

PROVIDING BARIATRIC SURGERY

BOMSS Standards for Clinical Services & Guidance on Commissioning

INTRODUCTION

Established Severe Obesity is becoming more widely understood as a patho-physiological state (i.e. a disease) rather than misconceived as a behavioural issue, thus implying an ordinary treatment imperative to healthcare professionals. Furthermore, the magnitude of the obesity pandemic (engulfing not just the western world) is now becoming recognised in its full health-economic and socio-economic implications.

Accordingly bariatric surgery is more widely accepted as the only current clinically effective and cost-effective treatment of this disease. This has been one of several drivers to an increased provision of bariatric surgery, both within the NHS, for the NHS in the independent sector and for self-paying (and rarely insurance-funded) patients in the private sector.

The British Obesity and Metabolic Surgery Society (BOMSS) is the UK's specialist professional society representing both bariatric surgeons and those colleagues in other disciplines and professions who work with them in the provision of bariatric surgery and associated care. Its membership comprises the majority of clinicians active in the field in the UK. BOMSS is internationally accredited with the International Federation for the Surgery of Obesity and Metabolic Disease (IFSO). BOMSS therefore perceives professional duties (in this order) to bariatric patients, to its members and to the requirements and recommendations of IFSO as an umbrella body.

BOMSS recognises lay perceptions and media reports of adverse outcomes, dramatic outcomes and outcomes in "celebrity patients". Behind this speculative interest there currently persist:

- a range of differing service specifications and concepts among NHS commissioners
- a range of perceptions and reports on safety
- a range of understandings of minimum good practice, both institutional and individual
- problematic health-economic and medico-legal climates

At the same time there is already a comprehensive set of national and international guidelines, which BOMSS fully supports as a bedrock consensus on principles of practice. The purpose of the present Standards is to give more detailed practical guidance on the translation of these principles into practical service structures, appropriate to circumstances in the UK. This guidance is offered to

- NHS Commissioners or their counterparts,
- Clinician colleagues and service leaders,
- Medical Directors and Clinical Governance leads, as well as
- Independent sector providers and private hospital executives

Good practice evolves.

Thus we make no claim that the present standards are definitive: they are work-in-progress. They do, however, represent a consensus gathered among our membership at the time of writing and will be regularly revised and updated. Although we recognise that good practice evolves from a plurality of practice the following guidance has the authority of that consensus and represents the official position from which The United Kingdom's national Specialist Society will proceed if asked to advise in any given case.

In drawing up these standards BOMSS further recognises that micro-managing service process through overly prescriptive procedural guidelines may harm, just as much as benefit, the interest of patients. Ultimately it will be for senior professionals in each bariatric team to satisfy themselves and their Medical Director or other Clinical Governance Lead, explicitly, that their practice and service meets both the existing published consensus frameworks and practical principles they can defend. It is in support of the latter that these standards are issued. Health professionals are already subject to recognised sanctions if their practice does not meet accepted standards and BOMSS fully supports that process.

Our guiding principle has been that bariatric care should be safe and kind, based on recognised best practice, yet be effective and cost-effective. This requires integrity within a service structure that also is also realistic and pragmatic. In placing our patients at the forefront of this structure, factors such as patient safety, quality of outcome, patient convenience need to be given appropriate priority.

Accordingly principles already familiar from the Calman-Hine cancer treatment re-organisation may aptly apply. (There is no reason why bariatric patients should receive a lower standard of consideration.) Patients should be treated in an appropriate facility by the appropriate clinicians. It is now widely accepted that these factors take precedence over clinician convenience or indeed over individual /institutional / organisational interests.

Finally in considering standards it is important

1. to reiterate the understanding of Bariatric Surgery as treatment of a disease state and its consequences. Thus the standards of probity, process and outcome to be applied should be those relevant to the clinical treatment of any other disease state.
2. to note the increasing international professional support for the concept of Metabolic Surgery – the application of bariatric surgery operations and derived procedures to the treatment of metabolic diseases.

This may legitimately address patients with a Body Mass Index below the thresholds set out in time-honoured guidelines for “weight-loss surgery”. BOMSS strongly recommends that this surgery be delivered only within a transparent and secure “off-guidelines” process based on documented peer support.

3. that BOMSS by contrast deprecates the promotion, marketing and provision of bariatric procedures with primarily cosmetic intent and/or at inappropriately low BMI. This practice threatens to bring genuine sufferers from Severe Obesity or Metabolic Disease and those who treat them conscientiously into disrepute.

Applicability of Guidance

The following guidance on Core Standards and Service Viability considers overall frameworks, but recognises that the exact application may differ between NHS units, commercial providers in the independent sector and private provision by free-standing clinician groups.

The optimum framework will depend on service volume and service setting, but BOMSS recommends that the following be upheld in all bariatric service provision.

CORE REQUIREMENTS FOR A BARIATRIC SERVICE

1. PURPOSE OF A BARIATRIC SERVICE

The purpose of a bariatric service should be to provide a safe and reasonable bariatric care on a complete and reproducible treatment pathway. The service should achieve outcomes that meet the standard of care but should do so with truthful consideration of cost and resource .

Any service should therefore comprise initial -and subsequently appropriately detailed -assessment, of both patient suitability and of treatment needs. There should also be a structured and documented process of information giving, followed by patient preparation, both personal and clinical. This is a necessary prelude to technically competent surgical treatment, transparently and appropriately chosen.

Patients require support pre-operatively and post-operatively in making adjustments to their lives after surgery. BOMSS considers careful, clinically safe and continued follow-up to be integral to any proper service and firmly deprecates the provision of surgery without that commitment.

2. GENERAL SERVICE STRUCTURE:

BOMSS wishes to re-enforce the existing national and international guidance on service delivery through a process based on a multidisciplinary and multiprofessional team (the MDT).

The core professions / disciplines within the MDT should at least comprise

- Specialist Bariatric Surgeon(s)
- Bariatric Nurse Specialist(s)
- Specialist bariatric dietitian(s)

There should be standing and immediate access to

- Specialist physicians with interest in and commitment to metabolic medicine and the peri-operative needs of bariatric surgery patients (a “bariatric physician”).
- Psychologist(s) and/or psychiatrists with knowledge of and interest in bariatric surgery
- Senior anaesthetist(s) with commitment to and experience of anaesthesia for bariatric surgery.

The core team will also need standing referral pathways to

- hepatologists,
- endocrinologists,
- diabetologists ,
- cardiothoracic physicians,
- plastic surgeons and
- Eating Disorder specialists

BOMSS believes the MDT should be led by a bariatric surgeon in terms of governance and as the final repository of clinical responsibility on the bariatric surgery pathway. However, a well functioning MDT will be cabinet of equals across professional boundaries, so that day to day operation of the team may be agreed to rest elsewhere. A bariatric surgery MDT may have links to a medical obesity service, with its own multidisciplinary structure, but the latter cannot be a substitute for a properly constituted bariatric surgery MDT. BOMSS does *not* recommend a structure in which

all preparatory, support and follow-up resides in the medical MDT, so that the surgical team is reduced to technician status.

All patients require access to a full MDT as described above, but many will not need to be seen by more than a few members. Typically every patient will need to be comprehensively assessed by the bariatric surgeon and **at least** by one other professional – usually the Specialist Dietitian (or occasionally Nurse Specialist, but preferably both) .

It is therefore a duty on the evaluating surgeon to be confident, in concert with the Service Lead and Head of Clinical Governance that an explicit, transparent protocol is applied (and documented) to determine which members of the wider team are needed to support a given patient. These protocols should be agreed with the professionals to whom referral would be made

Assessment

A bariatric service should be able to undertake a reproducible, comprehensive multidisciplinary assessment that corresponds to recognised (ie evidence-based) risk-scoring instruments. Once again, it is for the evaluating surgeon to be confident, in concert with the Service Lead and Head of Clinical Governance that a robust and defensible risk assessment took place. Additional and un-validated assessment practices and targets may be contraindicated and waste service resource.

Super-Obese and Super-Super-Obese patients with or without a self-evident major cardiothoracic history or other clinical signs of airway impairment warrant a particularly low threshold for careful pre-operative cardiothoracic and anaesthetic evaluation, on the responsibility of the Service Lead. Patients with complex medical problems (such as ischaemic heart disease, unstable diabetes or significant renal impairment) whose condition is not already optimally controlled may require review by an appropriate medical specialist prior to surgery

The surgeon / specialist nurse / specialist dietitian pre-operative assessments should include a screening for Eating Disorders agreed between Service Lead and Head of Clinical Governance to be robust and adequate in relation to the published impact of Eating Disorders on bariatric surgery outcomes. However, consideration should also be given to the cost-effectiveness and risk-effectiveness interests to patients of an Eating Disorders referral in any given case.

The same consideration applies to the proposed procedure, its duration and its inherent risk profile in the hands of the proposed operator.

Support and Counselling

A bariatric service must offer education, guidance and motivational support throughout the treatment process. Patient should understand which professional is providing this guidance, how / when access to that guidance is appropriate, and when it is not.

In support of this process BOMSS considers a regular, professional-moderated support group, based within the team, to be essential.

3. PERSONNEL

Professional personnel working with the team must meet *BOMSS Professional Standards* and it should be the duty of the MDT leader to ensure in concert with local Clinical Governance leads that this is the case. In particular each professional group within the MDT has a duty to ensure that its

personnel are demonstrably trained and / or competent with *knowledge, skills and attitudes* required for their role within the team.

All provider institutions need to be sure that their lay personnel as well as professional staff understand the sensitivities of bariatric surgery patients and desist from actions or remarks, however well intended, that may be seen as judgemental. (This will include porters, orderlies, cleaners, healthcare assistants and catering staff.)

4. FACILITIES

Facilities at which bariatric surgery is undertaken must meet *BOMSS professional standards*. These are in part re-iterated here, for clarity.

Facility requirements are significant and should encourage the development of networks, enabling patients to be operated on in the correct location within the network, which ever hospital within the network may have been at the beginning of their pathway.

Availability, especially bed availability, must enable smooth operation of the bariatric pathway. Failed admissions waste professional preparation resource and preoperative dietary process. They are psychologically devastating to patients. If access to elective beds limits hospital capacity, service providers should be committed to a bed allocation process that does not value one disease over another or in any other way unfairly discriminates against bariatric patients.

Equipment

Bariatric surgery should only be undertaken in facilities that are adequately equipped. As a matter of institutional and personal professionalism this is dealt with in greater detail in the *BOMSS Professional Standards*.

In general terms there must be a clearly documented and agreed institutional weight limit, taking equipment, (outpatient, diagnostic, surgical, manual handling, ward care & hygiene) on the local treatment pathway into account. The lack of suitable equipment should at no time stigmatise or single out a bariatric patient.

Where institutional escalation policies also require inter-hospital transfer, the facilities of the available ambulance service must be known and agreed.

Imaging

With regard to imaging, the global national lack of adequate weight-capacity in certain types of imaging equipment needs to be a factor in the design of process pathways (see below). Whereas the weight limit of modern CT scanners has greatly improved, BOMSS notes the well published superior sensitivity of careful, experienced, protocol-based clinical examination over radiology in the management of peri-operative emergencies, compared to reliance on difficult imaging.

Where imaging is nonetheless relied on, rather than early re-exploration, appropriate seniority and speed of reporting should be specified. In any event the weight limitation of available imaging equipment should at all times be explicit

Theatres

Operating theatres should be equipped with suitable tables, manual handling devices and anaesthetic equipment.

These should include:

- Suitable transfer facilities, e.g. hoist and / or hover mattress
- Electric Table that allows steep reverse Trendelenburg,
- Operating table leg extensions
- Operating table footplates
- Appropriate arm supports and padding
- Difficult intubation equipment including availability of fibre-optic laryngoscopy
- Suitable ventilator
- Availability of central lines catheters
- Availability of invasive arterial pressure monitoring
- Provision for maintaining normothermia
- Blood gas analysis must be onsite.
- Blood according to local protocols.
- Beds that allow patients to sit up to 45%, and to be woken and extubated on the bed

The majority of bariatric surgery is laparoscopic and it is the view of BOMSS that high-definition video equipment with ergonomic availability of monitors is mandatory. Appropriate instrumentation for laparoscopic and open bariatric surgery should be available at all times and as a minimum, there must be an adequate supply of instruments kept **available to enable emergency re-operation**, the preceding elective case-load notwithstanding. **Equipment for emergency re-operation must include a bariatric grade static retractor system for open surgery.**

All theatre personnel must be conversant with the use of equipment and deal respectfully and sensitively with the vulnerabilities of bariatric patients.

Post-operative Recovery

It is the overwhelming rule that elective bariatric surgery patients, properly prepared, anaesthetised, operated on and recovered are independent of advanced recovery facilities.

Nevertheless, no patient should spend the initial post-operative hours – usually the night in a lower than Level 1 ward facility. On-site Level 2 Critical Care facilities certified to the CQC are an essential prerequisite for units undertaking any bariatric surgery.

Patients should be able to bring in their own CPAP (Continuous Positive Airway Pressure)/BIPAP (Bilevel Positive Airway Pressure) machines and use them pre- and postoperatively as required. All units should have the ability to provide oxygen enriched CPAP acutely in an emergency situation and at least one nurse at any one time conversant with the principles of CPAP.

It is not recommended that any unit undertake a practice limited to gastric banding – the decision to undertake such a limited practice without any on-site Level 2 facility **is not advised** but is a matter for a clear and robust understanding of responsibility between Service Lead and Head of Clinical Governance and will depend on transfer distances, protocols and reliable off-site availability near at hand.

For uncomplicated cases undergoing gastric bypass or sleeve gastrectomy (excluding Super-Super-Obese and High risk super-obese patients) It may equally be appropriate for Service Lead and Head of Clinical Governance to accept a limited period of service at Level 2 (12 hours minimum), but *only* where transfer distances, protocols and proximity of documented continuous off-site availability permit.

No patient outside the above risk category should be operated in a facility without continuous (and actually available) on-site level 2 availability.

In all cases, not only should the appropriate equipment and monitoring be immediately available and functional, but there should be appropriately trained staff. Nursing staff should have documented training in caring for Level 2 patients and in managing and recognising specific clinical scenarios relating to bariatric surgery patients.

Robust postoperative care pathways, observation and escalation policies appropriate and specific to bariatric patients should be available and all relevant staff, including night staff and resident doctors must be familiar with and trained in them.

Resident Medical Officers with some critical care/anaesthesia experience are recommended, but as a minimum standard all RMO's must be supported by the availability of 24/7 consultant bariatric surgical and anaesthetic cover. Where this is not available there is an additional front-line responsibility on consultant bariatric surgeon and anaesthetist.

Depending on the experience of the team (and on the responsibility of Service Lead and Head of Clinical Governance), patients undergoing Duodenal Switch procedures, all super-super-obese patients and all patients undergoing revisional surgery (except re-banding) should only be operated on in facilities with on-site level 3 critical care, unless the latter is reliably and continuously (actually) available close at hand.

This will be partly dependent upon the clinical experience of the unit performing the surgery. Although data on the relationship of surgical volume to outcome may be crude and subject to publication bias, there is some evidence that groups performing higher volumes per year have better outcomes than those performing under 50.

MDTs with long experience or experience of 100 or more cases per year and who have validated outcomes, should be at liberty to decide which patients can be operated on safely without the requirement for an onsite Level 3 critical care unit. However, robust postoperative observations and, critically, the availability of senior doctor review should be demonstrated.

Clear guidelines for transfer to a critical care bed in a neighbouring facility should be demonstrated, usually in the form of a Service Level Agreement either with a nearby facility or with a critical care network. This requires that the local ambulance service can provide an emergency ambulance within a guaranteed transfer time agreed between Service Lead and Head of Clinical Governance. The responsibility for ensuring this is in place rests jointly with the Surgeon, Anaesthetist and Hospital Manager/Director of Nursing. Appropriate equipment to manage a transfer of a critically ill bariatric patient (including transfer ventilators) should be available.

The final risk assessment and location of surgery for each patient is the responsibility of the operating surgeon and anaesthetising anaesthetist, but only in concert with agreed MDT standards and with Service Lead and Head of Clinical Governance.

5. PROCESS

Patients should receive bariatric care along a standardised, albeit flexible, transparent pathway governed by agreed protocols, risk assessments and risk management strategies.

Referral

Such a pathway will begin with management of referrals. In the NHS setting, and beyond, BOMSS perceives value in agreeing pre-referral processes with referring doctors – for example it might be appropriate for every referral not only to state height, weight and co-morbidities, but also to document TSH status or the criteria by which co-morbidities such as diabetes have been diagnosed.

It should be explicit with Commissioners that a referral is only genuinely funded and validated if there is commitment to provide for clinical needs established during MDT evaluation.

Self-referral

Self-referral has become widespread in the independent sector and the balance between the self-determination of patients and secure professional frameworks needs to be considered. BOMSS urges members to ensure that GMC guidance on doctor-doctor communication and on the duty of doctors to work in concert for the benefit of patients is scrupulously observed. In particular, whilst self-referral for consultation may be beyond objection, BOMSS advises against undertaking surgery without the clear acquiescence of a referring doctor – usually the General Practitioner, wherever feasible.

“Rapid Access”

BOMSS strongly discourages a process which does not allow sufficient time for the assessment of, transfer of information to and giving of consent by patients. A process lasting just a few days would in the view of the Society be inherently deficient in all three respects.

Working Roles

Roles within the MDT should be clearly defined. As previously noted, it is for the evaluating surgeon to be confident, in concert with the Service Lead and Head of Clinical Governance that an explicit, transparent protocol is applied (and documented) to determine which members of the wider team are needed to support a given patient.

Governance

At the outset it is the view of BOMSS that responsibility for the physiology and fitness of patients should rest principally with the assessing surgeon, always based on standards agreed with senior anaesthetists and on protocols defining the need for pre-operative anaesthesiology input.

It is thus ultimately also the responsibility of the surgeon to ensure that patients are operated on within the competence of the surgeon and experience care that is not only kind and careful but also safely based on continuity of competent clinical assessment post-operatively.

6. INFORMATION & CONSENT

Along the treatment pathway patients must be given information that enables them to give genuine consent to the treatment pathway and the surgery.

This information should be accurate, truthful (evidence based) and unbiased, couched in plain language. It should comprise:

- Information about the role of surgery in the treatment of Severe Obesity compared and contrasted to non-operative alternatives.
- Information contrasting alternative surgical treatments in terms of their known or supposed effects, efficacy and risks.

- Clear advice why a specific procedure is advised. BOMSS holds that bariatric MDTs have a duty to give best professional advice, as would apply in the treatment of any other disease. The GMC wishes doctors and patients to make treatment decisions *jointly*. Giving patients some information *without advice* and leaving them to choose a treatment does not meet either standard.
- More detailed information about the risks and benefits of the operation agreed on. This should be integral to a process that ends with signing the consent form. An example (only) of such information is given in Appendix 1. This information should not only list complications in writing but go alongside a discussion that enables patients to weigh up and understand the consequences of a given complication, should it occur, (including, in the independent sector, the financial consequences). A consent process lacking this element may be of limited validity, especially if taken “on the morning”.
- Postoperative advice covering healing and recovery expectations, dietary transition, weight loss expectations, alcohol consumption and alarm signals. MDTs have a duty to ensure that patients understand these alarm signals and know how they can obtain access to proper emergency care (see below). This should include a list of emergency telephone details by which the MDT can be contacted on a continuous basis and a clear understanding of the available emergency return pathway.
- Pre-operative attendance at patient support groups has a valuable role in broadening patient understanding of bariatric surgery (and indeed the MDT’s understanding of patient needs) and BOMSS would encourage inclusion of mandatory attendance in the preparation pathway.

7. FOLLOW-UP

There are two important components to follow-up care in bariatric surgery.

The care of post-operative complications and delayed emergencies.

As set out above, patients must have a clear understanding of alarm features relevant to the surgery they had, and of the time frame on which emergencies may occur.

The MDT must establish, in concert with the institution as appropriate, how patient access to expert care can be facilitated. Usually this will mean expeditious return to the hospital where surgery was undertaken. BOMSS regards the provision of this pathway as an absolute duty, except where overriding circumstances prevent it.

As a back-up, the MDT must make appropriate telephone advice available to professionals at other hospitals and facilitate the return of the patient where this will result in improved care. That advice should stress the standard application of standard clinical and surgical principles.

The means by which patients and colleagues can access that support must be clearly provided to the patient in writing. An example (only) of such information is provided in Appendix 2.

Continuous clinical follow-up

The International Federation for the Surgery of Obesity (IFSO) and NICE have both given clear professional guidance on the responsibility of the bariatric team to provide follow-up and of the patient to observe it. BOMSS strongly supports this stance.

The content of such follow-up should include regular, specialist postoperative dietetic and / or specialist nurse monitoring according to patient need and practitioner competency. Patients must have access to either discipline as needed. Clinical follow-up should mirror the written post-operative information and should include:

- Information on the appropriate diet for the bariatric procedure
- Micronutrient monitoring and supplementation
- Information on patient support groups
- Individualised support and guidance to achieve long-term weight loss and monitor weight maintenance.

In practice much good follow-up can be delivered by joint dietitian / nurse clinics, but follow-up **must** include regular if infrequent bariatric surgeon review, ideally within the multidisciplinary clinic. Bariatric physician support will share this workload, but cannot replace it. This review can also be reduced in frequency, but cannot be completely substituted for, by doctor-to-surgeon progress reporting (e.g. from a GP under agreed protocol).

Failure to provide **any** surgical or surgeon-led consultations over the ensuing period should not reasonably be supported by any responsible body of bariatric surgeons.

BOMSS therefore advises strongly against the commissioning of services within the NHS that omit or seek to limit the period of follow-up in Secondary Care. The commissioning of services with only 6 months of follow up is deprecated and commissioners are advised that periods of secondary follow-up as short as 2 years may represent poor risk management as well as leading to poor weight maintenance outcomes. The concept of shared care is well understood and appears superficially to be good resource management, but its applicability to bariatric surgery may be limited and will depend on closely reasoned protocols.

The metabolic consequences of gastric bypass require long-term monitoring and the timely detection of mechanical consequences requires an index of suspicion. Judgements about gastric band adjustment require considerable experience.

Independent sector providers should be explicit to patients about best-practice needs for long-term follow-up and the financial implications of this commitment. The promotion of bariatric care packages in the independent sector or in private practice that either ignore the provision of proper multidisciplinary follow-up over appropriate periods of time, fail to inform patients of the importance of long-term follow-up, or financially dis-incentivise patients from maintaining follow-up is deplorable. BOMSS advises professionals participating in such processes to consider whether they are placing themselves in professional jeopardy.

Notwithstanding poor practices in this regard there are also genuine cases in which patients self-fund for treatment they were unable to obtain in the NHS (despite meeting NICE criteria) – fully recognising the follow-up issue. The financial circumstances of such patients may genuinely change and BOMSS deplores the practice of denying such patients access to urgent or emergent treatment in the NHS on the grounds of the previous private operation. Since a patient presenting to an NHS orthopaedic surgeon with a loose hip prosthesis would receive proper treatment whoever had inserted it- BOMSS regards such denial as overtly discriminatory.

8. AUDIT

BOMSS is committed to national data collection and to audit through the National Bariatric Surgery Registry.

Service commissioning must recognise the need to allocate job-planned personnel, time and office resource to collection and entry of data. Where a process of shared care is agreed, this resource must include the collection of data returns from the follow-up care setting.

National audit includes *long-term* outcome audit. This must be recognised in the commissioning of follow-up care.

9. KEY QUALITY INDICATORS

The purpose of the present guidelines is to facilitate quality control in the interests of patients. It is thus important for Commissioners to consider which outcome indicators are appropriate and which may be less so:

Morbidity and mortality

These are strong data that may be easy to collect, with the obvious inference that high figures denote weakness in the care process. However, as in other specialist surgical disciplines commissioners will also need to consider the confounding effects of case mix in individual institutions. The NBSR reports provide national benchmark data.

Co-morbidity improvement

This, rather than weight reduction per se, is the central ethos of bariatric surgery. Amelioration of co-morbidity is arguably the most important health-economic indicator and may reflect the quality of a service that correctly supports patients through *and after* a correctly selected operation. However BOMSS urges that commissioning specifications operationalise and stratify the pre-operative diagnosis of co-morbidities, so as to bench-mark their post-operative amelioration. As co-morbidities improve over time, it is essential that service specifications provide adequate *long-term* follow-up (and audit through the NBSR).

Satisfaction and Quality of Life

BOMSS would advise that recognized validated instruments (such as the SF36) be used if Quality of Life is to be used as a KQI. The ethos behind patient satisfaction surveys is well understood, but the latter may have limited comparability and reproducibility.

BMI and Weight Loss

BOMSS recognises that these indicators are easy to collect. However overemphasis on weight reduction per se misunderstands the purpose of bariatric surgery. Crude weight loss alone is not useful as a sole or principle outcome indicator.

Waiting time

BOMSS recognises that inappropriate periods spent waiting for service are harmful to patients. Commissioners are however advised that assessment and preparation for surgery are a process which may legitimately extend over a period of time. Specifying a single limited period from referral to operation may result in a rushed preparation process of poor quality and safety.

BOMSS advises that clear and stringent time limits are specified between *validated and funded* referral and a defined starting point of the preparation process (say 4 weeks). This limit should be mirrored by a requirement for expeditious surgery within a short period (say 4 weeks) once the MDT judges a patient ready to proceed. A single 18 week timeframe may thus leave insufficient residual time to prepare more complex patients. By analogy, a patient undergoing multimodal cancer

treatment would not be rushed to surgery before neo-adjuvant chemotherapy had been completed. Thus waiting time specifications must allow for agreed “clock-stops” during preparation.

10. SERVICE INTEGRITY

The following key features of a bariatric surgery service have already been described above, but are re-iterated together here:

The Service must ensure patient access to pre-op and post-op support.

The Service must have established, reliable and expeditious access to supporting specialties.

The Service must set out a clear Emergency Returns pathway comprising proper information to patients, access to advice for patients and for professionals at other hospitals and pathways for rapid return to the care of the Service. It is the view of BOMSS that such a pathway will comprise *as a minimum* continuous telephone availability of a professional member of the team (who will have an agreed action and call-down plan); clear written switch-board procedures; continuous availability of consultant bariatric surgeon advice.

These requirements will determine the minimum “critical mass” required within a Service or Service network. BOMSS strongly discourages the de novo commissioning of *stand-alone* services that are unable to offer this level of service integrity.

Independent sector providers and private practice clinician groups will need their own mechanisms for emulating these minima.

SERVICE VIABILITY

Reference has been made in the Core Requirements to issues that will determine the “critical mass” of a service. The following should be considered in specifying minimum service size:

BOMSS champions the need to develop service capacity in the UK and thus supports the aspirations of new providers. BOMSS is also aware of the literature relating quality of outcome to annual operated volume, both for surgeons and for institutions. This literature should be treated with caution, as it may reflect publication bias (there are a few publications demonstrating excellent outcomes in small units), largely reports US practice and may be driven by a variety of interests. Furthermore the annual volume treated by a given surgeon or hospital should be balanced against their respective long-term experience. Thus actual minimum numbers are subject to a degree of conjecture.

Nevertheless, the argument that volume supports quality is persuasive and must inform service development strategy.

However, BOMSS recognises that in many instances high quality service is currently provided by very experienced individuals and teams with **lower volumes and personnel establishment** than is set out below. The following guidance should not be interpreted to disestablish these excellent services. It may be of use to Commissioners in developing services that are not meeting the quality targets set out above and is intended to guide both the integration of current services and the establishment of new ones.

Furthermore the co-location of service for complex upper gastro-intestinal surgery and possibly with oesophago-gastric cancer services will be modifying factors on the exact volume needed for viability.

1. SIZE & SCOPE OF SERVICE

Services within the NHS for NHS patients,

BOMSS proposes that, by analogy to cancer services, NHS provision should recognise Bariatric Units and Bariatric Centres. Any Bariatric Unit will have a network relationship to a Centre. These relationships will constitute a Bariatric Network

Bariatric Units - Volume

As a minimum a Unit will comprise 3 consultant bariatric surgeons with sufficient anaesthetic cover, supported by 3 half-time equivalent specialist dietitians and 3 half-time equivalent specialist nurses. Each surgeon shall on average operate on at **least** 40 cases per annum (1 a week).

As a matter of aspiration and development support, a new Unit, supported within a Network, may have a lower service volume at the outset. The service specification should require (and commissioning volume should support) that this minimum volume be achieved by the end of an agreed period – usually the second or third year of service (reflected in agreed projections for years 3&4).

BOMSS regards a Unit of this size as the minimum sustainable in the long term, but considers that an established Unit should aim to comprise 4 consultant bariatric surgeons, supported by at least 2 WTE nurses (distributed so as to ensure continuous cover, usually 3 individuals) and 2 WTE dietitians (likewise).

Such a Unit is the minimum to provide continuous consultant bariatric surgeon on-call availability, which may otherwise have to be provided by explicit networking arrangements

Bariatric Units – Scope

An established Bariatric Unit cannot provide a single treatment modality in the long term. All established units should be competent to provide treatment by gastric banding, gastric bypass and sleeve gastrectomy as primary procedures.

Patients will be suitable for treatment at Units if they are below a BMI / weight limit agreed within the Network for the Unit and if they are below thresholds levels of co-morbidity and physiological risk likewise agreed.

Units will need to ensure the competence of their personnel and the adequacy of their facilities (as set out in Core considerations above) to provide this service.

Only minor revisions to gastric bands should be undertaken at Bariatric Units. The level of emergency surgery provided should be agreed within the network.

Bariatric Centres - Volume

At a Bariatric Centre there should be **at least** 5 operations a week. Each consultant bariatric surgeon will undertake at least 2 full bariatric operations a week. These figures should be regarded flexibly and will depend on the experience of each surgeon, but overall it is clear that higher quality should be expected at a service volume of 300 cases a year than at 100.

With the caveats set out above, the world literature suggests that an establishment of 4 surgeons will deliver high quality with a volume of 400 a year. This ideal may take several years to achieve, but should be the aspiration supported by commissioning plans

The provision of specialist nurses and dietitians together with expert anaesthetic cover and availability of internal medicine and psychiatry / psychology will be scaled to this volume.

Bariatric Centres - Scope

In addition to the work undertaken at Units, a Centre will provide primary surgery for more complex patients, patients of weight / BMI limited only by prudence and patients requiring less common procedures.

Overtly mal-adsorptive surgery, surgery for patients with complex physiological needs (e.g. renal or cardiopulmonary failure) and all complex revision surgery should **only** be undertaken at Centres.

Centres will therefore need to demonstrate all the Facility and Personnel provision set out above as Core Requirements.

Over time, Units may wish and be able to develop into Centres and should set a time frame for that development. Commissioning should support that development, so that new Units can be supported around them.

2. COMPETENCE OF SERVICE

Providers must be competent to provide a stated range of primary operations and to support the preparation and follow-up needs of patients in each case.

Patients should be advised of that range and of the appropriate operation for them, according to a documented transparent clinical protocol adapted, which should also set out the balance between professional advice and patient choice.

Patients may therefore need to be advised that a given Unit is not the appropriate setting for their treatment and that they may need to be treated at a Centre. Commissioners must support that allocation.

Commissioners should only support Revisional Surgery at appropriate providers and should recognise that a surgical revision rate of 10-20% is documented in the world literature, depending on case-mix and type of primary procedure. Thus some Units will be net generators of revision cases. This is *not* inherently an indicator of poor quality.

3. ACCESS TO SERVICE

BOMSS recognises the criteria for suitability for bariatric surgery set out in NICE CG43 as well founded, fair and evidence based. These guidelines reflect IFSO, NIH, ASMBS and SIGN guidance. They are thus also peer supported.

BOMSS recognises that the differentiation of patients below and above a BMI of 50 is at variance with the international criteria, which make no such distinction. It is of self-evident value that patient should be documented as having conscientiously attempted all non-operative options. However, the evidence base for delivery of that pre-treatment in a formal "weight management" setting is still to be established.

In any event BOMSS deplores the misreading of CG 43 to debar patients below a BMI of 50 from any surgical treatment.

BOMSS recognises the resource constraints faced by NHS commissioners and is available and willing to give support in the difficult task of targeting these means appropriately. However, it is the Society's view that simply raising the threshold on Body Mass Index (weight for height) over and above NICE recommendations is neither a rational nor an appropriate way to allocate treatment:

- It requires sufferers of a known disease to suffer further health loss before they can receive treatment.
- When the patients do get access to treatment they will, on average, require more complex and thus more costly care.
- On average the longer the treatment of any disease is delayed, the less likely is eventual full rehabilitation.
- There is no evidence in clinical science or professional ethics to support this simplistic strategy.

Other accepted approaches to resource allocation are available.

Attention is drawn to the ground-breaking work of South-East Coast Specialized Commissioners, in demonstrating that standard application of NICE criteria represent the most cost-effective long-term approach.

Resources can also be released by discontinuing ineffective or cost-ineffective treatments for other conditions. Commissioners deserve professional support in this difficult task.

4. APPLICABILITY TO INDEPENDENT SERVICE PROVIDERS

The standards determining the viability, safety and integrity of service by Independent and commercial providers of bariatric surgery should be no different in principle.

The principles of course require some adaptation. The guideline produced by IHAS has a very great deal to recommend it in this respect and is strongly supported by BOMSS.

Independent providers should ensure that their service in every way **at least** meets the standards of competence, volume, facility and process required for provision within the NHS.

Where NHS service is commissioned with such a provider, that compliance will inevitably be required – and it is the view of BOMSS that commissioners have a duty to so require. Commissioners are asked to direct special attention to the outsourcing of Service from NHS providers to local private hospitals and to consider the responsibilities they may thus unwittingly incur.

5. PROVIDING TO INDIVIDUAL PATIENTS IN PRIVATE PRACTICE

Applicability of Service Standards

It is the view of BOMSS that private clinical groups providing bariatric surgery to individual self-funding (or rarely insurance-funded) patients should at all times at least meet the standards set out above for NHS services.

Thus surgeons will need to ensure that they are providing a comparable process, are competent to undertake the proposed surgery and have adequate current and past experience to do so safely. Surgeons will have a duty of care to ensure that they operate only in facilities that meet the standards set out above and that they work only with colleagues who do so. Audit through the NBSR is most strongly encouraged.

In addition

The attention of private bariatric surgeons is drawn to the introductory section of the present guidance. BOMSS welcomes the existence of a trade in the provision of bariatric surgery services, because this increases the availability of treatment. BOMSS requires that a joint interest between clinician and patient on health-improvement be the primary focus at all times and deprecates the exploitation of vulnerable people.

Surgeons have a duty of care to ensure post-operative safety and to support the success of treatment in the long term by providing and ensuring follow-up. GMC guidance of the transfer of patient care should apply. It is the view of BOMSS that failure to provide any credible surgeon-based follow-up process may be a matter of professional jeopardy.

for and on behalf of BOMSS Council, October 2012

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