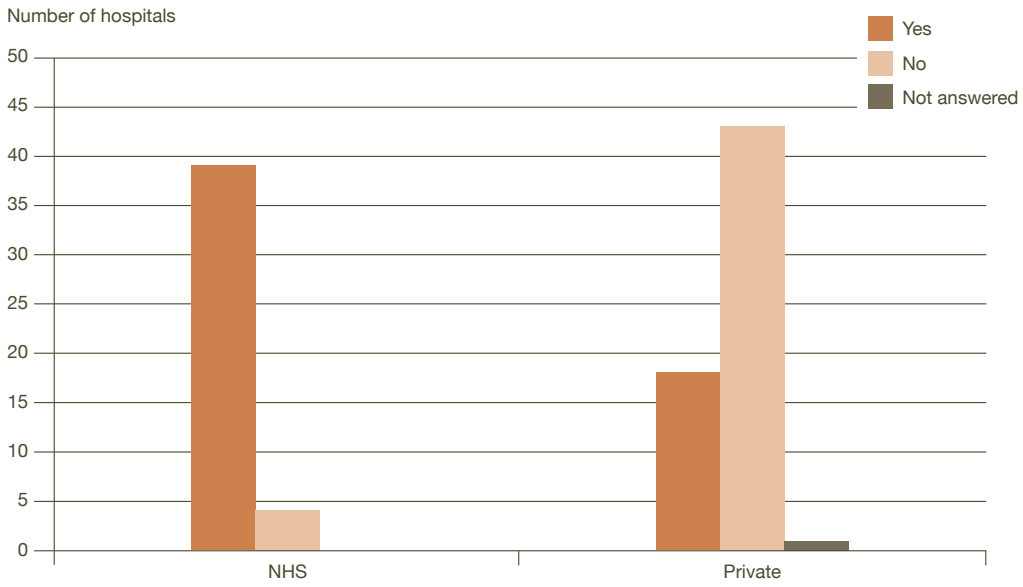

Figure 3.3 Utilisation of MDT meetings by type of hospital

Table 3.9 shows the specialties that routinely attends MDT meetings at the 57 hospitals that run them onsite. Almost all hospitals reported that MDT meetings were attended by a surgeon, dietitian and specialist nurse, with bariatric physicians and anaesthetists attending less routinely (31/57 and 32/57 respectively). A psychologist or psychiatrist would usually attend the MDT in 31/57 hospitals.

Table 3.9 MDT meeting attendees

Health care professional	Number of hospitals
Bariatric surgeon	57
Dietitian	56
Specialist nurse	51
Anaesthetist	32
Psychologist/Psychiatrist	31
Bariatric physician	31
Administrator	30
Other	6
Physiotherapist	5
Respiratory physician	4

**Answers may be multiple n/57*

Table 3.10 Types of pre-assessment clinics/service

Pre-assessment clinics/service	Number of hospitals
Dietitian	87
Echocardiography	71
Specialist nurse	64
Psychology service	61
Diabetic clinics	54
Sleep clinics	51
Psychiatric services	41
Exercise physiologist	19
Other	13

**Answers may be multiple n/97*

Table 3.10 shows the services that were available to patients at those hospitals that said they ran pre-assessment clinics (97/101 hospitals).

Table 3.11 shows the staff that were available for the clinical management of patients during their inpatient stay.

Table 3.11 Availability of inpatient staff

Inpatient staff	Number of hospitals
Surgeon	105
Anaesthetist	105
Dietitian	91
Physiotherapist	77
Specialist nurse	67
Respiratory physician	39
Psychologist/Psychiatrist	34
Bariatric physician	28
Other	7

**Answers may be multiple n/105*

Although bariatric surgery for weight loss has been practiced for over 50 years, the concept that it can ameliorate the deleterious metabolic changes associated with being overweight is relatively new. Furthermore the population of patients that could benefit from this surgery, has increased rapidly over the last two decades, it would therefore seem important to provide training for surgeons, theatre nurses and surgical assistants in this area of surgery/patient care. Table 3.12 shows the type of training available at each hospital. Forty hospitals reported that training was provided to surgeons, three of these were private hospitals. All of the sites providing training for trainee surgeons were high volume sites for one or more procedure. Fifty one of the 56 hospitals that did not provide any kind of specialist training in bariatric surgical procedures were private hospitals.

Table 3.12 Availability of training in bariatric surgical procedures

	Type of hospital		
Specialist training in bariatric surgical procedures	**NHS**	**Private**	**Total**
Trainee surgeons , Theatre nurses and Surgical assistants	15	1	**16**
Trainee surgeons & Theatre nurses	14	2	**16**
Trainee surgeons	8	0	**8**
Theatre nurses and Surgical assistants	1	2	**3**
Theatre nurses	0	6	**6**
None	5	51	**56**
Total	**43**	**62**	**105**

Table 3.13 Highest care level of bed available at each hospital

	Type of hospital		
Highest level beds	**NHS**	**Private**	**Total**
Level 3	42	17	59
Level 2	1	31	32
Level 0/1	0	14	14
Total	**43**	**62**	**105**

Information on the levels of care (e.g. high dependency unit, intensive care unit) available at each hospital was collected (see glossary for level of care definitions). Table 3.13 shows the highest level bed type each hospital reported having. There were 13 private hospitals that did not have Level 2 or 3 beds.

It is clear from Table 3.13 that a substantial number of hospitals (46/105) carrying out surgery for weight loss, do not have Level 3 beds. Whilst this level of care will rarely be needed for patients undergoing weight loss surgery, if level 3 beds are not available on-site there must, just as for any other form of complex major surgery, be a transfer policy in place should the need for a level 3 bed arise. Reassuringly, all 46 hospitals that did not have Level 3 beds on-site reported that they had an escalation in care transfer policy in place.

Hospitals were asked if in the event of a peri-operative complication, there was a standard procedure for transferring patients to a higher care area or a nearby acute hospital (Table 3.14). Fifty of the 62 private hospitals had a standard procedure in place that resulted in transferring the patient, should they develop peri-operative complications, to a nearby acute hospital. Thirty six of the 42 NHS hospitals reported that the patient would be kept on-site, being transferred to Level 3 care or the emergency department.

Table 3.14 Peri-operative complication transfer procedure

	Type of hospital		
Peri-operative complication transfer procedure	**NHS**	**Private**	**Total**
Nearby acute hospital	1	43	**44**
Level 3 care on-site	29	10	**39**
Level 3 care on-site or nearby acute hospital	0	7	**7**
Emergency department or Level 3 care on-site	7	0	**7**
Emergency department or Level 3 care on-site or nearby acute hospital	3	2	**5**
Other	1	0	**1**
No standard procedure	2	0	**2**
Total	**43**	**62**	**105**

Table 3.15 Emergency readmission policy

	Type of hospital		
Emergency readmission policy	**NHS**	**Private**	**Total**
Same hospital	35	42	**77**
Same or another hospital	2	11	**13**
Another hospital	1	2	**3**
No policy	5	7	**12**
Total	**43**	**62**	**105**

All bar 12 hospitals had an emergency readmission policy for patients that have received bariatric surgery (Table 3.15). For the large majority of hospitals (77/93) the standard policy was to readmit the patient (i.e. back to where the surgery took place). Thirteen hospitals (eleven private and two NHS) said they would readmit the patient or the patient would be admitted to another hospital, depending on the nature of the emergency and whether or not additional services not provided at the site of surgery, were needed.

Patient information

Figure 3.4 shows the modalities that were used to inform patients about the procedure(s) that they will undergo. The majority of hospitals provided patients with written information as well as one on one, verbal explanations from a surgeon or doctor and nurse. Approximately half of the hospitals also ran patient seminars.

There is often a considerable time period between the referral for bariatric surgery and the operation itself. During this time period the patient may have numerous outpatient appointments with surgical, physician, dietitian, nursing and psychological input. With all of this input and possible patient apprehension, it is important that the patient has access to support/advice when needed, prior to surgery. Eighty-two hospitals provided patients with a card or document carrying contact details and other information regarding pre-operative support (Table 3.16). Thirteen of the 19 hospitals that did not provide this type of card/ document to patients were private hospitals.

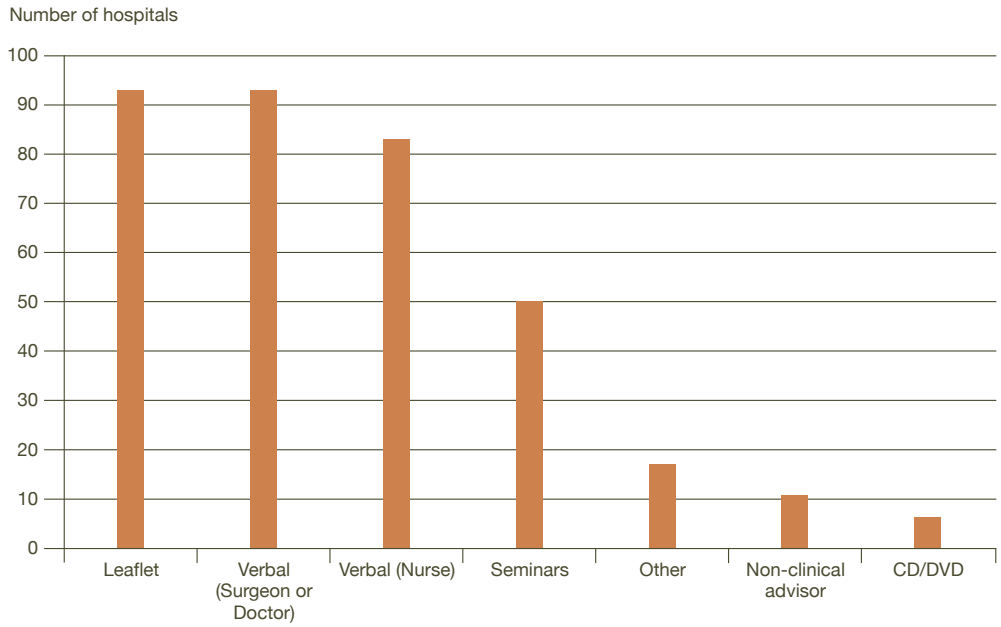

Figure 3.4 Patient information modalities

Table 3.16 Use of patient pre-operative support card or document

Pre-operative support card or document	Number of hospitals
Yes	82
No	19
Subtotal	**101**
Not answered	4
Total	**105**

Patient follow-up

Follow-up is an integral part of the clinical care pathway for patients undergoing bariatric surgery. For most patients in this study, the first follow-up clinic appointment was approximately six weeks post surgery (see Chapter 6). This may be insufficient to detect initial problems, including dietary and psychological issues that the patient may be reluctant to report themselves. One way to address this is by early telephone follow-up, prior to scheduled outpatient appointments. Seventy-two hospitals routinely used this form of follow-up, whilst 30 (12 NHS and 18 private hospitals) said they did not (Table 3.17).

Table 3.17 Patient telephone follow-up

Followed up by telephone	Number of hospitals
Yes	72
No	30
Subtotal	**102**
Not answered	3
Total	**105**

The timing of the telephone follow-up varied from 1-2 days post surgery to 2 weeks. Many hospitals stated that telephone follow-up was then at regular intervals thereafter to complement the outpatient follow-up appointments.

In Chapter 2 it was shown that the majority of patient referrals were made by GPs. This and the fact that many patients suitable for weight loss surgery have comorbidities that are managed in the community, suggests that it would be good practice to contact GPs when a patient has undergone surgery. The majority of hospitals routinely did this (Table 3.18). Whilst this is encouraging, data from Chapter 5 of this report will show that the quality of information contained within discharge summaries is often inadequate/incomplete.

Table 3.18 Post discharge contact with GP surgeries

Contact GP surgery	Number of hospitals
Yes	96
No	7
Subtotal	**103**
Not answered	2
Total	**105**

Ninety-five of the 105 hospitals ran follow-up clinics onsite with surgeon and dietitian led clinics being the most common (Table 3.19).

Table 3.19 Types of follow-up clinics

Follow-up clinics	Number of hospitals
Bariatric surgeon	95
Dietitian	86
Specialist nurse	58
Psychologist/Psychiatrist	24
Bariatric physician	21
Other	2

**Answers may be multiple n/95*

Forty seven of the hospitals that ran follow-up clinics onsite provided this service for patients that were operated on elsewhere, in addition to their own patients. It is of note that 17/21 hospitals that ran bariatric physician led clinics and 16/24 that ran psychiatrist/psychologist clinics provide this service to patients operated on outside their hospital.

Table 3.20 Types of follow-up clinics for patients operated on outside own hospital

Follow-up clinics	Number of hospitals
Bariatric surgeon	47
Dietitian	44
Specialist nurse	33
Bariatric physician	17
Psychologist/Psychiatrist	16

**Answers may be multiple n/47*

Of the 10 hospitals that told us that they did not run follow-up clinics, six stated that this was the responsibility of the surgeon and the other four were part of a larger group of hospitals that shared follow-up responsibilities.

Facilities and equipment

A section of the organisational questionnaire was designed to collect data on facilities and equipment relevant to obesity, at not only hospitals that undertook weight loss surgery, but also hospitals that admit patients as an emergency, whether or not they carried out weight loss surgery at the time of the study. Whilst the majority of patient follow-up is carried out at the sites which perform weight loss surgery, unexpected/emergency admissions may occur to hospitals not performing bariatric surgery.

In addition to the 105 completed questionnaires received for hospitals that undertook bariatric surgery for weight loss, 138 questionnaires were returned from hospitals that did not perform bariatric surgery but did admit patients as an emergency (Table 3.21).

Table 3.21 Patients admitted as a general emergency and whether or not weight loss surgery is performed

	Emergency admissions		
Bariatric surgery	**Yes**	**No**	**Total**
Yes	41	64	**105**
No	138	0	**138**
Total	**179**	**64**	**243**

Table 3.22 shows data on whether a hospital has the ability to weigh patients greater than 200 Kg.

Twenty hospitals that undertook bariatric surgery were unable to weigh patients over 200 Kg, eight of these hospitals were however able to weigh patients up to 200 Kg. Whilst at first it may appear peculiar that 20 hospitals that carried out weight loss surgery were unable to weigh patients over 200 Kg, all were private hospitals that did not admit patients as general emergencies and are more likely to operate only on lower BMI patients.

Thirteen hospitals, including seven that undertook weight loss surgery did not have specialist transfer equipment, such as mechanical or electrical hoists, sliding sheets and hover mattresses, for morbidly obese patients (Table 3.23).

Table 3.22 shows data on whether a hospital has the ability to weigh patients greater than 200 Kg.

	Weigh patients > 200 Kg				
Bariatric surgery	**Yes**	**No**	**Subtotal**	**Not answered**	**Total**
Yes	85	20	**105**	0	**105**
No	130	7	**137**	1	**138**
Total	**215**	**27**	**242**	**1**	**243**

Table 3.23 Specialist transfer equipment for morbidly obese patients

	Specialist transfer equipment				
Bariatric surgery	**Yes**	**No**	**Subtotal**	**Not answered**	**Total**
Yes	98	7	**105**	0	**105**
No	130	6	**136**	2	**138**
Total	**228**	**13**	**241**	**2**	**243**

Table 3.24 Specialist training for the care of morbidly obese patients

	Specialist training				
Bariatric surgery	**Yes**	**No**	**Subtotal**	**Not answered**	**Total**
Yes	91	13	**104**	1	**105**
No	107	31	**138**	0	**138**
Total	**198**	**44**	**242**	**1**	**243**

Specialist training for the care (e.g. moving) of morbidly obese patients was not available to staff in 44/242 hospitals.

A substantial number of hospitals reported that they did not have appropriate anti-embolism stockings (59/241; 24%) or surgical equipment (44/238; 18%), such as extra long laparoscopic instruments, for morbidly obese patients (Tables 3.25 and 3.26). Unsurprisingly the majority of these hospitals did not undertake weight loss surgery. However, considering the number of morbidly obese patients in the UK it might be expected that more hospitals to which patients are admitted as an emergency would have appropriate anti-embolism stockings and surgical equipment for these patients. The current study was unable to determine the availability of bariatric grade static abdominal retractors which would be a prerequisite for safe emergency or elective laparotomy in morbidly and super obese patients.

Table 3.25 Availability of appropriate anti-embolism stockings for morbidly obese patients

	Anti-embolism stockings				
Bariatric surgery	**Yes**	**No**	**Subtotal**	**Not answered**	**Total**
Yes	95	10	**105**	0	**105**
No	87	49	**136**	2	**138**
Total	**182**	**59**	**241**	**2**	**243**

Table 3.26 Availability of appropriate surgical equipment for morbidly obese patients

	Appropriate surgical equipment				
Bariatric surgery	**Yes**	**No**	**Subtotal**	**Not answered**	**Total**
Yes	100	4	**104**	1	**105**
No	94	40	**134**	4	**138**
Total	**194**	**44**	**238**	**5**	**243**

Table 3.27 Availability of appropriate anaesthetic equipment for morbidly obese patients

	Appropriate anaesthetic equipment				
Bariatric surgery	**Yes**	**No**	**Subtotal**	**Not answered**	**Total**
Yes	102	3	**105**	0	**105**
No	129	7	**136**	2	**138**
Total	**231**	**10**	**241**	**2**	**243**

Table 3.28 Availability of appropriate monitoring equipment for morbidly obese patients

	Appropriate monitoring equipment		
Bariatric surgery	**Yes**	**No**	**Total**
Yes	104	1	**105**
No	131	7	**138**
Total	**235**	**8**	**243**

Table 3.29 Availability of CT, MRI and fluoroscopy onsite

	Bariatric surgery		
Imaging modality	**Yes**	**No**	**Total**
CT, MRI & Fluoroscopy	83	125	**208**
CT & MRI	6	7	**13**
MRI & Fluoroscopy	5	0	**5**
MRI	3	1	**4**
Fluoroscopy	1	0	**1**
CT & Fluoroscopy	1	2	**3**
CT	1	0	**1**
None	5	3	**8**
Total	**105**	**138**	**243**

There were fewer reported deficiencies in anaesthetic and monitoring equipment for morbidly obese patients (Tables 3.27 and 3.28) than for other aspects of care.

The majority of hospitals (208/243; 86%) had CT, MRI and fluoroscopy on-site (Table 3.29). Five hospitals that undertook weight loss surgery and three that admitted patients as an emergency reported that they had none of these three imaging modalities on-site.

Table 3.30 Availability of CT onsite

	CT				
Bariatric surgery	**Yes**	**No**	**Subtotal**	**Not answered**	**Total**
Yes	91	12	**103**	2	**105**
No	134	3	**137**	1	**138**
Total	**225**	**15**	**240**	**3**	**243**

Table 3.31 Availability of MRI onsite

	MRI				
Bariatric surgery	**Yes**	**No**	**Subtotal**	**Not answered**	**Total**
Yes	97	1	**98**	7	**105**
No	133	1	**134**	4	**138**
Total	**230**	**2**	**232**	**11**	**243**

Table 3.32 Availability of Fluoroscopy onsite

	Fluoroscopy				
Bariatric surgery	**Yes**	**No**	**Subtotal**	**Not answered**	**Total**
Yes	90	13	103	2	**105**
No	128	5	133	5	**138**
Total	**218**	**18**	**236**	**7**	**243**

Table 3.33 Policy for imaging at another hospital

	Policy		
Bariatric surgery	**Yes**	**No**	**Total**
Yes	23	18	**41**
No	53	38	**91**
Total	**76**	**56**	**132**

A large number of hospitals (132/243; 54%) reported that they did not have imaging modalities adequate for morbidly obese patients. For these hospitals it was asked if there is a policy to arrange imaging at another hospital, should this be required for a morbidly obese patient. As can be seen in Table 3.33, 56/132 (42%) hospitals did not have this policy in place, 18 of which undertook bariatric surgery and 38 which admitted patients as an emergency.

Key Findings

13/96 (14%) hospitals that undertook weight loss surgery reported that they operate on patients who did not meet NICE criteria.

40/84 (48%) hospitals that performed gastric banding carried out 10 or less operations in the 2010 – 2011 financial year. Furthermore 16/40 of these hospitals performed no other bariatric procedures and 9/40 were also low volume sites for other surgical weight loss procedures.

57/104 (55%) hospitals held MDT meetings for bariatric surgery patients, 38 of which were NHS hospitals.

56/105 (53%) of hospitals did not carry out any specialist training in bariatric surgical procedures for trainee surgeons, theatre nurses or surgical assistants. Fifty one of these hospitals were private hospitals.

30/102 (29%) hospitals did not routinely follow-up patients by telephone.

Fifty nine hospitals, 49/136 (36%) that admit patients as emergency and 10/105 (10%) that perform weight loss surgery, did not have appropriate anti-embolism stockings for morbidly obese patients.

132/243 (54%) hospitals reported that they had one or more imaging modality that was not adequate for morbidly obese patients. 56/132 (42%) of these hospitals did not have a policy in place to arrange imaging at another hospital, should this be required for a morbidly obese patient.

Recommendations

It should be the duty of all bariatric surgery teams to follow-up patients by telephone or in person at regular intervals post surgery. The first of these follow-up calls should be within seven days of surgery and frequently thereafter to complement outpatient follow-up. *(Clinical Directors and Consultants)*

In common with other types of specialist surgery, bariatric surgery is not for the occasional operator. The Specialist Associations involved with bariatric surgery should provide guidance regarding the numbers of procedures which both independent operators and institutions should achieve in order to optimise outcomes. *(Specialist Associations)*

All hospitals that undertake weight loss surgery on morbidly obese patients or admit patients as an emergency must have appropriate, properly fitting anti-embolism stockings (or equivalent). *(Ward Managers)*

There is a global need to provide imaging modalities that are suitable for morbidly obese patients, wherever they are admitted and this may be best dealt with by an escalation process and by specification at the time of refurbishment. *(Executive Boards and Clinical Directors)*

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4 – Pre-surgery and Referral

The National Institute for Health and Clinical Excellence (NICE) clinical guidelines[1] for the management of patients with obesity includes the following referral criteria for surgery:

Bariatric surgery is recommended as a treatment option for people with obesity if all of the following criteria are fulfilled:

- *'they have a BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight*
- *all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months (except for those with BMI > 50 where surgery may be considered as first line treatment)*
- *the person has been receiving or will receive intensive management in a specialist obesity service*
- *the person is generally fit for anaesthesia and surgery*
- *the person commits to the need for long-term follow-up.*

Severely obese people who are considering surgery to aid weight reduction (and their families as appropriate) should discuss in detail with the clinician responsible for their treatment (that is, the hospital specialist and/or bariatric surgeon) the potential benefits and longer-term implications of surgery, as well as the associated risks, including complications and peri-operative mortality.'

The Advisors were asked to assess from the records whether there was evidence that NICE guidelines had been adhered to.

Table 4.1 Compliance with NICE (Advisors' opinion)

NICE guidance	Number of patients	%
Yes	295	85.5
No	50	14.5
Subtotal	**345**	
Unknown	36	
Total	**381**	

Overall it can be seen that in 295/345 (86%) of cases where it was possible to make an assessment, NICE criteria were adhered to. However in addition to the 15% which did not adhere to NICE guidelines, there were 36 cases where Advisors were unable to assess whether or not the guidelines had been followed.

There were eight NHS patients who did not meet the NICE criteria and 42 that were funded privately. The main deviations from the guidance noted were the BMI was less than 40 with no comorbidities or a BMI less than 35 at the time of referral. Of the 89 patients who were self referred, in nine cases it could not be ascertained whether NICE guidelines had been met, but from the remaining 80, 26 (33%) did not meet them.

Of those patients where Advisors were able to make an assessment, only 81/147 (55%) of those referred either by their GP or from another specialty had details of weight and height included in the referral. In these cases Advisors used other sources of information within the records to ascertain whether the NICE criteria had been met.

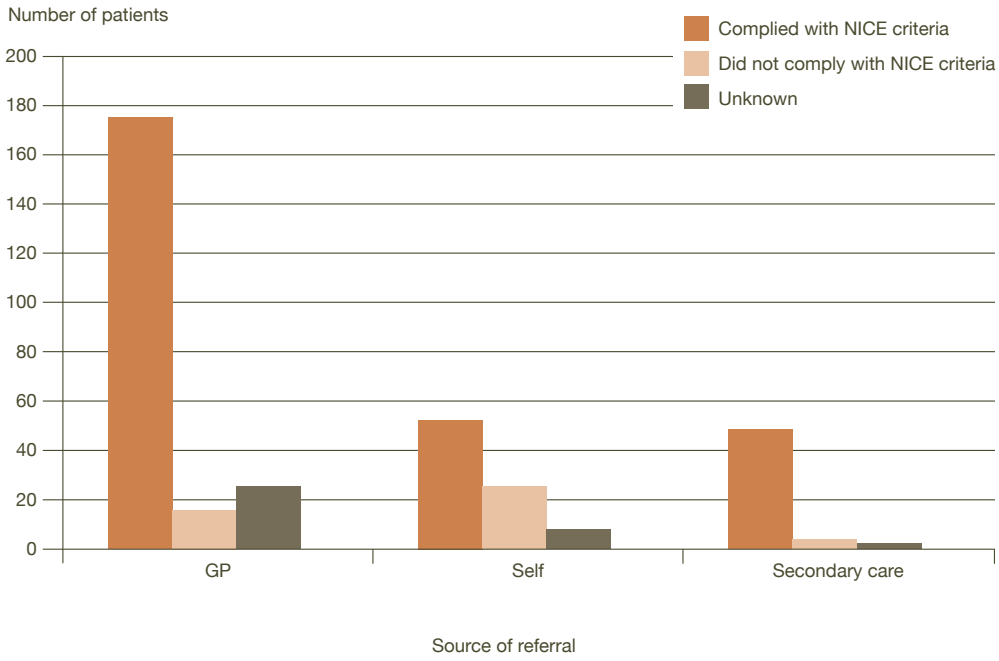

Figure 4.1 Compliance with NICE criteria by source of referral

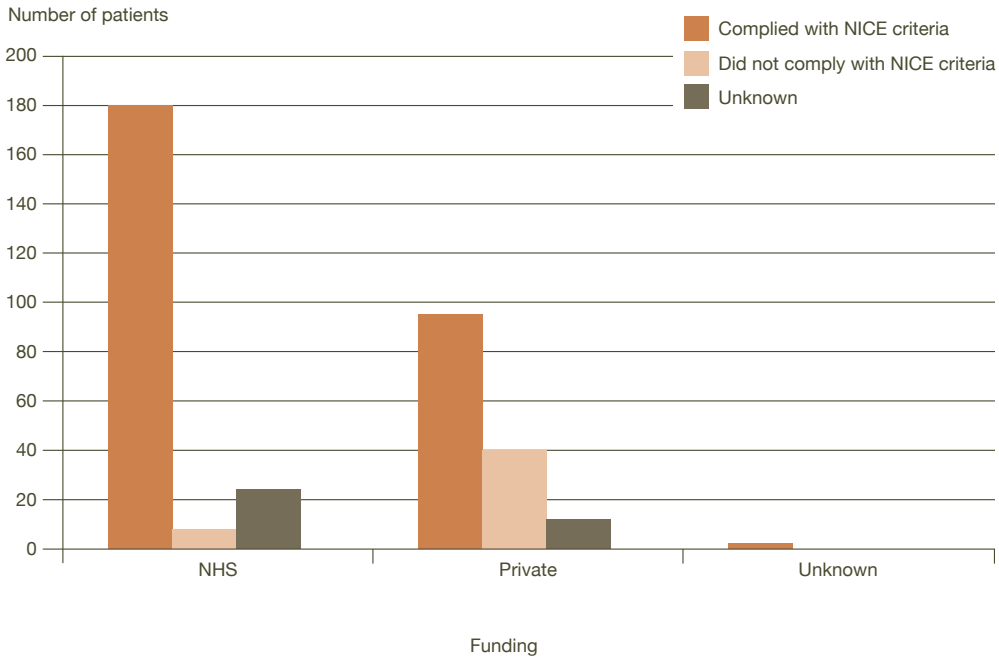

Figure 4.2 Compliance with NICE criteria by type of funding

There was quite marked variation in the proportion of patients fulfilling NICE criteria dependant upon the source of referral (Figure 4.1). Whilst the majority of patients who were referred either by their GP or from secondary care met the criteria, about one third of patients who self referred did not.

The majority of patients who self referred were also privately funded and about one third of privately funded patients did not meet the NICE criteria.

It should be considered that by its very nature, NICE guidance is designed to maximise health gain for a population, and takes not only clinical effectiveness but also the cost effectiveness and affordability of treatments within the publicly funded health care system into account. It is therefore not necessarily inappropriate for patients who seek treatment outside of the publicly funded system to receive surgical treatment rather than other interventions, provided that they choose to undergo surgery having clearly understood the potential benefits and risks of surgery versus non-surgical approaches to their weight loss.

However, it was suggested by some Advisors that there should be criteria below which surgery should not be offered to any patient, because there is insufficient evidence of clinical benefit to justify a surgical approach below a certain threshold. The original Health Technology Appraisal (HTA 046) conducted on behalf of NICE in 2002[14], identified benefits based primarily upon systematic assessment of data from studies in morbidly obese women. This was influential in determining the current NICE guidelines (CG 43 2006). The more recent HTA conducted in 2009 (HTA 134110)[7] considered the clinical and cost effectiveness of surgical intervention in patients with moderate obesity (class I obesity, BMI range >30-<35). For BMI ≥30 and <40, incremental cost effectiveness ratios (ICERs) were £18,930 at two years and £1,397 at 20 years, and for BMI ≥30 and <35, ICERs were £60,754 at two years and £12,763 at 20 years. Statistical analysis produced ICERs which were generally within the range considered cost-effective, particularly at the long twenty year time horizons; although for the BMI 30-35 group some ICERs were above the acceptable range. The authors concluded that good-quality randomly controlled clinical trials were required to provide evidence on the role of bariatric surgery for young people and for adults with class I or class II obesity. They also went on to say that more work was required to define the benefits in terms of quality of life and also to assess whether early intervention is appropriate for the prevention of comorbidities such as Type 2 diabetes and hypertension. Based upon the evidence presently available, it does not seem unreasonable that there should be a minimum threshold for a publicly funded service, but nor does it seem unreasonable for privately funded individuals to choose to undergo bariatric surgery, where they fail to meet the NICE criteria.

It is apparent from the review of advertising strategies in Chapter 8 of this report, that marketing is being directed toward privately funded patients on the basis not only of health gain, but also body image and lifestyle choice. Where no clear evidence of health gain can be demonstrated, the ethical and professional considerations which surround the provision of bariatric surgery are more closely aligned to the issues around cosmetic surgery.

What this study does not quantify is the number of obese patients, who despite meeting the NICE criteria, and who could benefit from bariatric surgery, are not referred either because of restrictions placed by commissioners which are more stringent than the criteria recommended by NICE, or because the patient chooses not to accept referral.

Multi-disciplinary teams (MDTs)

Data around the availability, and structure of MDT process were obtained from: the organisational questionnaire, the clinical questionnaire and the Advisors assessment of the case notes.

From the organisational questionnaire (see Chapter 3) 57/104 hospitals in which bariatric surgery was performed indicated that regular MDTs were undertaken and that in most cases a bariatric surgeon, dietitian and specialist nurse attended. Of the 62 private hospitals only 18 ran MDTs on site. In contrast only four of the 43 NHS hospitals did not provide regular MDTs.

From the clinical questionnaire the treating surgeons indicated that 251/377 (67%) of patients had been discussed in an MDT (Table 4.2).

Table 4.2 Patient discussed at an MDT

Discussed in an MDT meeting	Number of patients	%
Yes	251	66.6
No	126	33.4
Subtotal	**377**	
Unknown	20	
Total	**397**	

Table 4.3 Professionals attending the MDT

MDT attendees	Number of patients	%
Bariatric surgeon	236	93
Dietitian	230	91
Specialist nurse	207	81
Anaesthetist	114	45
Administrator	90	35
Bariatric physician	87	34
Psychologist/Psychiatrist	82	32
Other	18	7
Respiratory physician	14	6

**Answers may be multiple n/251*

As can be seen (Table 4.3), the majority of MDTs involved a bariatric surgeon, and/or a dietitian, and/or a specialist nurse. However the number of patients that were discussed by all three of these professionals at an MDT was 170/251 (68%).

When the Advisors sought evidence from the case notes of documented evidence of the patient having been discussed in an MDT (Table 4.4), they had insufficient data in 61 cases. Where they were able to make an assessment, they found documented evidence of an MDT process having taken place in only 128/320 (40%) of cases. Whilst it may be the case that a multi-disciplinary process took place, the benefit of that encounter may be compromised if it is not recorded in the case notes.

Table 4.4 Documented evidence of MDT discussion

Documented evidence that the patient was discussed at MDT	Number of patients	%
Yes	128	40.0
No	192	60.0
Subtotal	**320**	
Insufficient data	61	
Total	**381**	

It is important to be cautious when interpreting the data regarding MDTs. In the 60% of cases where there was no evidence within the notes to identify that a patient had been discussed in an MDT, and even in the 33% of patients where the clinician reported that the patient had not been discussed in an MDT, some of those patients might have had access to all of the appropriate health care professionals, and they may have collaborated, but not necessarily in one place at the same time. This is more likely to have occurred within the independent sector, since we know from the organisational data that whilst MDTs were available in most (39/43; 91%) of NHS hospitals they were less frequently available in the independent hospitals (18/61; 30%) (Figure 4.3). Furthermore in this sample according to the treating clinician 82% of patients treated within the NHS were discussed in an MDT as opposed to 46% of patients treated within the independent sector.

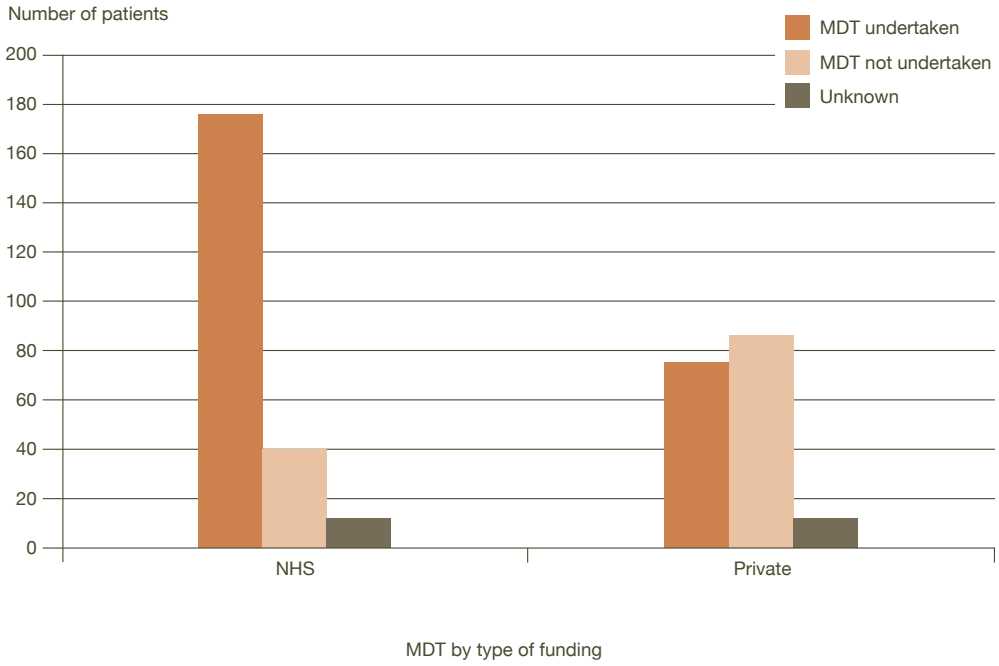

Figure 4.3 Clinician reported MDT discussion by type of funding

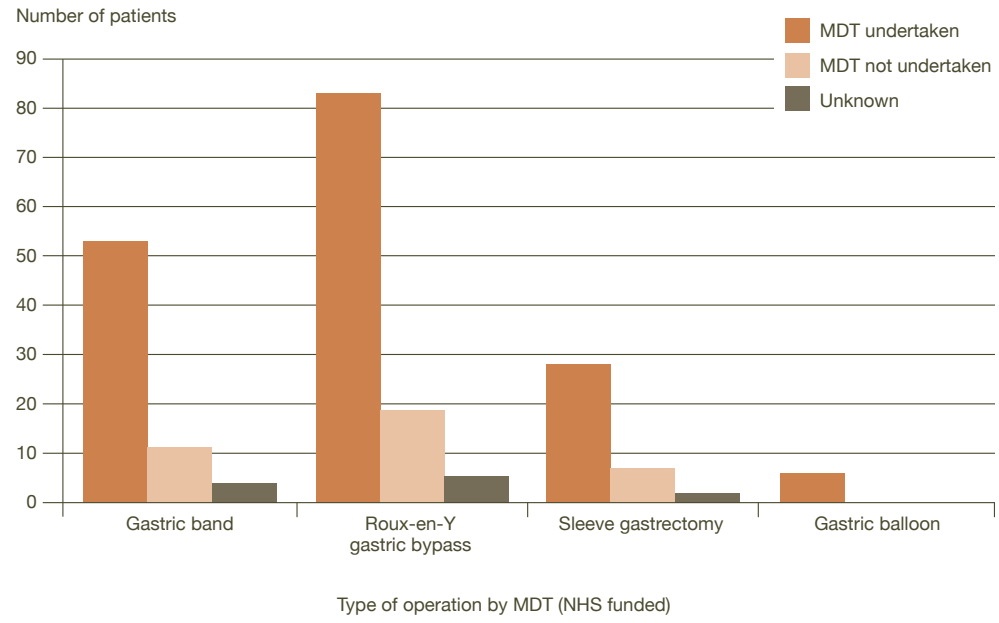

Figure 4.4 Clinician reported MDT discussion by type of procedure (NHS funded patients)

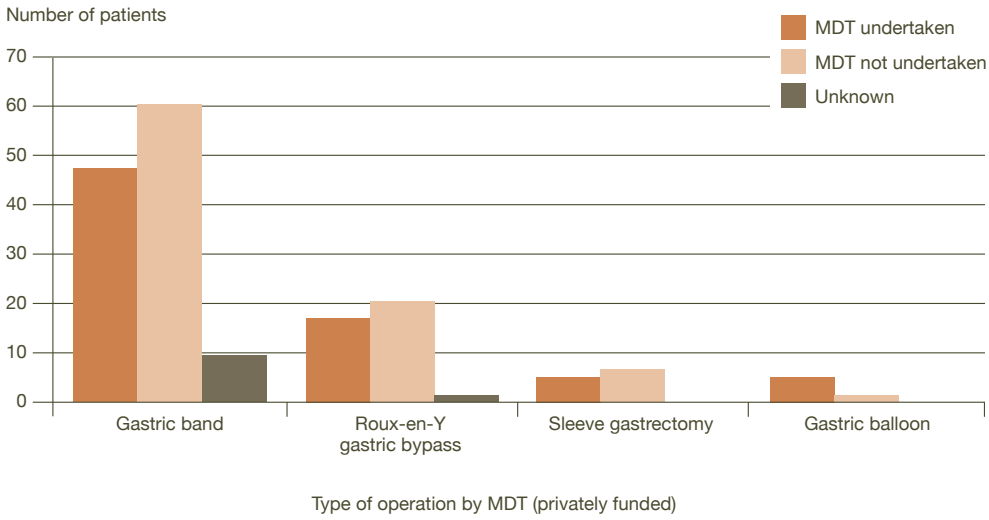

Figure 4.5 Clinician reported MDT discussion by type of procedure (privately funded patients)

In order to determine whether this difference could be explained on the basis of a different type of procedural case-mix within the two sectors, the data were analysed for the NHS and independent sectors by procedure type. As might have been expected there were proportionally more gastric bands undertaken in the independent sector than in the NHS.

However as can be seen from Figures 4.4 and 4.5, whether a patient was discussed at an MDT does not appear to have been influenced by the complexity of the procedure. Less than half of the privately funded patients were discussed at an MDT regardless of the procedure undertaken.

Advisors identified a number of cases which despite the patient not having been seen or discussed in a formal MDT nonetheless received a good standard of care.

Case Study 1

A middle-aged patient with a BMI of 40 had multiple comorbidities including: hypertension, severe ischaemic heart disease with atrial fibrillation, multiple transient ischaemic attacks, type 2 diabetes with neuropathy, peripheral vascular disease and impaired mobility, chronic renal failure and sleep apnoea with type I respiratory failure. There was excellent documentation to show that all the relevant specialists were fully involved in optimising the patient's condition prior to surgery and also managing them in the post-operative period. There was detailed documentation of the liaison between the various health care professionals involved. The patient underwent an uneventful laparoscopic gastric bypass.

Advisors were of the view that they received exemplary care, despite the case not being reviewed in a formal MDT.

Whilst there is considerable evidence that formal MDTs are of benefit in managing patients with cancer, the routine use of MDTs for bariatric patients is more controversial. The clinical Experts and Advisors involved in this study had a range of views about the value of formal MDTs. On one hand it was stated that there was no evidence of any demonstrable benefit from attending an MDT, and at the other extreme, there was opinion that all patients should be discussed in an MDT. It is perhaps worth considering that on some occasions, potential problems for individual patients may only be recognised when a patient is discussed in an MDT where a wide range of experience is available. There is no published evidence which demonstrates that an MDT improves outcomes in bariatric surgery, although most publications, including NICE guideline CG43 advocate a multi-disciplinary approach. The majority view however was that MDTs should be available for all NHS patients and also those high risk patients treated within the independent sector who are judged to need them.

Table 4.5 Advisors' opinion on the adequacy of the MDT

Adequate for patient (with documented evidence of MDT)	Number of patients	%
Yes	90	87.4
No	13	12.6
Subtotal	**103**	
Insufficient data	25	
Total	**128**	

For the 128 patients where Advisors identified evidence of an MDT discussion having occurred, in the majority 90/103 (87%) that level of involvement was judged to be appropriate, however in 13 cases it was judged to be inadequate, and in a further 25 cases there were insufficient data provided to judge whether the MDT involvement was adequate or not (Table 4.5).

Table 4.6 Advisors' opinion on whether not having an MDT was adequate for the patient

MDT was dequate for patient	Number of patients	%
Yes	23	46.9
No	26	53.1
Subtotal	**49**	
Unknown	38	
Total	**87**	

In those patients where the treating clinicians reported that the patient had not been discussed by an MDT, and where Advisors had sufficient data to make an assessment they judged that in 23/49 that this was adequate for the patient (Table 4.6). Indeed some Advisors were of the view that for low risk patients, with no comorbidities, undergoing a simple band procedure, the involvement of an MDT has not been demonstrated to be cost effective and was unnecessary.

Given the observations above, it is perhaps more important to consider what range of clinicians and other health care professionals were actually involved in the patients care pathway, and whether they had access to those with expertise of relevance to their particular circumstances and needs.

Table 4.7 demonstrates data from the clinical questionnaire. What is perhaps most surprising is that almost one in five patients were not assessed by a dietitian prior to surgery. It was common ground amongst the majority of our multi-disciplinary Expert and Advisory group, that substitution of the dietetic input by another health care professional giving dietary advice was not satisfactory.

Table 4.7 Who assessed the patient prior to surgery?

Assessed by prior to surgery	Number of patients	%
Bariatric surgeon	384	96.5
Dietitian	326	81.9
Anaesthetist	268	67.3
Specialist nurse	248	62.3
Bariatric physician	89	22.4
Psychologist/Psychiatrist	70	17.6
Other	40	10.1
Respiratory physician	34	8.5

Table 4.8 Documented evidence of dietetic input prior to surgery.

Documented dietetic assessment/education pre-surgery	Number of patients	%
Yes	237	72.5
No	90	27.5
Subtotal	**327**	
Insufficient data	54	
Total	**381**	

**Answers may be multiple n/397*

The data from the clinical questionnaire correlate well with the evidence of dietetic assessment identified by the Advisors, where 237/327 (73%) patients were documented to have received pre-surgical dietetic input, but in over a quarter of cases there was no evidence that there had been dietetic input prior to surgery (Table 4.8).

There were relatively few cases in which Advisors were able to identify within the records evidence of pre-referral dietetic input (Table 4.9). In total 79/225 (35%) had documented evidence of pre-referral input, despite the fact that NICE guidance recommends that: *"all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months"* (except for

Table 4.9 Documented timing of dietetic input

Timing of dietetic assessment/education pre-surgery	Number of patients	%
Pre-referral	41	18.2
Post-referral	146	64.9
Pre- and post-referral	38	16.9
Subtotal	**225**	
Insufficient data	12	
Total	**237**	

those with BMI > 50). However even in this high BMI group, where surgery is considered appropriate as a first line treatment, NICE guidance would suggest that early involvement of a dietitian to facilitate the lifestyle dietary change, which is a vital adjunctive pre-requisite to successful surgery, is essential. The experts and Advisors were of the view that these findings probably reflected a lack of specialist dietetic support in primary care, and that there are many competing priorities for the limited dietetic resources available.

It seems likely therefore, that despite the fact that the Advisors identified that 86% of patients met the NICE criteria, this judgement was primarily based upon the hard objective evidence of BMI and existence of comorbidities.

Table 4.10 Advisors' opinion on the adequacy of dietetic input for those with evidence of having received input pre-surgery

Adequate dietetic assessment/education for patient	Number of patients	%
Yes	195	92.9
No	15	7.1
Subtotal	**210**	
Insufficient data	27	
Total	**237**	

Advisors were asked to consider whether the dietetic input for each patient was adequate (Table 4.10). In 210/237 patients where there was evidence of dietetic input, an assessment of the adequacy of that dietetic input was possible. Of these 195/210 (93%) were judged to have received adequate input. When the whole group is considered, Advisors were of the view that overall, 78% of patients received adequate dietetic input to their care, which is consistent with the data from other sources, indicating that between 20% and 25% of patients did not apparently receive any dietetic input from a dietitian prior to surgery (Table 4.11).

Table 4.11 Adequacy of pre-surgical dietetic input for all patients

Adequate dietetic assessment/education for patient	Number of patients	%
Yes	200	77.5
No	58	22.5
Subtotal	**258**	
Insufficient data	123	
Total	**381**	

Psychological input

There is considerable evidence that obese patients have a high incidence of psychological disorders, and in a recent study two thirds of patients presenting for bariatric surgery had a lifetime history of at least one psychiatric disorder, the most common of which was a major depressive disorder[15]. Despite this less than a third of patients had any documented evidence of having received psychological support (Table 4.12).

Table 4.12 Documented evidence of psychological support

Documented psychological support	Number of patients	%
Yes	91	29.4
No	218	70.6
Subtotal	**309**	
Insufficient data	72	
Total	**381**	

In those patients who actually did receive some form of psychological input, in the majority this occurred following referral. Given the known level of psychological disorders in this patient group, it might seem more appropriate for assessment to be made at an earlier stage in the care pathway, prior to referral for consideration of surgical intervention. It is possible that a greater number of patients received formal or informal psychological assessment and support within primary care prior to referral, but our Advisors were only able to identify that this had occurred in 20 patients, from the records provided to them (Table 4.13).

Table 4.13 Documented timing of psychological support

Timing of assessment/ education	Number of patients	%
Pre-referral	20	23.3
Pre and post-referral	7	8.1
Post-referral	59	68.6
Subtotal	**86**	
Insufficient data	5	
Total	**91**	

Advisors were asked to judge whether the level of psychological input was appropriate for those who had documentary evidence of having received some input. They were of the opinion that in 91% of cases where they had sufficient data, that input was adequate in the circumstances of the particular patient (Table 4.14).

Table 4.14 Advisors' opinion on the adequacy of psychological input for those with documented evidence of having received input pre-surgery

Adequate psychological support for those receiving input	Number of patients	%
Yes	72	91.1
No	7	8.9
Subtotal	**79**	
Insufficient data	12	
Total	**91**	

Table 4.15 Adequacy of pre-surgical psychological input for all patients

Adequate psychological support for all patients	Number of patients	%
Yes	108	66.7
No	54	33.3
Subtotal	**162**	
Insufficient data	219	
Total	**381**	

However when considering the psychological needs of the whole patient group, they were unable to make an assessment based on the data provided in 219/381 (57%) of patients. Where they could make an assessment it was their opinion that 54/162 (33%) patients did not have adequate psychological support (Table 4.15).

Case Study 2

A middle-aged patient with a BMI of 41 and longstanding depression and other mental health problems was referred because of being self conscious and unable to exercise. The patient admitted eating and smoking more when depressed. Although they had been under the care of psychiatrists in the past, there was no evidence of liaison and no psychological input prior to surgery. The patient underwent gastric bypass because of concerns about their ability to comply with band surgery. Surgery was uneventful but by 6 weeks the patient had lost 3.5 stone and was complaining of swallowing problems. At 6 months the patient weighed 44 Kg with a BMI of 18, and was admitted for intravenous feeding.

Advisors were concerned that a patient with a known history of depression who had previously been under the care of a psychiatrist, received no psychological assessment prior to surgery. There was also concern that rapid weight loss and difficulty swallowing had not been investigated at an earlier stage post-operatively.

Case Study 3

A middle-aged patient with a BMI of 38 was referred for revision bariatric surgery because of increasing appetite and weight gain, and concern about their appearance. The patient had had a gastric band eight years previously but had also had numerous unrelated cosmetic surgical procedures. The patient was admitted within 3 weeks of referral to an independent hospital for gastric bypass. There was no psychological input despite concerns about dysmorphophobia being recorded. The correspondence to the patient stressed that financial penalties would apply if the patient cancelled surgery.

Advisors were concerned about the haste with which the patient was admitted for surgery, and felt that there was undue financial pressure. They were also concerned about the lack of formal psychological input, in a patient in whom the possibility of dysmorphophobia had been identified.

Pre-assessment and comorbidities

Table 4.16 Documented evidence of comorbidities

Comorbidity	Yes	No	Subtotal	Unknown	Total
Type 2 diabetes	80 (25%)	238	**318**	63	**381**
Sleep apnoea	58 (20%)	234	**292**	89	**381**
Hypertension	126 (39%)	201	**327**	54	**381**
Cardiovascular disease	27 (9%)	268	**295**	86	**381**
Gastro oesophageal reflux	74 (25%)	222	**296**	85	**381**

The frequency of those comorbidities most commonly associated with obesity, which could be identified from the records is shown in Table 4.16. Whilst hypertension was common, occurring in 126/327 (39%), type 2 diabetes occurred in 80/318 (25%), sleep apnoea in 58/292 (20%) and other cardiovascular disease in 27/295 (9%). In the overwhelming majority of cases, comorbidities were judged to have been managed appropriately. Only five patients with diabetes were not seen in a pre-assessment clinic, but 9/48 of patients with sleep apnoea were not seen in a pre-assessment clinic. Only 21/51 of patients with sleep apnoea were seen by an anaesthetist prior to admission. Of the 30 sleep apnoeic patients who were not seen by an anaesthetist, Advisors felt that two thirds (20) should have been seen, in the main because of potential airway problems or the seriousness of their sleep apnoea and other pre-existing comorbidities. Only 11/58 of patients with sleep apnoea were seen by a respiratory physician prior to admission.

The majority of patients 239/311 (77%) had documentary evidence of having been assessed in a pre-anaesthetic assessment clinic (PAAC), however it is clear from the data about patients having been assessed by an anaesthetist (Table 4.17), that the majority of the clinics did not involve a review by an anaesthetist.

Table 4.17 Documented evidence of attendance at a pre-assessment clinic

Seen in pre-assessment clinic	Number of patients	%
Yes	239	76.8
No	72	23.2
Subtotal	**311**	
Insufficient data	70	
Total	**381**	

Advisors were of the opinion that 30/57 patients who were not seen in PAAC would have benefited from being seen and assessed (Table 4.18).

Table 4.18 Advisors' opinion on whether or not patients not seen in a pre-assessment clinic, should have been seen

Patient should have been seen in pre-assessment clinic	Number of patients	%
Yes	30	52.6
No	27	47.4
Subtotal	**57**	
Insufficient data	15	
Total	**72**	

Case Study 4

A middle-aged patient with a BMI of 35 was referred to the NHS for weight loss surgery because of depression about their weight. The patient had been referred to the haematologists after a recent admission for chest pain where haemoglobin of 10g/dL was discovered.
The patient did not attend a pre-assessment anaesthetic clinic and no pre-operative blood tests were performed. By the time they were admitted for bariatric surgery the patient had still not seen the haematologists. The patient was admitted on the day of surgery. Due to past substance abuse the patient had poor IV access they therefore had gas induction followed by IM suxamethonium and was then ventilated on a laryngeal mask while a central venous line was inserted. The patient underwent a gastric bypass, and post operatively required an 11 unit blood transfusion with the haemoglobin falling to 5.4g/dL at one stage. No source of haemorrhage was sought or identified and the patient was discharged on the second post-operative day. Six weeks following surgery the patient was discovered to have myelodysplasia and following a marrow transplant their weight dropped to 62Kg.

Advisors had concerns about several aspects of this patient's care, but noted that the patient would undoubtedly have benefitted from being discussed at an MDT and receiving a pre-anaesthetic assessment and appropriate investigations prior to admission.

Advisors were also asked to identify whether or not patients had been seen by an anaesthetist prior to admission (Table 4.19).

Table 4.19 Documented evidence that the patient was seen by an anaesthetist prior to admission for surgery

Seen by anaesthetist prior to admission for surgery	Number of patients	%
Yes	100	31.6
No	216	68.4
Subtotal	**316**	
Insufficient data	65	
Total	**381**	

In the 216/316 (68%) of cases where assessment was possible the patient had not been seen by an anaesthetist prior to admission.

Whilst less than ideal, this in itself is perhaps not surprising because despite obesity, many of the patients are young and do not have any comorbidities. However there are a substantial number of patients who do have comorbidities which are of clinical significance for the anaesthetist, and have a bearing on the determination of anaesthetic risk. The ASA status of the patient did not appear to have had a major impact on whether the patient was seen by an anaesthetist or not (ASA 1 27%, ASA 3 34%). Ideally all obese patients should be seen pre-operatively prior to admission not only for assessment but also to be given information about the anaesthetic in order to enable the patient to reach an informed decision about treatment.

In a third (60/185) of those patients who did not see an anaesthetist before admission and where assessment could be made, the Advisors were of the opinion that they should have been seen by the anaesthetist prior to admission (Table 4.20).

Table 4.20 Advisors' opinion on whether the patient should have seen an anaesthetist before admission

Should they have been seen by anaesthetist	Number of patients	%
Yes	60	32.4
No	125	67.6
Subtotal	**185**	
Insufficient data	31	
Total	**216**	

Whilst it is recognised that not all patients undergoing bariatric surgery need to be assessed prior to admission, The Royal College of Anaesthetists recommends that all patients, (particularly those at risk of being difficult to intubate with a BMI > 26), should have an assessment of the predicted difficulty of intubation recorded in their records[16], even if this is only done immediately prior to induction of anaesthesia. Furthermore a recent National audit of serious airway complications identified that in almost half of the patients in which serious airway complications arose, obesity was a significant contributory factor. The ultimate outcomes following airway complications were also more serious for obese patients, with more suffering serious brain injury or death[17].

Table 4.21 Documentation of predicted difficulty of intubation

Predicted level of intubation (documented evidence)	Number of patients	%
Yes	230	68.5
No	106	31.5
Subtotal	**336**	
Insufficient data	45	
Total	**381**	

As can be seen from Table 4.21, in almost a third of patients, there was no documented evidence of the predicted difficulty of intubation. Advisors were of the view that this should be recorded in all cases.

Physical status of patients

The majority of patients receiving surgery in this sample were relatively fit ASA grade 1 or 2. However there were 60 (22%) patients identified as being grade 3. In 97/375 (26%) of patients the ASA was not recorded (Table 4.22).

Table 4.22 Documented ASA grade

ASA grade	Number of patients	%
1	37	13.3
2	181	65.1
3	60	21.6
Subtotal	**278**	
Not recorded	97	
Insufficient data	6	
Total	**381**	

Whilst the limitations of ASA status are well recognised, the benefits of recording ASA status as a simple component of risk assessment for an individual patient, and in facilitating more meaningful comparative audit, are generally accepted.

Table 4.23 Advisors' opinion on the overall quality of pre-assessment

Pre-assessment	Number of patients	%
Good	112	36.1
Adequate	140	45.2
Poor	46	14.8
Unacceptable	12	3.9
Subtotal	**310**	
Insufficient data	71	
Total	**381**	

Taking all factors into account for each patient, the Advisors were asked to consider the quality of the pre-assessment process for each patient. In 71 cases they had insufficient data to make a judgement, however of the 310 patients where they had sufficient information, they stated that 58 (19%) had received poor or unacceptable levels of pre-assessment (Table 4.23). The Royal College of Anaesthetists stresses the importance of early pre-assessment to ensure that essential resources and obstacles can be anticipated before the day of surgery. Pre-assessment also ensures that patients can be appropriately risk assessed and given sufficient information, and an opportunity to discuss their planned care, in order to allow them to engage properly in the consent process[18].

Key Findings

There was wide variation in the composition and use of MDT processes in bariatric surgery. 251/377 (67%) patients were discussed at a formal MDT. Only 170/251 (68%) MDTs involved a surgeon, dietitian and specialist nurse.

90/327 (28%) patients had no documented evidence of having received dietetic input from a dietitian at any stage during their care prior to weight loss surgery.

Despite the fact that psychological disorders are known to be common in obese patients seeking bariatric surgery, in only 91/309 (29%) of patients was there evidence to demonstrate that they had received any psychological input into their care, and in the majority of those, this input occurred following referral for bariatric surgery.

The ASA grade was not recorded in 97/375 (26%) cases.

The predicted difficulty of intubation was not recorded in a 106/336 (32%) of patients, despite obese patients being known to be at greater risk.

Only 100/316 (32%) patients had documented evidence that they were seen by an anaesthetist prior to admission for surgery.

The Advisors were of the opinion that 60/185 (32%) patients that were not documented as being seen by an anaesthetist prior to admission for surgery, should have been.

In the opinion of the Advisors 58/310 (19%) patients had a less than adequate standard of pre-assessment.

Recommendations

All patients considered for weight loss surgery should receive dietary assessment and education preferably prior to referral, but definitely prior to surgery. *(Consultants, Dietitians and General Practitioners)*

All patients must have access to the full range of specialist professionals appropriate for their needs in line with NICE guidelines. *(Clinical Directors and Medical Directors)*

The value of MDTs, their optimal configuration, and their appropriateness for bariatric patients with different needs to be agreed by the healthcare professionals involved in their care. *(Specialist Associations)*

The outcome of all MDT discussions must be documented in the medical records. Where an MDT discussion has not taken place this must also be documented with reasons. *(Consultants)*

There should be a greater emphasis on psychological assessment and support and this should occur at an earlier stage in the care pathway for obese patients. Psychological screening tools are available and may be of value in identifying those patients requiring formal psychological intervention. *(Consultants)*

All bariatric patients should have an assessment of the predicted difficulty of intubation recorded. *(Anaesthetists)*

All bariatric patients should attend a pre-assessment clinic, during which they should have access to a full range of health professionals appropriate to their needs, including where required pre-admission assessment by an anaesthetist. *(Clinical Directors and Consultants)*

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5 – The inpatient episode including surgery

Consent

In all but emergency care in those patients who have capacity, a two-stage delayed consent process is regarded as good practice and is advocated by the relevant Departments of Health, in order to comply with the principles set out by the General Medical Council (GMC)[19].

The Department of Health England guidance states: *"The seeking and giving of consent is usually a process, rather than a one-off event. For major interventions, it is good practice where possible to seek the person's consent to the proposed procedure well in advance, when there is time to respond to the person's questions and provide adequate information. Clinicians should then check, before the procedure starts, that the person still consents. If a person is not asked to signify their consent until just before the procedure is due to start, at a time when they may be feeling particularly vulnerable, there may be real doubt as to its validity. In no circumstances should a person be given routine pre-operative medication before being asked for their consent to proceed with the treatment"*[20].

All patients included in this sample were admitted for elective procedures, and therefore it would have been expected that a two stage deferred consent process should have been adopted in line with GMC principles and DH guidance.

In 342/381 cases, the consent form was identified within the records and in 336/342 there was sufficient information provided for the Advisors to make an assessment of the quality of the consent form (Table 5.1).

Table 5.1 Advisors' opinion on the appropriateness of the information contained on the consent form

Information appropriate	Number of patients	%
Yes	257	76.5
No	79	23.5
Subtotal	**336**	
Insufficient data	6	
Total	**342**	

Whilst the majority of consent forms were regarded as providing appropriate information, in 79/336 (24%) the information provided on the consent form was not regarded as adequate. In the main the deficiencies identified were absence of specific risks, and the failure to quantify risks.

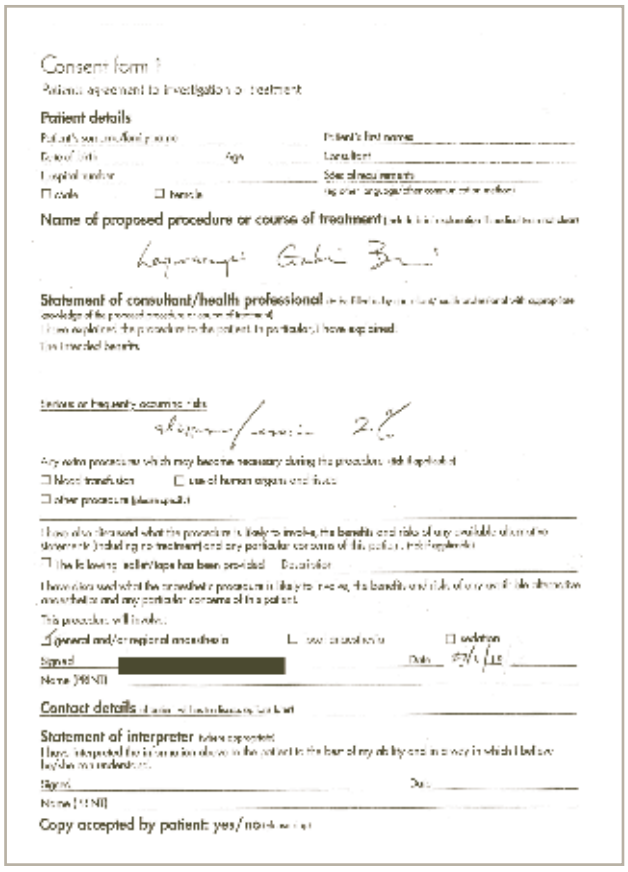
Given the vulnerability of many patients seeking bariatric surgery, and the potential side effects particularly in those patients who have significant comorbidities, it is noteworthy that over one in five patients did not have documented evidence of appropriate information having been provided to them on the consent form.

As the DH guidance highlights, obtaining consent is a process rather than a one off event. Ideally the patient should be given sufficient information, including a copy of the consent form in the outpatient consultation at the time that a decision is made for them to be listed for surgery. There should be adequate time for the patient to reflect without any undue pressure, and to seek additional advice from the treating clinicians. Ideally the signature of the patient should be obtained on the consent form at a pre-assessment clinic where the patient has a further opportunity to clarify any points of uncertainty, however it is recognised that in practice, this final signature is often only obtained at the time of admission for surgery.

Case study 5

A middle-aged patient with morbid obesity and hypertension was admitted for a gastric band. The consent form was written on the day of surgery, and gave little detail about the risks of surgery, or the anticipated benefits. Unfortunately the small bowel was damaged by the laparoscopic trochar, and the patient developed peritonitis, requiring a laparotomy the following day. The patient remained in hospital for 10 days.

A consent form is reproduced here. Advisors were of the view that failure to use a two stage consent process coupled with the paucity of information on the consent form was unsatisfactory.



Consent form

Patient agreement to investigation or treatment

Patient details

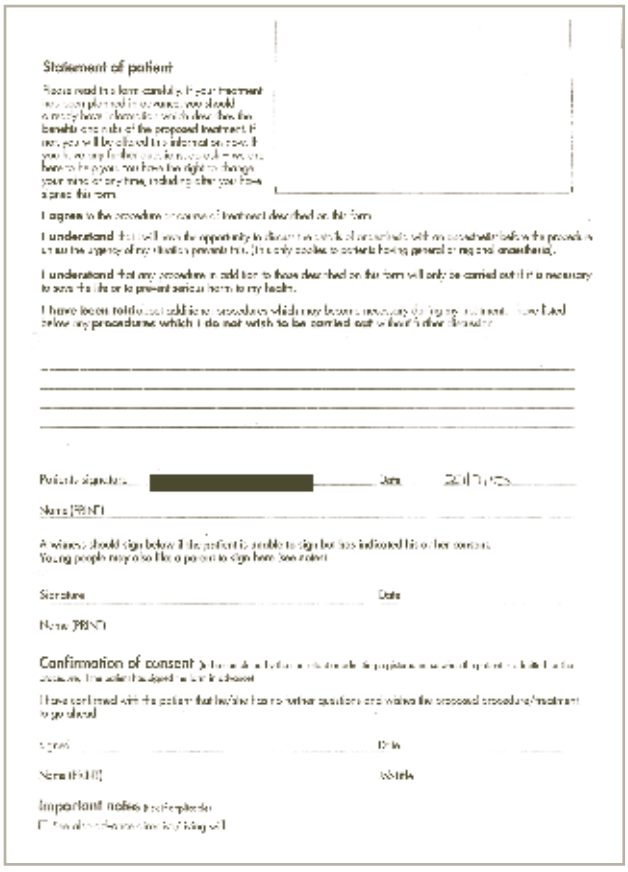
Name of proposed procedure or course of treatment

Statement of consultant/health professional

Contact details

Statement of interpreter

Copy accepted by patient: yes/no



Statement of patient

I agree to the procedure or course of treatment described on this form

I understand that I will have the opportunity to discuss my wishes with my consultant before the procedure or (unless the urgency of my situation prevents this). (This only applies to patients having general or regional anaesthesia).

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

Patient signature [redacted] Date

Name (PRINT)

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people may also like a parent to sign here, see notes.

Signature Date

Name (PRINT)

Confirmation of consent

I have explained to the patient that he/she has no further questions and wishes the proposed procedure/treatment to go ahead

Signature Date

Name (PRINT) Grade

Important notes

Case study 6

A middle-aged patient with a BMI of 60 self referred to an independent hospital because of refusal of funding by the Primary Care Trust. The patient had no comorbidities and had been unable to achieve weight loss through diet and exercise. The patient was admitted for a gastric band three weeks after initial consultation. The consent form was completed on the day of admission and stated the intended benefits as: "Weight reduction", and the risks as: "bleeding/ injury to stomach/infections". No supplemental written information was provided. A year later the patient's BMI had only reduced to 58.

Advisors were of the opinion that the consent should have been undertaken using a two stage deferred process, and written advice should have been provided at the time of the consultation. They were of the opinion that there had been undue haste and that the details recorded on the consent form were inadequate.

Anaesthetic induction

It was not possible to determine the grade of anaesthetist in 217/381 patients, but in all bar five cases where the seniority of the anaesthetist was recorded, it was a consultant. The Royal College of Anaesthetists recommends that the seniority of the anaesthetist and the level of supervision should be recorded in all cases[16].

There were 12/381 (3.1%) cases where problems were identified at induction. In six cases this related to airway management and in five cases there was profound hypotension on induction. It was only possible to determine the grade of anaesthetist in six of these cases, but in all of these the anaesthetist was a consultant.

The operation

In all but 22 cases, the primary operator was a consultant. Of the remainder all were either categorised as specialist fellows or specialist trainees, and all were supervised, in most cases with the consultant scrubbed at the operating table. Operations within this specialty are presently being provided mainly by consultants. The small number of cases which were performed by trainees may in part reflect the sampling method which is biased towards low volume independent hospitals where training is less frequent (see Chapter 3). Nonetheless this represents less than 6% of the operative activity, and raises questions about access to training in this rapidly growing area of surgery.

In this sample, most of the cases were primary procedures 371/389 (95%). Only 18 procedures were revisions or conversions.

The majority of patients underwent a laparoscopic procedure (94%), and in only three cases did a laparoscopic approach require conversion to an open approach (Table 5.2).

Table 5.2 Type of surgical approach

Operation	Number of patients	%
Laparoscopic	366	93.6
Endoscopic	11	2.8
Open	11	2.8
Laparoscopic converted to open	3	<1
Subtotal	**391**	
Not answered	6	
Total	**397**	

Table 5.3 Type of surgical procedure

Operation	Number of patients	%
Gastric band	185	46.8
Roux-en-Y gastric bypass	145	36.7
Sleeve gastrectomy	47	11.9
Gastric balloon	12	3.0
Other	6	1.5
Subtotal	**395**	
Not answered	2	
Total	**397**	

Table 5.3 shows that the most commonly performed procedure in this sample group was gastric banding (47%) followed by gastric bypass (37%). Given the sampling method, where the number of cases was limited to a maximum of three cases per surgeon per hospital, it is possible that this sample may not reflect the overall distribution of operation type. The proportion of gastric bands performed was much higher in those patients who were privately funded, compared to those receiving NHS treatment (Figure 5.1).

The National Bariatric Surgery Registry (NBSR)[8] reported in 2010 that overall gastric bands represented 31% of surgical procedures against 55% for gastric bypass. In their sample, 69% were publicly funded compared with 57% in this sample. The NBSR data are therefore likely to be biased toward the NHS units which submit a proportionately greater number of returns to the audit. Taking these factors into account, we believe that the data presented in Figure 5.1 are consistent with the range of surgical procedures reported within the NBSR.

Those patients with a greater BMI were more likely to undergo either a sleeve gastrectomy or a bypass procedure, with gastric bands being more commonly performed for those patients with lower BMIs (Figure 5.2).

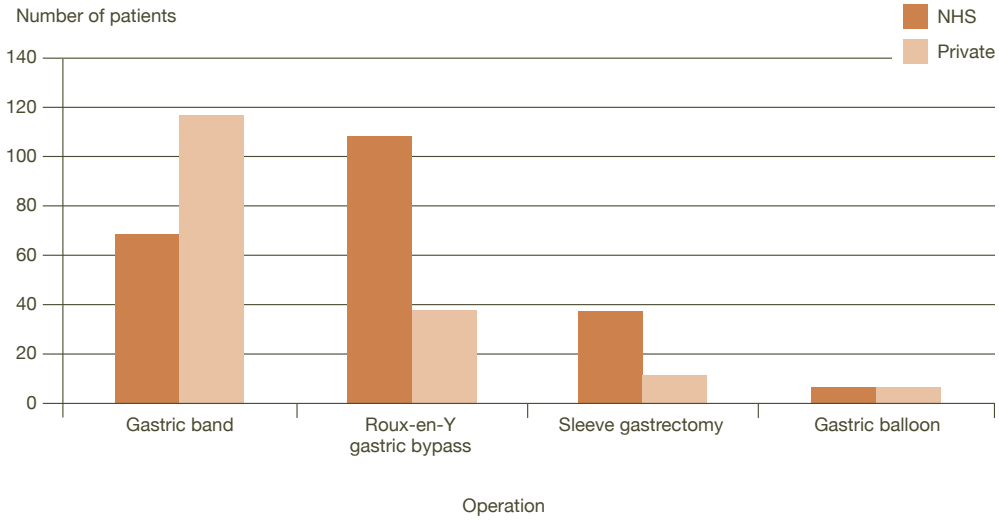


Figure 5.1 Type of surgical procedure by type of funding

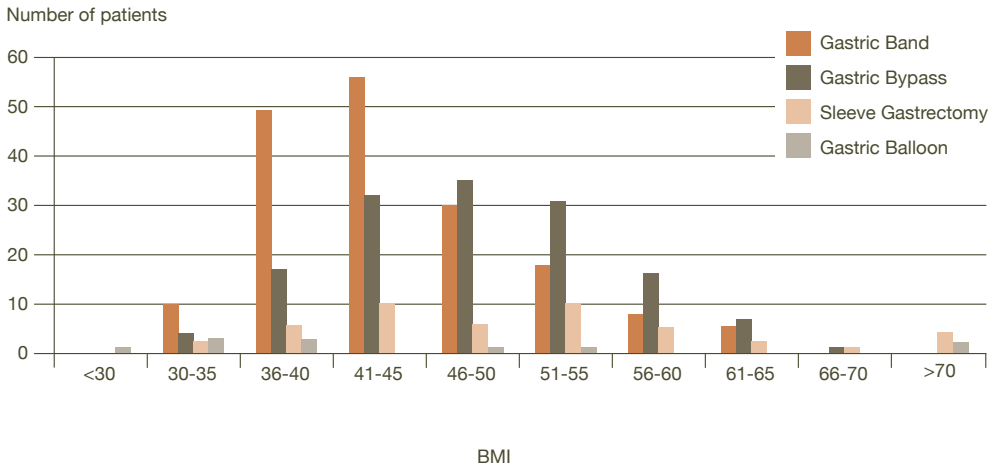


Table 5.2 Type of operation performed by BMI

Intra-operative monitoring

In most cases intra-operative monitoring was judged to be adequate. The small number of patients (13) where this was not the case had deficiencies in temperature monitoring or the frequency with which observations were recorded (Table 5.4).

Table 5.4 Advisors' opinion on the adequacy of the intra-operative monitoring

Adequate monitoring	Number of patients	%
Yes	315	96.0
No	13	4.0
Subtotal	**328**	
Insufficient data	53	
Total	**381**	

There were 18 cases where the operation deviated from the planned procedure.

Table 5.5 Type of untoward event

Type of untoward event	Number of patients
Minor surgical event	17
Potentially serious surgical event	13
Minor anaesthetic event	2
Potentially serious anaesthetic event	5
Total	**37**

In 37/367 (10%) there was an intra-operative untoward event or complication recorded. These were categorised as shown in Table 5.5.

Ten of the potentially serious surgical complications were related to bleeding either from the stomach, liver or spleen, but in only four cases in the whole sample was a blood transfusion required.

Post-operative care

The majority of patients 282/394 (72%) were nursed in Level 0/1 wards in the post-operative period (Table 5.6).

Table 5.6 Level of post-operative ward care

Ward Level	Number of patients	%
Level 0	199	50.5
Level 1	83	21.1
Level 2	94	23.9
Level 3	18	4.6
Subtotal	**394**	
Not answered	3	
Total	**397**	

Patients were more likely to be cared for in Levels 2 and 3 facilities when they had received either a gastric bypass or sleeve gastrectomy (Figure 5.3).

When patients were nursed within Level 0/1 facilities most were managed using a track and trigger system. However in just 13% (33/248) of patients, a track and trigger system was not used (Table 5.7).

Table 5.7 Use of 'track and trigger' system on Level 0/1 wards

Track and trigger	Number of patients	%
Yes	215	86.7
No	33	13.3
Subtotal	**248**	
Unknown	34	
Total	**282**	

In only six of the cases nursed on Level 0/1 wards was the trigger actually activated. In those cases three simply had clinical review, one required resuscitation for rapid atrial fibrillation, one required analgesia and anti-emetics for prolonged vomiting, and one was transferred to Level 3 care. Notwithstanding this, Advisors judged that the

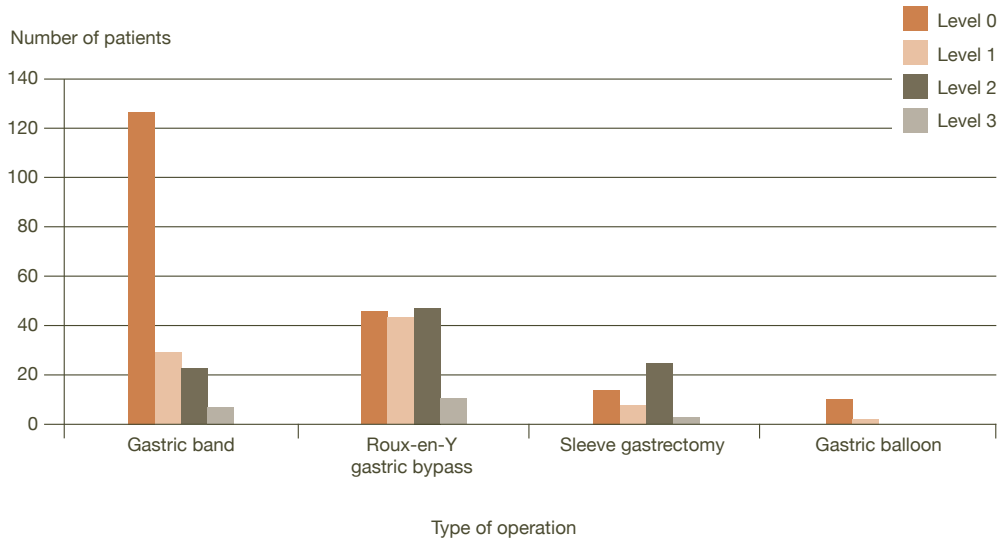


Figure 5.3 Level of ward care by type of operation

majority of patients had received an adequate level of post-operative monitoring (Table 5.8).

Table 5.8 Advisors' opinion on the adequacy of post-operative monitoring

Adequate monitoring	Number of patients	%
Yes	325	95.9
No	14	4.1
Subtotal	**339**	
Insufficient data	42	
Total	**381**	

Escalation of care was required in 18 patients (Tables 5.9 and 5.10).

Table 5.9 Documented evidence of an escalation in care

Escalation in care	Number of patients	%
Yes	18	4.9
No	350	95.1
Subtotal	**368**	
Insufficient data	13	
Total	**381**	

Table 5.10 Reason for escalation in care

Reason for escalation	Number of patients
Respiratory	5
Peritonitis/leak	3
Cardiovascular/cardiac	3
Bleeding	2
Sepsis	2
Urinary retention	1
Ketoacidosis	1
Unspecified	1
Total	**18**

Case study 7

A middle-aged patient with a BMI of 53 and chronic obstructive pulmonary disease was listed for laparoscopic sleeve gastrectomy and cholecystectomy. Technical difficulties during the procedure resulted in conversion to an open procedure. The patient was transferred to critical care. On the first post operative day the patient was noted to be tachycardic and tachypnoeic with hypotension. A CT scan showed basal atelectasis. There was progressive deterioration over the next week. On the 10th post-operative day it was decided to take the patient back to theatre and a large defect in the gastric tube was found. The patient died on day 13.

Advisors made the following observations on this case: Post operative tachycardia and tachypnoea should be considered as being indicative of complications and a leak must always be excluded.

Only 11 patients had either an unexpectedly prolonged stay in critical care, or required unexpected readmission to Level 2 or 3 facilities (Table 5.11).

Table 5.11 Unexpected duration of stay or readmission to Level 2/Level 3

Unexpected Level 2/Level 3 stay or readmission	Number of patients	%
Yes	11	2.8
No	383	97.2
Subtotal	**394**	
Not answered	3	
Total	**397**	

Unplanned interventions were required in 28 cases. The majority of these were relatively minor procedures for port problems, however some were more significant (Table 5.12).

Table 5.12 Documented unplanned interventions or imaging

Unplanned interventions/ imaging	Number of patients	%
Yes	28	7.6
No	340	92.4
Subtotal	**368**	
Insufficient data	13	
Total	**381**	

Imaging can give a high false negative rate for detecting leak[21]. All staff caring for bariatric patients in whatever care setting should be familiar with the significance of physical signs which may herald the development of underlying serious complications. Laparoscopy or laparotomy is the procedure of choice where a leak is suspected. Timing is of the essence; delay of greater than 48 hours leads to poor outcomes.

Advisors were of the view that despite the fact that the majority of patients who are cared for in a Level 0/1 ward area post-operatively experience an uneventful recovery, a 'track and trigger' system should always be used in order to identify the deteriorating patient and ensure that appropriate escalation of care is initiated when required, so that complications are identified at an early stage and to mitigate against potentially catastrophic consequences.

Post-operative clinical review

It was notable that in 121/381 (32%) cases, Advisors were unable to assess whether there was an adequate level of senior clinical review in the post-operative period. As with many previous NCEPOD studies, it was noted that the grade of doctor undertaking clinical review was often difficult to ascertain.

Table 5.13 Advisors' opinion on the adequacy of senior clinical reviews

Adequate senior reviews	Number of patients	%
Yes	228	87.7
No	32	12.3
Subtotal	**260**	
Insufficient data	121	
Total	**381**	

However where the information was available, the majority of patients received an adequate level of appropriate seniority of clinical review (Table 5.13).

When asked to make a global assessment of the standard of post-operative care, Advisors judged that most patients received good or adequate care, but it was poor or unacceptable in 31 cases (Table 5.14).

Table 5.14 Advisors' opinion on the overall quality of post-operative care

Post operative care	Number of patients	%
Good	184	55.8
Adequate	115	34.8
Poor	27	8.2
Unacceptable	4	1.2
Subtotal	**330**	
Insufficient data	51	
Total	**381**	

A discharge summary was included in the notes in 279 cases. The quality of discharge summaries was assessed as poor or unacceptable in almost 20% (54/275) of cases (Table 5.15).

Table 5.15 Advisors' opinion on the quality of the discharge summary

Discharge summary	Number of patients	%
Good	119	43.3
Adequate	102	37.1
Poor	42	15.3
Unacceptable	12	4.4
Subtotal	**275**	
Insufficient data	4	
Total	**279**	

The most common reasons for the discharge summaries being judged to be poor or unacceptable related to lack of clinical details, drug and dietary information and contact details. Some discharge summaries had several deficiencies (Table 5.16).

Table 5.16 Reasons for poor discharge summary - Advisors' opinion

Poor discharge summaries	Number of patients
Clinical details	23
Drug information	18
Diet information	10
Emergency contact	9
Other	8

**Answers may be multiple n/54*

In the 244 cases where there were sufficient data available to assess the appropriateness of discharge drugs, 26 patients did not receive appropriate discharge prescriptions (Tables 5.17 and 5.18).

Table 5.17 Advisors opinion on the appropriateness of the discharge drugs

Appropriate discharge drugs	Number of patients	%
Yes	218	89.3
No	26	10.7
Subtotal	**244**	
Insufficient data	35	
Total	**279**	

Table 5.18 Reasons for inappropriate discharge prescription - Advisors' opinion

Reason for inappropriate discharge prescription	Number of patients
Lack of venous thromboembolism prophylaxis	9
Lack of vitamins/supplements	10
Inappropriate diabetic regimen	2
Lack of anti-emetic or proton pump inhibitors	2
Failure to prescribe pre-operative medication	1
Inappropriate dispersible analgesia	2
Inappropriate vitamin B12	1

**Answers may be multiple n/26*

Management of diabetes

In 10/80 of diabetic patients the post-discharge regimen for management of diabetes was identified as inappropriate. However of the remaining 70 patients, in only 33 cases was good information identifiable, and in the remaining 37, Advisors were unable to assess. It is important to recognise that following bariatric surgery, patients undergo rapid and significant metabolic changes, and therefore, close observation and appropriate modification of drug therapy is required in diabetic patients to ensure good glycaemic control, and there must be clear and timely communication about the treatment plan with the GP.

Dietetic regimen

In 17 cases Advisors identified that insufficient or inappropriate dietary advice was identifiable on discharge. Also in 189/381(50%) of cases Advisors were unable to assess whether the dietetic advice given was appropriate or not. In the absence of adequate dietetic support, patients who undergo bariatric surgery may fail to achieve or sustain the planned weight loss, and may suffer from nutritional deficiency.

Length of hospital stay

The majority of patients receiving a gastric band stayed no more than 24 hours in hospital. Most patients undergoing gastric bypass or sleeve gastrectomy had been discharged within 72 hours (Figure 5.4). These figures for length of stay are consistent with the data reported to the NBSR.

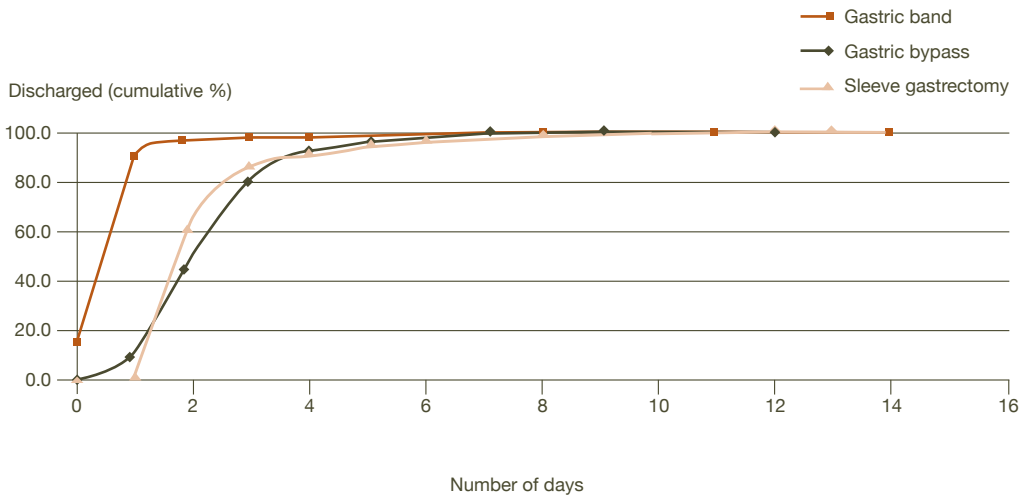


Figure 5.4 Length of hospital stay by type of operation

Key Findings

Consent forms did not contain appropriate information in 79/336 (24%) of cases.

An intra-operative untoward event or complication occurred in 37/367 (10%) cases. 18/37 were potentially serious, with bleeding being the most common complication.

A 'track and trigger' system was not employed in 33/282 of patients nursed on level 0/1 wards.

54/275 (20%) discharge summaries were judged to be poor or unacceptable often providing insufficient clinical detail and drug information.

Recommendation

As for all elective surgery, a deferred two-stage consent process with sufficient time lapse should be utilised, and details of benefits and risks should be clearly described, and supported with written information. The consent process should not be undertaken in one stage on the day of operation for elective bariatric surgery. *(Medical Directors [policy] and Consultants [implementation])*

Given the potential for significant metabolic change (and its dietary dimension) after bariatric surgery, good quality care is supported if patients have clear post-operative dietary guidance and a timely and complete discharge summary, with full clinical detail and post discharge plan to ensure safe and seamless care. This must be provided to the GP as soon as possible following discharge, preferably within 24 hours. *(Consultants and Dietitians)*

All patients nursed outside of critical care should be managed with a 'track and trigger' system. *(Medical Director or Nursing Director)*

6 – Follow-up

From the case notes the Advisors could see evidence that the patient was readmitted during the first six months post surgery in 58/315 cases (Table 6.1). For 66 patients it was not possible to determine this from the case notes provided.

The data on readmissions are displayed by type of operation in Table 6.2. A similar percentage of patients were readmitted within six months of surgery for gastric band and bypass patients. The six patients that were readmitted after insertion of a gastric balloon all had their balloon removed, three of which complained of nausea and vomiting (unable to tolerate the balloon).

Table 6.1 Documented evidence of patient being readmitted during the first six months post discharge

Patient readmitted	Number of patients	%
Yes	58	18.4
No	257	81.6
Subtotal	**315**	
Unknown	66	
Total	**381**	

Table 6.2 Documented evidence of patient being readmitted during the first six months post discharge by type of operation

	Readmitted within six months of surgery				
Operation	**No**	**Yes**	**Subtotal**	**Unknown**	**Total**
Gastric band	121	26 (18%)	**147**	32	**179**
Roux-en-Y gastric bypass	97	23 (19%)	**120**	22	**142**
Sleeve gastrectomy	32	2 (6%)	**34**	11	**45**
Balloon	4	6 (60%)	**10**	1	**11**
Other	3	1 (25%)	**4**	0	**4**
Total	**257**	**58 (18%)**	**315**	**66**	**381**

Table 6.3 Documented reasons for readmission

Reason for readmission	Gastric band	Roux-en-Y gastric bypass
Re-operation	13	8
Pain, dysphagia or vomiting	5	6
Medically unwell	1	0
Unconnected admission	2	2
Other	1	6
Unknown	4	1
Total	**26**	**23**

Whilst the percentage readmission rates for both gastric bands and bypasses was almost 20%, Advisors were of the opinion that bariatric surgeons have a very low threshold for re-admitting patients, in order to exclude post-operative complications which if left undiagnosed may be fatal. The reasons for readmission are shown for the gastric band and bypass patients in Table 6.3. Thirteen gastric band (13/147, 9%) and eight gastric bypass (8/120, 7%) patients, required a re-operation within six months of their initial surgery. Eight of the re-operations for the gastric band patients were for minor port alterations.

Table 6.4 Follow-up with operating surgeon in the first six months post-discharge

Seen by surgeon in first six months	Number of patients	%
Yes	281	74.7
No	95	25.3
Subtotal	**376**	
Not answered	21	
Total	**397**	

As shown in Chapter 5 the large majority of patients were operated on by a consultant grade surgeon. Table 6.4 shows that approximately 75% (281/376) of patients were seen by the operating surgeon, as part of their follow-up, within six months of surgery.

When these data were split by type of funding, a major difference is revealed (Figure 6.1). Ninety percent (142/157) of privately funded patients were seen by the operating surgeon within six months of surgery. The corresponding figure for NHS funded patients was 63% (139/219). It should be noted that the large majority of patients that weren't seen by the operating surgeon, were seen by an alternative consultant bariatric/upper GI surgeon within six months of surgery.

The Advisors peer reviewing the case notes were asked if they felt the patient had received adequate follow-up in the first six months post surgery. This opinion was based on the outpatient notes and follow-up/clinic letters and also information in the clinician questionnaires. It is of concern that, in the opinion of the Advisors, almost one third of patients did not receive adequate follow-up.

When only the cases in which there was documented evidence of follow-up were analysed, a similar percentage (30%, 54/179) were judged to have had inadequate follow-up in the first six months post surgery (Table 6.5).

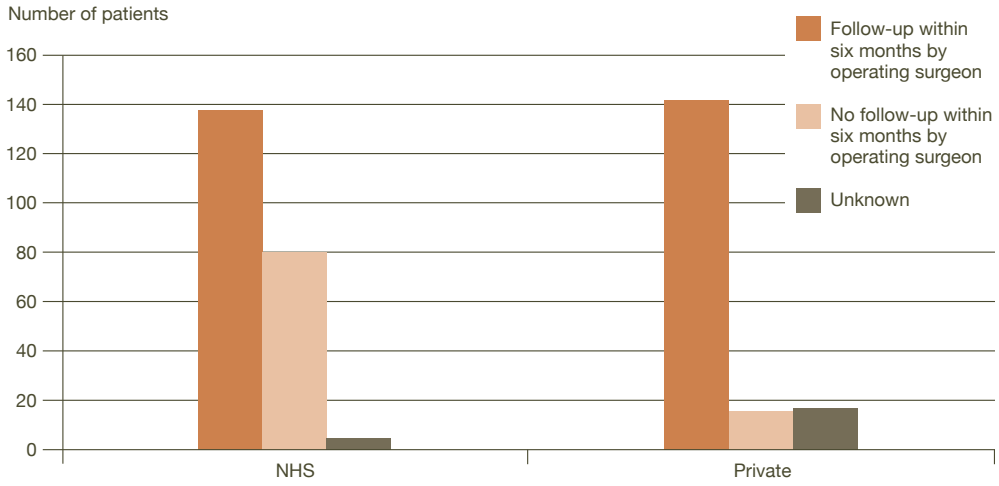


Figure 6.1 Follow-up with operating surgeon in the first six months post-discharge by type of patient funding

Table 6.5 Advisors' opinion on the adequacy of patient follow-up

Adequate follow-up	Number of patients	%
Yes	215	67.8
No	102	32.2
Subtotal	**317**	
Unknown	64	
Total	**381**	

There was no difference in the Advisors' opinion on adequacy of follow-up when the data were split by type of patient funding, 57/178 (32%) of NHS and 37/121 (31%) privately funded patients were judged to have had inadequate follow-up in the first six months post surgery (Figure 6.2).

One of the reasons the Advisors commonly gave for inadequate follow-up was the timing of the first post-discharge appointment. Figure 6.3 shows the time to first follow-up appointment for all the patients that had a date of discharge and follow-up recorded in the clinician questionnaire (348/397 cases). The median time to first follow-up post discharge was six weeks (range 1–26 weeks). One hundred and fifty four patients had their first follow-up appointment more than six weeks after discharge.

In addition to time to first follow-up appointment, common reasons given for judging follow-up to be inadequate were concerned with the frequency of follow appointments, lack of dietitian and/or surgeon involvement, particularly when potential problems were seen in the initial follow-up (failure to act).

Data extracted from the clinician questionnaire (which were completed by the operating surgeon) revealed that 57% (216/381) of the study population had been entered into the NBSR (Table 6.6). This figure may not represent the actual percentage of cases that are entered into the NBSR as a whole, since the study sample was limited to 3 patients per surgeon per hospital. However it does

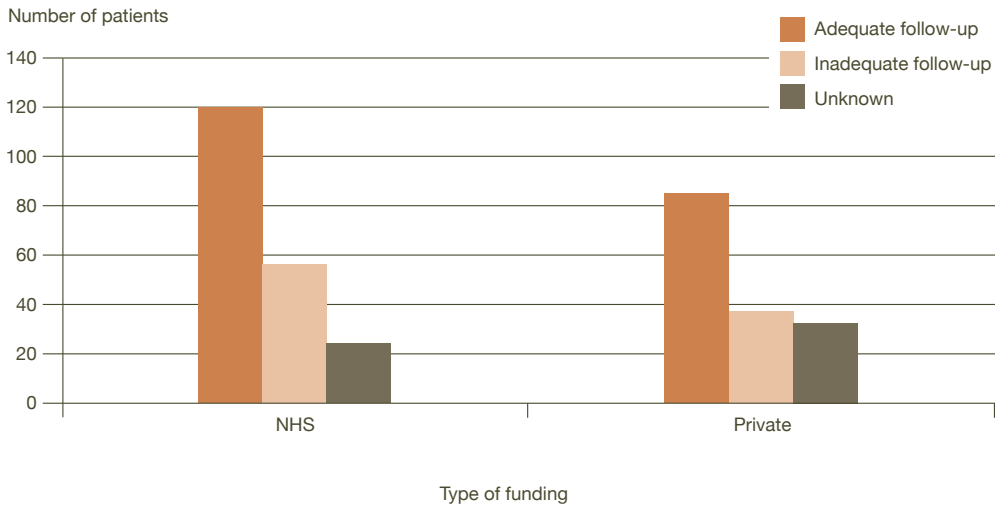


Figure 6.2 Advisors' opinion on the adequacy of patient follow-up by type of funding

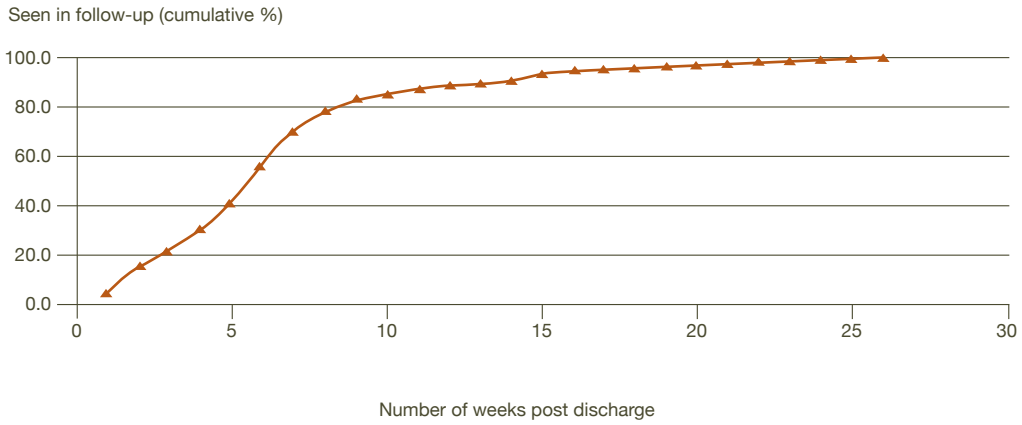


Figure 6.3 Time from discharge to first outpatient appointment

Table 6.6 Patient entered into the NBSR

Patient entered into the NBSR	Number of patients	%
Yes	216	56.7
No	165	43.3
Subtotal	**381**	
Not answered	16	
Total	**397**	

demonstrate that data for a large number of patients were not being entered into the NBSR at the time of this study. When these data were assessed by type of funding (Figure 6.4), a marked difference is seen, with approximately 149/213 (70%) of NHS funded patients compared to 64/166 (40%) of privately funded patients being entered into the NBSR.

In addition to time of surgery data, the NBSR also collects follow-up data, which allows information on areas such as progression of weight loss, remission of obesity related disease and complications to be accumulated. Almost 30% of the cases initially entered into the NBSR at the time of surgery, did not have any follow-up data entered into the registry at the time data were collected for the present study (in most cases this was approximately one year post-surgery) (Table 6.7).

Of the 165 patients who were not entered into the NBSR at the time of surgery, 92 were entered into an audit or registry of some description. This tended to be a surgeon's personal database or one collated by the hospital in which the operation took place (Table 6.8).

Table 6.7 Patient follow-up data entered into the NBSR

NBSR follow-up data	Number of patients	%
Yes	145	71.1
No	59	28.9
Subtotal	**204**	
Not answered	12	
Total	**216**	

Table 6.8 Participation in other bariatric surgery audits or registries

Other audit or registry	Number of patients	%
Yes	92	61.3
No	58	38.7
Subtotal	**150**	
Not answered	15	
Total	**165**	

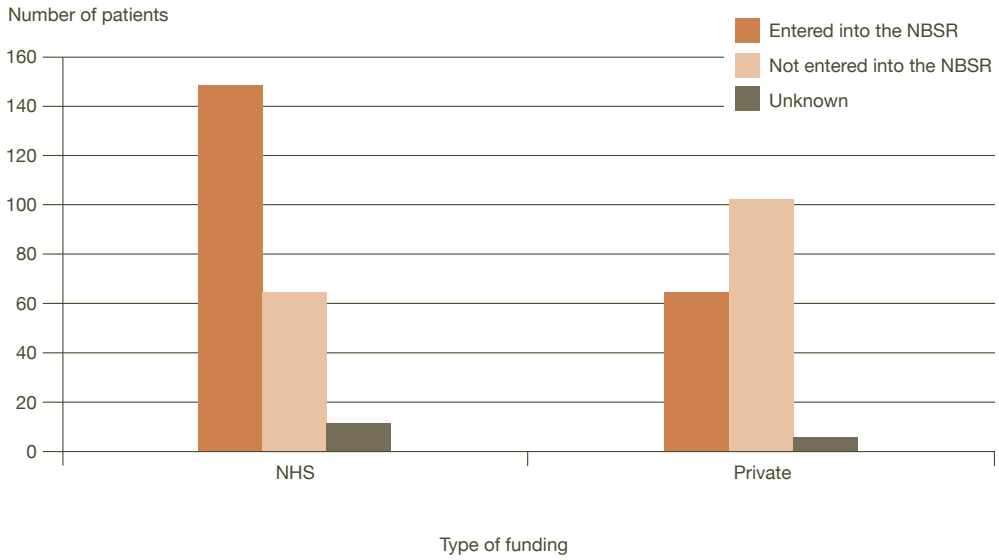


Figure 6.4 Patient entered into the NBSR by type of funding

When the above 92 patients were combined with those entered into the NBSR, 308/381 (81%) of patients were entered into some form of audit/registry.

Case study 8

A middle-aged patient with BMI of 54, type 2 diabetes, hypertension, back pain and depression, underwent a laparoscopic gastric band. Surgery was uneventful and the patient was discharged the following day. The discharge summary was brief and made no reference to post-operative diabetic management regimen. Although the discharge summary stated that the patient would be reviewed in 6 weeks, the review appointment with the specialist nurse was in fact arranged for just over 3 months later. The patient was subsequently re-admitted as an emergency to another hospital 4 weeks following discharge, and transferred back to the treating team. Following conservative management, abdominal pain and vomiting settled and after 8 days the patient was discharged. The subsequent discharge summary was even more brief. The only documented review appointment was with the specialist nurse 3.5 months after the initial operation, following which the patient was discharged.

Advisors were of the view that discharge communication with the GP should have been much better, there should have been a planned earlier post-discharge review, and there should have been review by a clinician, particularly as the patient had encountered complications.

Key Findings

58/315 (18%) patients were readmitted within the first six months of surgery, 21 of which required a re-operation.

154/348 (44%) patients had their first follow-up appointment greater than six weeks after discharge.

In the opinion of the Advisors, 102/317 (32%) patients did not receive adequate follow-up in the first six months post surgery.

216/381 (57%) patients in the study population were entered into the NBSR. This figure fell by a further 59 patients when it was determined whether follow-up data had been entered into the NBSR.

If all databases and registries are considered 308/381 (81%) patients were included in some form of audit/data collection tool.

Recommendations

Surgery and follow-up data on all patients undergoing bariatric surgery, in the NHS and independent sector, should be entered into the NBSR. *(Consultants)*

A clear, continuous long-term follow-up plan must be made for every patient undergoing bariatric surgery. This must include appropriate levels of informed surgical, dietitian, GP and nursing input. An assessment for the requirement of physician and psychology/psychiatric input must be made and provided should the patient require it. *(Consultants)*

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7 – Overall assessment of care

Figure 7.1 Advisors' overall assessment of care

The Advisors were asked to assign a grade to the overall care received by each patient in the study (Figure 7.1). This grade relates to the care the patient received during the whole patient pathway, from referral to six months follow-up.

Overall care was graded as good in just 115/357 (32%) cases. In the large majority (215/357; 60.2%), the Advisors' judged that there was room for improvement in the clinical and/or organisational care of the patient. There were 27 patients for which it was felt that the overall care was less than satisfactory.

The next two chapters give an overview of two separate aspects of bariatric surgery – advertising and the cause of death following surgery. These chapters are sub-studies within this report and draw on analysis from two different datasets.

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8 – Advertising

Background

Standards of medical advertising are guided by the code of conduct laid down by the Committee for Advertising Practice (CAP), which in turn is overseen by the Advertising Standards Authority (ASA). Certain associations such as the British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS) and the Independent Healthcare Advisory Services (IHAS) have laid down additional guidelines for the advertising of cosmetic surgical procedures, but there is no similar guidance for bariatric surgery in the UK. In 2007, The American Society of Metabolic and Bariatric Surgeons (ASMBS)[22] published a short series of guidelines for advertising which promote an approach based on professional integrity and the appropriate conveyance of accurate and factual information that should not be misleading.

Marketing materials must be drafted and designed to safeguard patients from unrealistic expectations and unjustifiable claims. Advertisements should depict real life and discounts or financial incentives must not be offered. Good medical practice states that any information that appears in print about the services a doctor provides must be verifiable, truthful and must not make claims that one practitioner is better than another. Claims should not be made about the quality or outcomes of services in any information provided to patients. Advertising must not offer guarantee of cure nor exploit a patient's vulnerability or lack of medical knowledge. Equally a patient's vulnerability must not be exploited in making charges for treatment or services.

Bariatric patients may have psychological issues that render them vulnerable. If exposed to suggestion this could lure them into agreements that promise unrealistic and unattainable goals, particularly if they focus on cosmesis and not on the central issues of comorbidity improvement and health risk reduction.

Method

Data for this review were collected in two ways:

1) An internet search for bariatric surgery advertisements in the UK using the following keywords: weight loss, obesity, surgery, bypass, band, bariatric and balloon. This included the social networking sites Twitter and Facebook.
2) An internet review of NHS Trust websites which provide bariatric services.

Information was gathered on the following eleven criteria, based on the recommendations for advertising of services as published by the American Society of Bariatric Surgeons and supplemented by observations which were felt to be of relevance:

1. Before and after photographs
2. Offers of a defined package
3. Financial incentives
4. Inclusion of outcome information at institution
5. Information about number of procedures annually/total
6. References to particular surgeons
7. Claims of association with international institutions
8. Care Quality Commission (CQC) logo/number
9. Official/unofficial quality logo
10. Social networking
11. Success stories

For the purposes of this review, bariatric surgery was defined as any intervention designed to result in weight loss through reduced caloric intake or reduced absorption of nutrients. This included advertisements for endoscopic procedures such as the Endobarrier® that are not part of mainstream NHS practice. Cosmetic procedures such as liposuction, apronectomy and other aesthetic procedures were excluded.

Results

The internet search identified a large number of websites that acted as forwarding agents for centres carrying out surgery abroad. These websites were excluded from the audit as they could not be expected to comply with UK standards of care delivery.

Twenty seven websites advertising bariatric service within the UK or as forwarding agents to UK third parties were identified. They ranged from large institutions with centres across the whole of the UK to websites set up by single surgeons advertising their own independent practice. Twenty one NHS Trusts offering bariatric services in the UK were identified and the same criteria were applied to analyse their approach to promoting their services.

Several sites offered a clear explanation of the different procedures, and a basic overview as to how they might work. Only 40% give a clear explanation of potential risks associated with surgery and the potential for failure to achieve the planned weight reduction. Before and after photographs are commonly included in advertisements, and were identified in 20/27 of independent websites and 7/21 of NHS Trust websites. The use of photographs may be beneficial to patients and provide encouragement, however they must not be misleading. In the independent sector, four websites used photographs or names of celebrities who had had surgery to promote weight loss services in a particular institution.

Offers of a defined care package were available from 15/27 of independent sector institutions compared to 2/21 of NHS Trusts. For clarification, the latter were Trusts that offer private services alongside the NHS services. These included free initial consultations and a defined period of follow-up surgery. In the independent sector, a third offered financial incentives such as interest free loans to pay for the package. One site enticed custom by offering free entry into a prize draw to win back the cost of their bariatric surgery.

Table 8.1 - Types of advertising undertaken by independent and NHS (Individual institutions may fulfil multiple criteria)

Advertising Criteria	Independent n = 27	NHS n = 21
Before and after photographs	20	7
Offers of a defined package	15	2
Financial incentives	9	1
Inclusion of outcome information for institution	0	1
Information about number of procedures annually	0	13
References to particular surgeon	15	20
Claims of association with International Institution	0	2
CQC logo/CQC registration number	1	0
Official/unofficial quality logo	2	5
Social networking	10	10
Success stories	20	8

No independent sector provider gave information about the number of procedures performed annually. In contrast, 13/21 of NHS institutions did.

Just over half of the independent units, and all but one of the NHS units gave information about the particular surgeons working in their institution and in some cases references to the number of procedures performed in total by a particular surgeon.

The Healthcare Commission previously allowed institutions that were registered with it to display its logo on advertisements, however the Care Quality Commission that replaced it has banned such practice. No NHS institution displayed the CQC logo, but it was used by one independent sector provider. There were several institutions who displayed unofficial 'quality logos' or made unsubstantiated claims of excellence. These included statements such as 'The UK's number one', offer of 'a world class service' and showing a 'guarantee of quality' rosette.

Success stories from particular patients were displayed in 20/27 of independent sector websites, compared with 8/21 of NHS websites. Although useful in informing patients, only 40% of websites were found to give clear information about the potential risks associated with the surgery associated with these stories.

Social networking through the use of websites such as Facebook and Twitter has become an extremely strong player in advertising. This audit identified links to provision of obesity services in 37% of independent institutions sites and 48% of NHS websites.

This review has identified wide variation in advertising standards. In the main, advertisements are objective but tend to portray interventions only in a very positive light. This raises some areas of concern. Independent sector advertisements seem to present bariatric procedures as quasi-cosmetic, quick-fix procedures rather than highlighting the improvement or potential risk reduction of obesity-related comorbidities. The important active role of the individual in achieving success is often obscured.

The ASMBS recommend advertisements provide accurate and factual information that should not be misleading. They advise against the *'use of superlatives or adjectives such as "premier", "best", and other laudatory statements'*[22]. The use of these superlatives has been identified in this review. The ASBMS also advises against *'claims of superiority over others and comparisons, whether direct or implied, between two or more bariatric surgeons, practices or hospitals are discouraged.'* The advertisement of one company claimed that their 'Study shows healthier weight patients lose 10% more weight than norm' The name of one independent institution could possibly be misconstrued as implying that it is a public body with the implication that it has the safeguards of the NHS. The use of celebrities in advertising is also evident and could possibly impart a false sense of quality. One company claims to have inserted a 'celebrity gastric band', with before and after photographs of a well known celebrity posing with a patient.

Key Finding

There is marked variation in the standard of weight loss surgery advertisements in the UK which would breach regulations and recommendations in other jurisdictions.

Recommendation

Professional associations and regulators should agree a code of conduct for advertisements for weight loss surgery in the UK which safeguard and appropriately advise patients seeking this increasingly popular method of weight control. *(Professional Associations)*

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9 – Pathology data: causes of death following bariatric surgery

The main study addresses the care pathway leading to bariatric surgery and some aspects of post-operative care in the following six months. This chapter, used a different methodology - since so few deaths were reported to NCEPOD - addresses generally the causes of death that may follow bariatric surgery procedures. Little is published in this area [23-26], and the results from the USA autopsy studies are heterogeneous regarding causes of death.

Methodology

With permission of the President of the Royal College of Pathologists, all active histopathologists on the RCPath email list working in the UK were approached with a request to submit autopsy reports on any post-bariatric surgery deaths they had encountered over the last 3 years. The types of bariatric surgery operations stipulated were as in Table 3.4 main report. This method was successful in 2009-10 in obtaining autopsy reports on patients dying with H1N1 infection[27].

A total of 29 autopsy reports form the dataset. All but one were medico-legal (coroner or fiscal) autopsies; one was consented, the surgeons being keen to find out what really happened in a patient with progressive liver failure.

Results

Many patients had more than one type of bariatric surgery (often gastric band then bypass), and many had revisions of primary surgery. Laparotomies following suspected leaks were universal in those who died from anastomotic leaks and sepsis/haemorrhage.

The types of most important operation prior to fatality differ in rank order from those in Table 5.3 (the types of bariatric surgery procedures reported in the main study), with gastric bypass the most common procedure preceding the reported deaths.

Gastric balloon	2
Sleeve gastrectomy	5
Gastric banding	6
Gastric bypass (laparoscopic)	16

Timing of death post-operatively

Early (up to 30 day post op)	14
Late (31 day and later)	15

The median time to death was 8 weeks, and the maximum was 16 years.

Causes of death

Qualitatively, the complications following the three operative bariatric surgery procedures (n=27) were similar, and are listed together. They are grouped as early or late deaths, and as surgery-associated or indirect.

Gastric balloon insertion preceded two deaths: one from problems in removing the balloon that resulted in the stomach splitting open; and the other due to cardiac arrest associated with a large heart.

Obesity-related liver cirrhosis was documented in 2/29 cases. It caused death directly in one patient, and contributed in another where there was post-leak peritonitis.

In one patient who died early from pulmonary embolism, the presence of a prophylactic inferior vena cava (IVC) filter did not prevent the fatality.

9 – PATHOLOGY DATA: CAUSES OF DEATH FOLLOWING BARIATRIC SURGERY

Table 9.1 Cause of death

Pathology	Surgery-related		Indirect		Total
	Early	Late	Early	Late	
Anastomotic leak and sepsis	5	5			**10**
Intra-abdominal haemorrhage	3				**3**
Adhesions and ischaemic bowel		1			**1**
Anaesthesia-related anaphylaxis	1				**1**
Malnutrition from short bowel		2			**2**
Pulmonary thrombo-embolism			4	2	**6**
Liver failure, cirrhosis				1	**1**
Cardiac arrest, large heart			1		**1**
Alcohol toxicity				1	**1**
Pandemic H1N1 influenza				1	**1**

Limitations of this autopsy data:
Clinical information is obtained only from the autopsy report and was variable

- The autopsies were not performed in a standardised manner (as noted also previously in coronial autopsy work.[28])
- The depth of clinico-pathological correlation and consistency of depiction of cause of death was variable. Where the internal evidence clearly indicated a different cause of death to the pathology reviewer, this was used for data analysis.
- There are no denominator data, i.e. we do not know what proportion of operations these cases represent nor the early or late case-fatality rates over the time period covered by the autopsies.

Discussion

The 2007 USA meta-analysis of >85,000 bariatric surgery patients' published outcomes did not focus specifically on causes of death post-bariatric surgery, but pulmonary thrombo-embolism and sepsis did stand out[24]. Early (<30 day) mortality was 0.28%, and the published 30 day to 2 year mortality was only 0.35%.

Among the published autopsy studies, the New York study found that anastomotic leak and pulmonary embolism were the top two causes of death[25]. In Los Angeles, such leaks, along with bowel necrosis and arterial injuries were most important[26]. In contrast, in Virginia[24], the majority of deaths resulted from cardiac arrhythmia in enlarged hearts, in the absence of coronary artery disease.

Most studies are agreed that late mortality (>30 days) is seriously underestimated, because significant complications ensue over months and years, and the patients are dispersed from their hospitals of primary operation.

This UK autopsy-derived data supports the previously published work, with anastomotic leaks leading to sepsis, and venous thromboembolism (VTE) as the main causes. Comparing the autopsy data with the main study data, where gastric banding and bypass were the commonest procedures (47% & 37% respectively), it might appear that Roux- en-Y gastric bypass has the higher mortality from surgical complications of anastomotic leaks and intra-abdominal haemorrhage. However, given the

methodology of the pathology review (see Limitations), this is not a solid evidence-based conclusion. The USA autopsy studies deal with bypass only[24,26] or 73% bypass procedure rate[25].

Some of the fatal emboli occurred long after the bariatric surgery procedure – obesity per se is associated with VTE. Cardiac death in those with large hearts was noted in the UK cases, supporting the concept of an obesity-associated arrhythmic cardiomyopathy. As 2/29 deaths followed gastric balloon insertion, this procedure is not necessarily free of risk.

Conclusion

Following bariatric surgery procedures, there is mortality that is not systematically audited at present, the causes of death are heterogeneous, and they include a significant proportion (about one third) that is not directly surgery-related. The proportion of post-bariatric surgery fatalities that are autopsied is not known, but from review of these 29 cases, most pathologists took the cases seriously and produced informative data. As bariatric surgery procedures will become ever more common, it will be important for pathologists to make themselves aware of the complex issues involved in the surgery and the subsequent clinical pathology. These autopsies can be very difficult. Bariatric surgery needs to feature regularly in autopsy update training sessions. Coroners should also request suitably experienced and interested pathologists to perform these cases.

We suggest a more systematic collection of post-operative clinical and pathological data, with comorbidities also evaluated. These must be correlated with the specific types of bariatric surgery. Since increasing numbers of bariatric surgery procedures are being done, time trends of mortality patterns will be important to document. Finally, the predominance of late deaths emphasises the importance of post-operative follow-up, both for individual patients and for public health data in this emerging clinical area.

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Appendices

Appendix 1 – Glossary

ASA grade	The American Society of Anesthesiologists (ASA) physical status classification system grades the fitness of patients before surgery. Where ASA1 is a healthy patient and ASA5 where the patient won't survive without an operation.
Bariatric surgery	The different types of surgery are shown in Appendix 2.
BMI	Body Mass Index: An individual's body weight divided by the square of his or her height to estimate their amount of body fat.
CT	Computed tomography
GMC	General Medical Council
IVC filter	Inferior vena cava filter: used to prevent blood clots reaching the heart and lungs.
Levels of care	Level 1: Ward care
	Level 2: High dependency unit; a specialist unit in a hospital, where patients requiring a high level of specialist intervention are cared for. High dependency unit care is appropriate for: patients needing support for a single failing organ, but excluding those needing advanced respiratory support; patients who can benefit from more detailed observation than can be safely provided on a general ward; patients no longer needing intensive care, but not yet well enough to be returned to a general ward; or postoperative patients who need close monitoring for longer than a few hours, i.e. the period normally spent in a recovery area.
	Level 3: Intensive care; an intensive care unit (ICU) is an area to which patients are admitted for treatment of actual or impending organ failure, especially when mechanical ventilation is necessary.
MDT	Multi-disciplinary team: a team made up of all different health care professionals involved in particular procedures.
MRI	Magnetic resonance imaging
NBSR	National Bariatric Surgery Registry
NCEPOD	National Confidential Enquiry into Patient Outcome and Death
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
Obesity Class II	A BMI of 35-39 Kg/m^2
Obesity Class III	A BMI of or greater than 40 Kg/m^2
PAAC	Pre-anaesthetic assessment clinic.
Track and Trigger	Track & Trigger system is used to calculate a patient's physiological score, and a designated trigger level is agreed; when this is reached, nursing staff alert a clinician.
Type 2 diabetes	Type 2 diabetes develops when the body can still make some insulin, but not enough, or when the insulin that is produced does not work properly. It is more common over the age of 40 and has been commonly known as adult onset diabetes.

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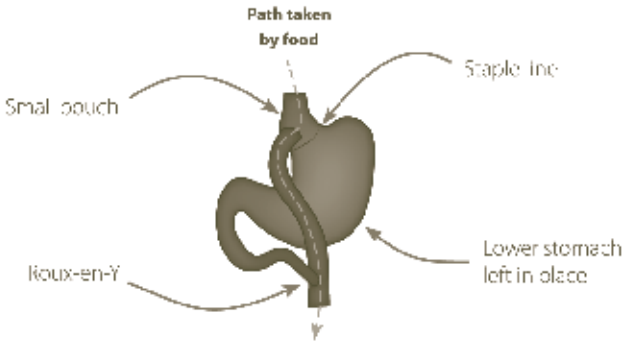
Appendix 2 – Types of bariatric surgery

Extracted from the National Bariatric Surgery Registry report, 2010 and reprinted with thanks to the NBSR Data Committee and Dendrite Clinical Systems

Gastric bypass

How it works: In this procedure the stomach is divided and stitched (by very small staples) to produce a small pouch (about 30 ml, similar to that in gastric banding). The rest of the stomach remains in the body. The intestine is rearranged so that food enters it directly, bypassing both the rest of the stomach and an initial length of intestine. These are reconnected to the remaining intestine lower down (*Roux-en-Y*).



Diagrammatic representation of a Roux-en-Y gastric bypass procedure

The operation significantly reduces the amount of food that can be eaten. It mildly reduces the amount of fat that can be absorbed from the food that is eaten. It has a direct effect that reduces appetite and this effect also improves type 2 diabetes

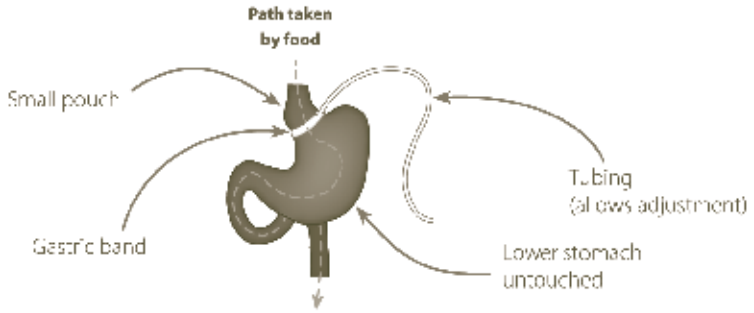
Advantages: Gastric bypass is an effective operation for producing good weight-loss with less requirement for a major change in eating habits and with lower long-term risks than other operations. It requires relatively little in the way of follow-up, but this cannot be ignored. In cases of diabetes it may be the best option.

Disadvantages: The risk at the time of surgery is greater than for simpler operations, although the risks of remaining overweight may be greater. It is irreversible and the patient must take vitamin supplements every day after their surgery.

Gastric banding

How it works: A gastric band is a synthetic ring, which is placed around the extreme upper stomach.

The result is a small pouch of about 25 ml above the band, which restricts intake capacity for solid food. A balloon on the inside surface of the band can be inflated or deflated by injecting liquid through the skin into a chamber placed under the skin (port). This simple ambulatory procedure is used to adjust restriction and produce gentle weight loss.



Diagrammatic representation of a gastric band in place

Advantages: The adjustable gastric band procedure is the safest and simplest procedure at the time of operation. This, and the feeling that nothing permanently harmful has been done to the stomach are seen by many as its great advantage.

Disadvantages: However, although it works well for most patients, it does not do so in every case. In the longer term, problems may arise which mean about 10-20% of patients may need a further operation, one-third of these as an emergency. It may not reduce appetite.

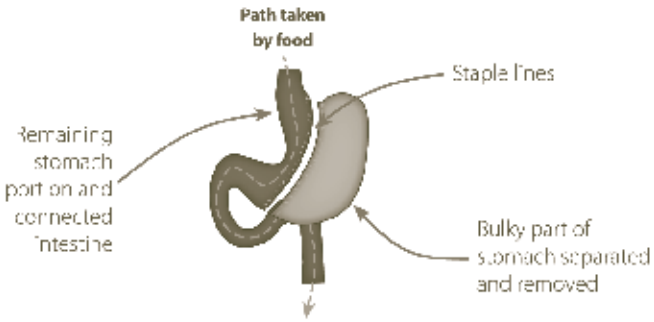
It may best suit those who seek participation in a process of change and it may be least suitable for those who cannot change or who desire complete freedom in eating.

Patients must be prepared to attend hospital for regular follow-up checks – frequently to begin with.

Appendix 2 – Types of bariatric surgery *(continued)*

Sleeve gastrectomy

How it works: In this procedure the bulky part of the stomach is separated from the rest with a long staple line and removed, leaving a narrow tube of stomach connecting the gullet to the first part of the intestine. Normal continuity is preserved, but the capacity for solid food is seriously limited. The part of the stomach that is removed produces a signalling chemical called *ghrelin* that makes people feel empty. Therefore there is also usually a reduction in appetite. The long-term weight loss is often enough, but if not, a further conversion procedure can be added later.



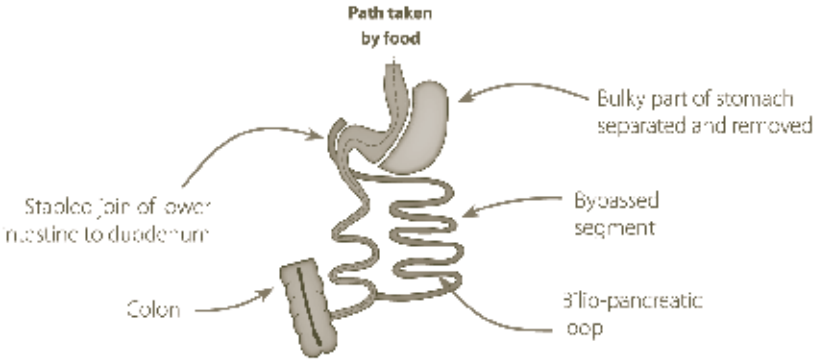
The basics of a sleeve gastrectomy procedure

Advantages: Sleeve gastrectomy is an effective operation for producing good weight-loss and can be regarded as a single-step procedure or as stage 1 of a more complicated operation in heavier patients. On its own it may be sufficient for patients with a BMI 40-50 kg m^{-2}. It is simpler than a gastric bypass, but in cases of diabetes it may be just as effective. Intestinal absorption is not interfered with, so there may be less need for long-term vitamin supplementation. Some other complications of gastric bypass will also not occur. It requires relatively little in the way of follow up, but this cannot be ignored.

Disadvantages: The long-term weight maintenance is less well proven than for gastric bypass. In patients who are more severely overweight it may not provide enough weight-loss on its own, so further surgery may be needed later. The effect on patients with severe acid reflux is not clearly established. The risk at the time of surgery is greater than for simpler operations, such as gastric banding, although the risks of remaining overweight may be greater. It is also an irreversible procedure.

Duodenal switch

How it works: In this operation the stomach is reduced in volume to some extent, usually by a sleeve gastrectomy (see above), but some patients will already have had some other stomach-reducing procedure. The purpose is to partly moderate the total intake volume.



Duodenal switch diagram

The intestine is divided once about 4 cm beyond the stomach and again 2.5 m from the large bowel. It is re-connected, so that food only passes through a very short section of the duodenum before reaching the lower intestine. The rest of the small bowel, containing bile and digestive juice, is reconnected just 1 m above the large bowel. As a result there is fixed limit to absorbing carbohydrate (starch) and fat. This imposes a fixed calorie intake capacity and so fixes the final weight.

Advantages: Duodenal switch is the most effective operation for producing weight loss and offers the best long-term weight maintenance. It allows a relatively normal volume intake capacity later on and the weight loss occurs however much is eaten.

Disadvantages: The risk at the time of surgery is greater than for simpler operations, although the risks of remaining overweight may be greater. The stomach reduction component may be irreversible. Patients who eat more fat than can be absorbed will get significant foul-smelling diarrhoea. Eating more starch than can be absorbed results in passage of foul wind. Patients who eat within these limits may get few digestive disturbances. Patients who eat beyond the limits will get the same weight loss, but will suffer these *social* side effects and are at much greater risk of long-term nutritional harm. These nutritional effects may force re-operation. The patient must take vitamin supplements every day after their surgery and careful follow-up is required.

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Appendix 3 – Role and structure of NCEPOD

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) is an independent body to which a corporate commitment has been made by the Medical and Surgical Colleges, Associations and Faculties related to its area of activity. Each of these bodies nominates members on to NCEPOD's Steering Group.

The role of NCEPOD is to describe the gap between the care that should be delivered and what actually happens on the ground. A process in which the professions themselves criticise the care that they deliver in the cause of improving the quality of the care provided to patients.

Steering Group as at 18th October 2012

Dr I Wilson	Association of Anaesthetists of Great Britain and Ireland
Mr F Smith	Association of Surgeons of Great Britain & Ireland
Dr C Mann	College of Emergency Medicine
Dr S Bridgman	Faculty of Public Health Medicine
Professor R Mahajan	Royal College of Anaesthetists
Dr A Batchelor	Royal College of Anaesthetists
Vacancy	Royal College of General Practitioners
Ms J Greaves	Royal College of Nursing
Dr E Morris	Royal College of Obstetricians and Gynaecologists
Professor Karwatowski	Royal College of Ophthalmologists
Dr I Doughty	Royal College of Paediatrics and Child Health
Dr R Dowdle	Royal College of Physicians
Professor T Hendra	Royal College of Physicians
Dr S McPherson	Royal College of Radiologists
Mr R Lamont	Royal College of Surgeons of England
Mr M Bircher	Royal College of Surgeons of England
Mr K Altman	Faculty of Dental Surgery, Royal College of Surgeons of England
Dr M Osborn	Royal College of Pathologists
Ms S Panizzo	Patient Representative
Mrs M Wang	Patient Representative

Observers

Dr R Hunter	Coroners' Society of England and Wales
Mrs J Mooney	Healthcare Quality Improvement Partnership (HQIP)
Mrs H Laing	Healthcare Quality Improvement Partnership (HQIP)
Dr J Wilson	Royal College of Physicians of Edinburgh
Mr W Tennant	Royal College of Surgeons of Edinburgh
Professor M Utley	Clinical Operational Research Unit, UCL

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	Professor L Regan
	Professor R Endacott
Company Secretary	Dr M Mason

Clinical Co-ordinators

The Steering Group appoint a Lead Clinical Co-ordinator for a defined tenure. In addition there are seven Clinical Co-ordinators who work on each study. All Co-ordinators are engaged in active academic/clinical practice (in the NHS) during their term of office.

Lead Clinical Co-ordinator	Dr G Findlay (Intensive Care)
Clinical Co-ordinators	Dr M Juniper (Medicine)
	Dr K Wilkinson (Anaesthesia)
	Dr A P L Goodwin (Anaesthesia)
	Mr I C Martin (Surgery)
	Professor M J Gough (Surgery)
	Professor S B Lucas (Pathology)

Supporting organisations

The organisations that provided funding to cover the cost of this study:

Healthcare Quality Improvement Partnership on behalf of the Department of Health in England, the Welsh Government and the Department of Health, Social Services and Public Safety (Northern Ireland) under the Clinical Outcome Review Programme into Medical and Surgical Care.

Aspen Healthcare Ltd
Beneden Hospital
BMI Healthcare
BUPA Cromwell
East Kent Medical Services Ltd
Fairfield Independent Hospital
HCA International
Hospital of St John and St Elizabeth
King Edward VII's Hospital Sister Agnes
New Victoria Hospital
Nuffield Health
Ramsay Health Care UK
Spire Health Care
St Anthony's Hospital
St Joseph's Hospital
The Horder Centre
The London Clinic
Ulster Independent Clinic

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Appendix 4 – Hospital participation

Numbers in brackets refer to questionnaires or case notes not returned with agreement from NCEPOD

Trust/Hospital name	Completed Organisational questionnaires	Number of cases included	Number of clinician questionnaires returned	Number of sets of case notes returned
Abertawe Bro Morgannwg University Health Board	2	-	-	-
Aintree Hospitals NHS Foundation Trust	1	-	-	-
Aneurin Bevan Local Health Board	2	-	-	-
Ashford & St Peter's Hospital NHS Trust	1	6	6	6
Barking, Havering & Redbridge University Hospitals NHS Trust	2	4	4	4
Barnet and Chase Farm Hospitals NHS Trust	2	-	-	-
Barnsley Hospital NHS Foundation Trust	1	-	-	-
Barts Health NHS Trust	1	-	-	-
Basildon & Thurrock University Hospitals NHS FoundationTrust	1	-	-	-
Bedford Hospital NHS Trust	1	-	-	-
Belfast Health and Social Care Trust	1	-	-	-
Benenden Hospital	1	3	3	3
Betsi Cadwaladr University Local Health Board	3	-	-	-
Birmingham Women's Healthcare NHS Trust	1	-	-	-
Blackpool, Fylde and Wyre Hospitals NHS Foundation Trust	2	-	-	-
Bradford Teaching Hospitals NHS Foundation Trust	1	5	5	5
Brighton and Sussex University Hospitals NHS Trust	1	-	-	-
Buckinghamshire Healthcare NHS Trust	0	1	1	1
BUPA Cromwell Hospital	1	5	3	5
Burton Hospitals NHS Foundation Trust	1	-	-	-
Calderdale & Huddersfield NHS Foundation Trust	1	6	5	6
Cambridge University Hospitals NHS Foundation Trust	1	-	-	-
Cardiff and Vale University Health Board	3	-	-	-
Central Manchester University Hospitals NHS Foundation Trust	2	3	2	2
Chelsea & Westminster Healthcare NHS Trust	1	8	7 (1)	7
Chesterfield Royal Hospital NHS Foundation Trust	1	-	-	-
Circle Health Limited	1	4	3	4
City Hospitals Sunderland NHS Foundation Trust	1	6	6	6
Colchester Hospital University NHS Foundation Trust	2	-	-	-
Countess of Chester Hospital NHS Foundation Trust	1	-	-	-
County Durham and Darlington NHS Foundation Trust	1	-	-	-
Croydon Health Services NHS Trust	1	-	-	-

Trust/Hospital name	Completed Organisational questionnaires	Number of cases included	Number of clinician questionnaires returned	Number of sets of case notes returned
Cwm Taf Local Health Board	2	-	-	-
Dartford & Gravesham NHS Trust	1	-	-	-
Derby Hospitals NHS Foundation Trust	1	6	6	6
Doncaster and Bassetlaw Hospitals NHS Foundation Trust	2	5	4	5
Dorset County Hospital NHS Foundation Trust	1	-	-	-
East & North Hertfordshire NHS Trust	2	-	-	-
East Cheshire NHS Trust	2	-	-	-
East Lancashire Hospitals NHS Trust	1	-	-	-
East Sussex Healthcare NHS Trust	2	-	-	-
Epsom and St Helier University Hospitals NHS Trust	2	-	-	-
Frimley Park Hospitals NHS Trust	1	-	-	-
Gateshead Health NHS Foundation Trust	2	-	-	-
Great Western Hospitals NHS Foundation Trust	1	-	-	-
Guy's & St Thomas' NHS Foundation Trust	1	3	3	3
Hampshire Hospitals NHS Foundation Trust	2	-	-	-
Harrogate and District NHS Foundation Trust	1	-	-	-
Heart of England NHS Foundation Trust	1	8	8	5
Heatherwood & Wexham Park Hospitals NHS Foundation Trust	1	-	-	-
Hillingdon Hospitals NHS Foundation Trust (The)	2	-	-	-
Homerton University Hospital NHS Foundation Trust	1	8	8	8
Hospital of St John and St Elizabeth	1	-	-	-
Hull and East Yorkshire Hospitals NHS Trust	2	5	5	5
Hywel Dda Local Health Board	7	-	-	-
Imperial College Healthcare NHS Trust	5	7	7	7
Ipswich Hospital NHS Trust	1	-	-	-
James Paget Healthcare NHS Trust	2	-	-	-
Kettering General Hospital NHS Trust	1	-	-	-
King's College Hospital NHS Foundation Trust	1	5	5	5
Kingston Hospital NHS Trust	1	-	-	-
Lancashire Teaching Hospitals NHS Foundation Trust	1	-	-	-
Leeds Teaching Hospitals NHS Trust (The)	2	3	3	3
Lewisham Hospital NHS Trust	1	-	-	-
Liverpool Heart and Chest Hospital NHS Trust	1	-	-	-
London Clinic	1	5	2	2
Luton and Dunstable Hospital NHS Foundation Trust	1	8	7	6

Appendix 4 – Hospital participation *(continued)*

Numbers in brackets refer to questionnaires or case notes not returned with agreement from NCEPOD

Trust/Hospital name	Completed Organisational questionnaires	Number of cases included	Number of clinician questionnaires returned	Number of sets of case notes returned
Maidstone and Tunbridge Wells NHS Trust	2	-	-	-
Medway NHS Foundation Trust	1	-	-	-
Mid Cheshire Hospitals NHS Foundation Trust	2	-	-	-
Mid Staffordshire NHS Foundation Trust	1	-	-	-
Mid Yorkshire Hospitals NHS Trust	1	9	7	8 (1)
Mid-Essex Hospital Services NHS Trust	1	-	-	-
Milton Keynes Hospital NHS Foundation Trust	1	-	-	-
Newcastle upon Tyne Hospitals NHS Foundation Trust	1	3	3	3
Norfolk & Norwich University Hospital NHS Trust	2	-	-	-
North Bristol NHS Trust	2	6	6	6
North Cumbria University Hospitals NHS Trust	2	-	-	-
North Tees and Hartlepool NHS Foundation Trust	2	-	-	-
North West London Hospitals NHS Trust	2	-	-	-
Northampton General Hospital NHS Trust	1	-	-	-
Northern Devon Healthcare NHS Trust	1	-	-	-
Northern Health & Social CareTrust	2	-	-	-
Northumbria Healthcare NHS Foundation Trust	3	8	6	7
Nottingham University Hospitals NHS Trust	1	-	-	-
Oxford University Hospitals NHS Trust	2	5	4 (1)	4 (1)
Pennine Acute Hospitals NHS Trust (The)	3	-	-	-
Peterborough & Stamford Hospitals NHS Foundation Trust	1	-	-	-
Plymouth Hospitals NHS Trust	1	-	-	-
Poole Hospital NHS Foundation Trust	1	-	-	-
Portsmouth Hospitals NHS Trust	1	-	-	-
Princess Alexandra Hospital NHS Trust	1	-	-	-
Queen Victoria Hospital NHS Foundation Trust	1	-	-	-
Royal Berkshire NHS Foundation Trust	1	6	6	6
Royal Bolton Hospital NHS Foundation Trust	1	-	-	-
Royal Bournemouth and Christchurch Hospitals NHS Trust	1	6	6	6
Royal Cornwall Hospitals NHS Trust	1	3	3	3
Royal Devon and Exeter NHS Foundation Trust	1	-	-	-
Royal Free London NHS Foundation Trust	1	-	-	-
Royal Liverpool & Broadgreen University Hospitals NHS Trust	1	-	-	-

Trust/Hospital name	Completed Organisational questionnaires	Number of cases included	Number of clinician questionnaires returned	Number of sets of case notes returned
Royal Surrey County Hospital NHS Trust	1	-	-	-
Royal United Hospital Bath NHS Trust	1	-	-	-
Royal Wolverhampton Hospitals NHS Trust (The)	1	-	-	-
Salford Royal Hospitals NHS Foundation Trust	1	6	3	5
Sandwell and West Birmingham Hospitals NHS Trust	3	-	-	-
Sheffield Teaching Hospitals NHS Foundation Trust	2	6	6	6
Sherwood Forest Hospitals NHS Foundation Trust	2	-	-	-
Shrewsbury and Telford Hospitals NHS Trust	2	3	3	2
South Eastern Health & Social Care Trust	1	-	-	-
South London Healthcare NHS Trust	2	3	3	3
South Tees Hospitals NHS Foundation Trust	2	-	-	-
South Tyneside NHS Foundation Trust	1	-	-	-
South Warwickshire NHS Foundation Trust	1	-	-	-
Southampton University Hospitals NHS Trust	1	-	-	-
Southend University Hospital NHS Foundation Trust	1	-	-	-
Southport and Ormskirk Hospitals NHS Trust	1	-	-	-
St Anthony's Hospital	1	12	6	12
St George's Healthcare NHS Trust	1	6	5 (1)	6
St Helens and Knowsley Teaching Hospitals NHS Trust	2	-	-	-
Stockport NHS Foundation Trust	1	-	-	-
Surrey & Sussex Healthcare NHS Trust	1	-	-	-
Tameside Hospital NHS Foundation Trust	1	-	-	-
Taunton & Somerset NHS Foundation Trust	1	6	6	6
The Dudley Group NHS Foundation Trust	1	-	-	-
The Hospital Management Trust	1	3	3	3
The Queen Elizabeth Hospital King's Lynn NHS Trust	1	-	-	-
The Rotherham NHS Foundation Trust	1	-	-	-
United Lincolnshire Hospitals NHS Trust	3	-	-	-
Univ. Hospital of South Manchester NHS Foundation Trust	1	-	-	-
University College London Hospitals NHS Foundation Trust	1	5	5	5
University Hospital Birmingham NHS Foundation Trust	1	-	-	-
University Hospital of North Staffordshire NHS Trust	1	-	-	-
University Hospitals Coventry and Warwickshire NHS Trust	2	-	-	-
University Hospitals of Bristol NHS Foundation Trust	1	-	-	-
University Hospitals of Leicester NHS Trust	1	8	8	8
University Hospitals of Morecambe Bay NHS Trust	2	-	-	-

Appendix 4 – Hospital participation *(continued)*

Numbers in brackets refer to questionnaires or case notes not returned with agreement from NCEPOD

Trust/Hospital name	Completed Organisational questionnaires	Number of cases included	Number of clinician questionnaires returned	Number of sets of case notes returned
Warrington & Halton Hospitals NHS Foundation Trust	2	-	-	-
West Hertfordshire Hospitals NHS Trust	1	-	-	-
West Suffolk NHS Foundation Trust	1	-	-	-
Western Health & Social Care Trust	1	-	-	-
Western Sussex Hospitals NHS Trust	3	8	8	8
Whittington Health	1	6	6	6
Wirral University Teaching Hospital NHS Foundation Trust	1	-	-	-
Worcestershire Acute Hospitals NHS Trust	2	-	-	-
Wrightington, Wigan & Leigh NHS Foundation Trust	1	-	-	-
Wye Valley NHS Trust	1	-	-	-
Yeovil District Hospital NHS Foundation Trust	1	-	-	-
York Teaching Hospitals NHS Foundation Trust	3	6	6	6
BMI Park Hospital	1	2	2	2
BMI Alexandra Hospital	1	9	7 (2)	8 (1)
BMI Beardwood Hospital	0	2	2	2
BMI Priory Hospital	1	6	4 (2)	4 (2)
BMI The Somerfield Hospital	1	2	2	2
BMI Chaucer Hospital	1	2	2	2
BMI Chelsfield Park Hospital	0	3	3	3
BMI Clementine Churchill Hospital	1	6	6	6
BMI Hampshire Clinic	1	2	2	2
BMI McIndoe Surgical Centre	1	5	0	5
BMI Mount Alvernia Hospital	1	2	2	2
BMI Ridgeway Hospital	1	1	1	1
BMI Runnymede Hospital	1	3	3	3
BMI Sandringham Hospital	1	1	1	1
BMI Sarum Road Hospital	1	3	3	3
BMI Sefton Hospital	1	6	6	6
BMI Shelburne Hospital	0	4	4	4
BMI South Cheshire Private Hospital	1	3	3	3
BMI The Garden Hospital	1	2	2	2
BMI The Meriden Hospital	1	1	1	1
BMI Thornbury Hospital	0	6	6	6
BMI Three Shires Hospital	1	3	3	3
BMI Werndale Hospital	1	4	4	4
Brentwood Nuffield Hospital	0	3	3	3

Trust/Hospital name	Completed Organisational questionnaires	Number of cases included	Number of clinician questionnaires returned	Number of sets of case notes returned
Cheltenham & Gloucester Nuffield Hospital	1	2	2	2
Newcastle Nuffield Hospital	1	-	-	-
North Staffordshire Nuffield Hospital	1	2	2	2
Nuffield Health Bournemouth Hospital	1	3	3	3
Nuffield Health Bristol Hospital	1	3	0	3
Nuffield Health Cambridge Hospital	1	-	-	-
Nuffield Health Derby Hospital	0	3	3	3
Nuffield Health Taunton Hospital	1	6	6	6
Nuffield Hospital Warwick	1	1	1	1
Plymouth Nuffield Hospital	1	-	-	-
The Grosvenor Hospital, Chester	1	4	2 (1)	3
The Manor Hospital	1	3	3	3
The Nuffield Hospital Leeds	1	8	7	4
Wolverhampton Nuffield Hospital	1	3	3	3
Ramsay Health Care UK Duchy Hospital	1	3	3	3
Ramsay Health Care UK Nottingham Woodthorpe Hospital	1	3	0	0
Ramsay Health Care UK Winfield Hospital	1	3	3	3
Ramsay Health Care UK Yorkshire Clinic	0	6	0	0
Spire Cambridge Lea Hospital	1	-	-	-
Spire Clare Park Hospital	1	3	3	0
Spire Fylde Coast Hospital	1	2	2	2
Spire Gatwick Park Hospital	1	2	2	2
Spire Hospital Bristol	1	4	4	4
Spire Hospital Cardiff	1	8	2	2
Spire Hospital Harpenden	1	5	5	5
Spire Hospital Manchester	1	9	9	9
Spire Hospital Norwich	1	3	3	3
Spire Hospital Portsmouth	1	5	3 (2)	5
Spire Hospital Southampton	1	8	8	8
Spire Hull & East Riding Hospital	1	5	5	5
Spire Leeds Hospital	1	9	9	9
Spire Little Aston Hospital	1	3	3	3
Spire Murrayfield Hospital	0	5	5	5
Spire Parkway Hospital	1	2	2	2
Spire Regency Hospital	1	6	5 (1)	6
Spire Roding Hospital	1	4	3 (1)	4
Spire St Saviour's Hospital	0	3	0	0
Spire Thames Valley Hospital	1	-	-	-
Spire Tunbridge Wells Hospital	1	3	3	3
Spire Washington Hospital	1	5	5	5
Spire Wellesley Hospital	1	-	-	-

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