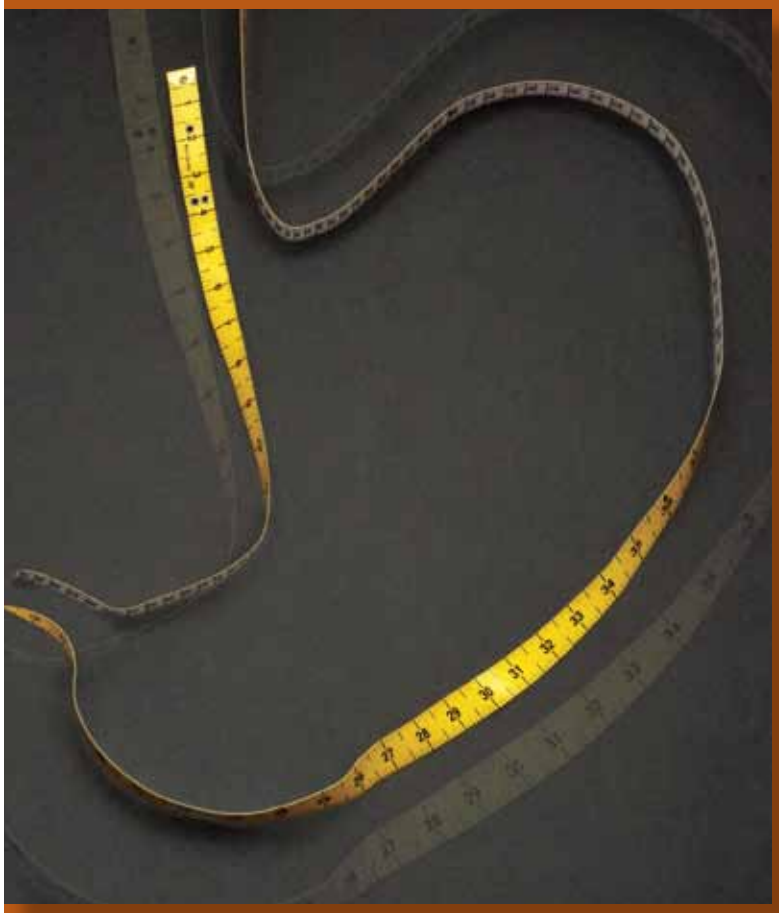
Too Lean a Service?

A review of the care of patients who underwent bariatric surgery



NCEPOD

SUMMARY

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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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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)*

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 of the full report)

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.

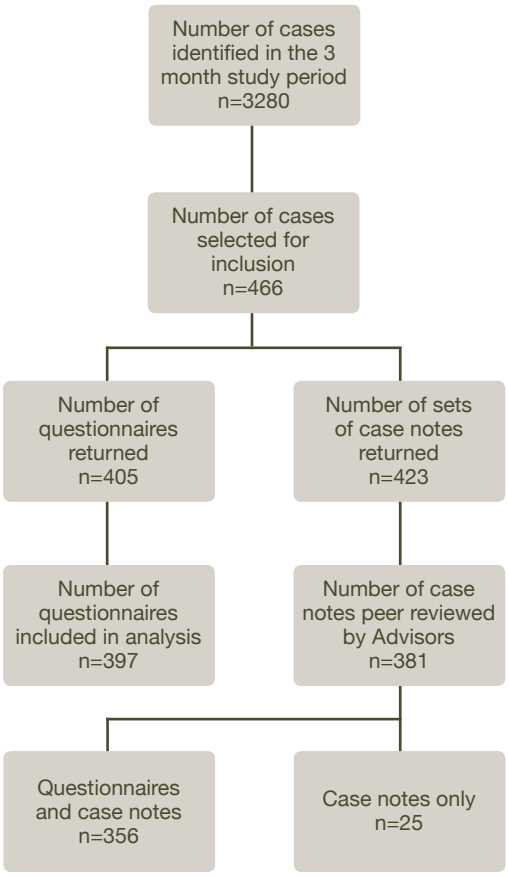
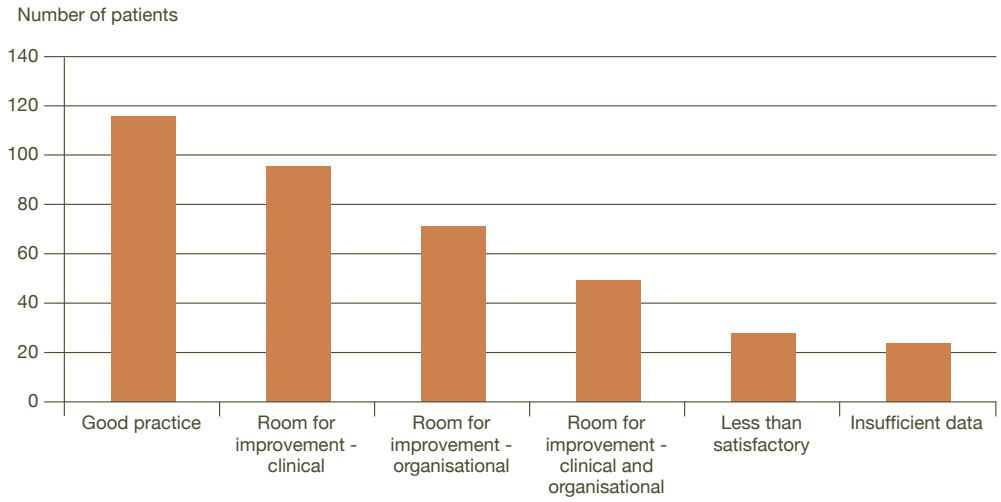


Figure 1. Data returns



Advisors' overall assessment of care

Overall assessment of care

The Advisors were asked to assign a grade to the overall care received by each patient in the study. 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.

2 – Demographics

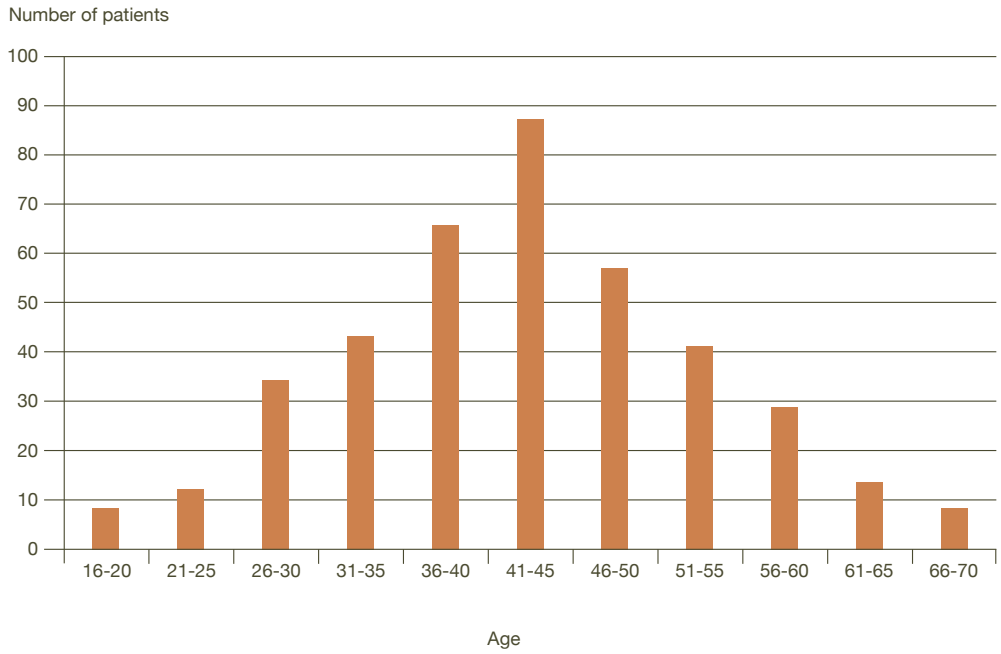


Figure 2.1 Age in years of the study population

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 of the full report).

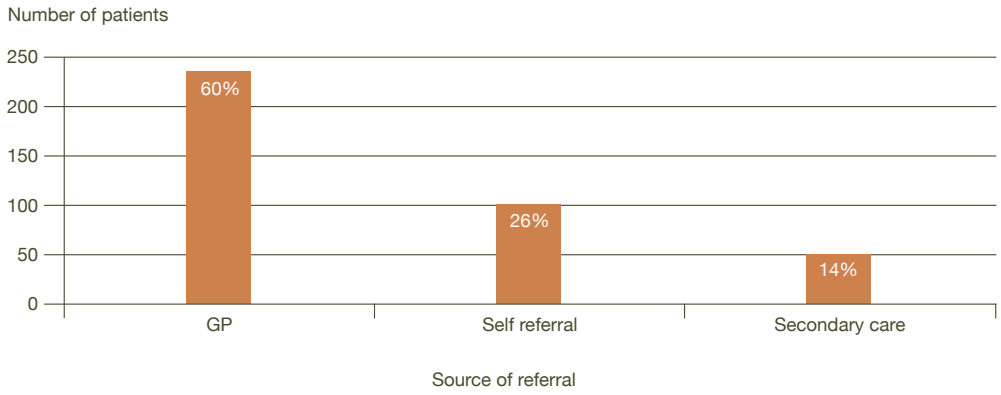


Figure 2.2 Source of referral

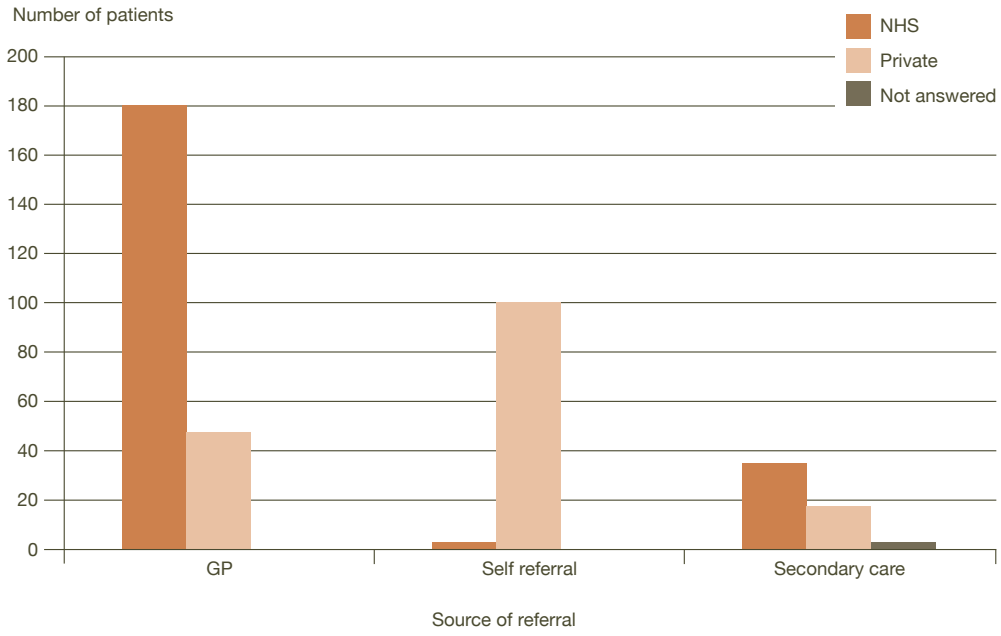


Figure 2.3 Source of referral by type of patient funding

Key findings and recommendations

Key Findings - Organisational data

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 - Organisational data

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)*

Key Findings - Pre-surgery and referral

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 - Pre-surgery and referral

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)*

Key Findings - The inpatient episode including surgery

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.

Recommendations - The inpatient episode including surgery

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)*

Key Findings - Follow-up

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 - Follow-up

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)*

Key Findings - Advertising

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

Recommendations - Advertising

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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