

Bariatric Surgery Study

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Introduction:

Bariatric surgery is surgical treatment to promote health in people who suffer from severe and complex obesity. It is indicated for patients who have a body mass index (BMI) $> 40 \text{ kg/m}^2$ 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 weight¹. 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 2050². Surgery has proved itself to be both clinically and cost effective and has been endorsed by NICE.

In 2008 a collaboration between The Association of Laparoscopic Surgeons (ALS), The Association of Upper GI Surgeons (AUGIS) and The British Obesity and Metabolic Surgery Society (BOMSS) was formed and The National Bariatric Surgery Registry (NBSR)³ established. 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 rapidly growing specialty develops, it would seem timely for a NCEPOD qualitative study, that will compliment the work of the NBSR.

Aims and objectives:

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

The primary aim would be met by addressing the following factors:

- Commissioning criteria
- Advertising
- Referral process
- Adherence to NICE guidance
- Level of psychological and nutritional support
- Comorbidity management
- MDT structure and process
- Availability of appropriate equipment and resources
- Consenting process
- Pre-anaesthetic process
- Anaesthetic and operation
- Training and supervision
- Unexpected adverse events or complications
- Recovery facilities
- Unexpected length of ICU stay or readmission
- Unexpected imaging or intervention
- Follow up management
- Discharge communications with GP
- Participation in NBSR/Audit

Methodology

Population:

All adult patients (>16 years old) who underwent bariatric surgery during the 3 month study period, 1st June 2010 to 31st August 2010 inclusive.

Patient identification:

Patients will be identified from all NHS hospitals and participating Independent Sector hospitals retrospectively via OPCS coding.

Sample size:

In 2008/2009 there were approximately 10000 consultant episodes for bariatric surgery in England (HES data). The present study will sample for 3 months and include all patients > 16 years old who have undergone a bariatric procedure in any NHS or independent hospital in England, Wales, Northern Ireland the Channel Isles or the Isle of Man. A population of ~ 500 patients (irrespective of outcome) will then be randomly selected and studied in detail. An additional

sample of 100 patients who stay in critical care for > 3 days post surgery or have an unexpected readmission to critical care will be identified and reviewed. It is hoped that this latter sample of patients will allow for a qualitative assessment of the management of early complications associated with bariatric surgery.

The final randomly selected study population(s) will be limited to include no more than 5 patients from any one hospital. This method will ensure that the study reflects activity across different types and sizes of institution, with different volumes of bariatric surgical practice. It will also prevent too onerous a burden of data collection on any one institution or surgeon.

Data Collection:

Patient identifier spreadsheet

NCEPOD Local Reporters will be asked to complete a patient identifier spreadsheet for all adult patients that underwent bariatric surgery between 1st June 2010 and 31st August 2010 inclusive. In addition to the patient identifiers and OPCS codes, the following data fields will be requested. Name and specialty of the surgeon, admission, operation and discharge dates, dates in and out of HDU/ICU, readmission to hospital during the first 6 months post operation.

Clinician questionnaire:

A short clinician questionnaire regarding the referral, inpatient care and follow up will be sent to the surgeon for each case selected from the main study population.

Photocopied case note extracts for Advisor assessment (peer review):

NCEPOD will request photocopied case note extracts covering the time from initial referral in primary care through to 6 months post surgery for each selected case. The notes requested will include referral letters and outpatient clinic notes, inpatient notes for the surgical episode and any readmissions (within 6 months post surgery), clinic notes for follow up appointments (within 6 months post surgery).

Organisational questionnaire:

For the purpose of this study, 'organisation' will be defined as a hospital/centre not a Trust. This will give a clearer picture of the facilities and care received by the patient at that particular site rather than by the Trust as a whole. An organisational questionnaire will be sent to the NCEPOD Local Reporter/study contact for each site undertaking bariatric surgery. The questionnaire is designed to collect data on topics such as hospital/site facilities, staffing and clinical protocols and commissioning arrangements.

Sites:

All hospitals that perform bariatric surgery or may admit patients with complications of bariatric surgery in the National Health Service and Independent sector in England, Wales and Northern Ireland, and public hospitals in the Isle of Man, Jersey and Guernsey, will be included in the study.

Analysis and Review of Data:

Advisors (peer review):

A multidisciplinary advisory group comprising surgeons, anaesthetists, physicians, dietitians and specialist nurses will review the data collected and provide expert opinion on the care received by this group of patients, from referral to 6 months post surgery.

All clinician questionnaire data will be electronically scanned and combined with data from the assessment form completed by the Advisors. Quantitative data analysis will be undertaken using Excel and qualitative analysis will be undertaken by reviewing the themes arising from the Advisor meetings.

Confidentiality and Data Protection:

Once the data have been extracted by the NCEPOD researchers, the forms and casenotes will be anonymised to remove patient, clinician and hospital identifiers prior to review by the Advisory Group.

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will anonymise paper documents. Section 251 (of the NHS Act 2006) approval has been granted by the National Information Governance Board for Health and Social Care (NIGB) to undertake this study without obtaining patient consent.

Dissemination:

On completion of the study a report will be published and widely disseminated.

Timescale:

Main Event	Date
Study protocol and questionnaire development	June 2010 to March 2011
Patient identifier spreadsheet	April 2011
Questionnaire dissemination/case note requests	May 2011 to June 2011
Advisor meetings	July 2011 to December 2011
Publication	November/December 2012

References:

1. National Institute for Health and Clinical Excellence CG43, 2006
2. First Report of the National Bariatric Surgery Registry 2011
3. <http://hostn3.e-dendrite.com/csp/bariatric/FrontPages/nbsrfront.csp>