NHS England

A05/S/a

2013/14 NHS STANDARD CONTRACT
FOR SEVERE AND COMPLEX OBESITY (ALL AGES)

PARTICULARS, SCHEDULE 2- THE SERVICES, A- SERVICE SPECIFICATIONS

Service Specification No.	A05/S/a
Service	Severe and Complex Obesity (All Ages)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

Interim for adoption from 01/10/13

1. Population Needs

1.1 National/local context and evidence base

Obesity and overweight are a global epidemic. The World Health Organisation (WHO) predicts that by 2015 approximately 2.3 billion adults worldwide will be overweight and more than 700 million will be obese. The prevalence of obesity in England is one of the highest in the European Union.

In England: Just over a quarter of adults (26% of both men and women aged 16 or over) were classified as obese in 2010 (Body Mass Index (BMI) 30kg/m2 or over). Using both BMI and waist circumference to assess risk of health problems, 22% of men were estimated to be at increased risk; 12% at high risk and 23% at very high risk in 2010. Equivalent figures for women were: 14%, 19% and 25%. There has been a marked increase in the proportion (doubling) that are obese, a proportion that has gradually increased over the period from 13.2% in 1993 to 26.2% in 2010 for men and from 16.4% to 26.1% for women.

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BMI Definition	BMI range (kg/m2)
Underweight	Under 18.5
Normal	18.5 to less than 25
Overweight	25 to less than 30
Obese	30 to less than 40
Obese I	30 to less than 35
Obese II	35 to less than 40
Morbidly obese/obese III/severe	40 and over
Overweight including obese	25 and over
Obese including morbidly obese	30 and over

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Obesity is directly associated with many different illnesses, chief among them insulin resistance, type 2 diabetes, metabolic syndrome, dyslipidaemia, hypertension, left atrial enlargement, left ventricular hypertrophy, gallstones, several types of cancer, gastro-oesophageal reflux disease, non-alcoholic fatty liver disease (NAFLD), degenerative joint disease, obstructive sleep apnoea syndrome, psychological and psychiatric morbidities. It lowers life expectancy by 5 to 20 years. Direct costs of obesity are estimated to be £4.2 billion (Department of Health)

As BMI increases the number of obesity-related comorbidities increases. The number of patients with ≥ 3 comorbidities increases from 40% for a BMI of < 40 to more than 50% for BMI 40-49.9 to almost 70% for BMI 50-59.9 and ultimately to 89% for BMI > 59-9.

The treatment of obesity should be multi-component. All weight management programmes should include non-surgical assessment of patients, treatments and lifestyle changes such as improved diet, increased physical activity and behavioural interventions. There should be access to more intensive treatments such as low and very low calorie diets, pharmacological treatments, psychological support and specialist weight management programmes.

Surgery to aid weight reduction for adults with morbid/severe obesity should be considered (when there is recent and comprehensive evidence that) an individual patient has fully engaged in a structured weight loss programme; and that all appropriate non-invasive measures have been tried continuously and for a sufficient period; but have failed to achieve and maintain a clinically significant weight loss for the patients clinical needs (NICE CG43 recommendations). The patient should in addition have been adequately counselled and prepared for bariatric surgery.

This surgery, which is known to achieve significant and sustainable weight reduction within 1-2 years, as well as reductions in co-morbidities and mortality, is commonly known as bariatric surgery. The current standard bariatric operations are gastric banding, gastric bypass, sleeve gastrectomy and duodenal switch. These are usually undertaken laparoscopically.

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Bariatric surgery is the most effective weight-loss therapy and has marked therapeutic effects on patients with Type 2 diabetes. The economic effect of the clinical benefits of bariatric surgery for diabetes patients with BMI 35 kg/m^2 has been estimated in patients aged 18-65 years. Surgery costs were fully recovered after 26 months for laparoscopic surgery. The data suggest that surgical therapy is clinically more effective and ultimately less expensive than standard therapy for diabetes patients with BMI of ≥35 kg/m^2. Other groups have been less well studied but bariatric surgery is reported to be cost effective against a wide range of co-morbidities.

Bariatric surgery is a treatment for appropriate, selected patients with severe and complex obesity that has not responded to all other non-invasive therapies. Within these patient groups bariatric surgery has also been shown to be a highly cost effective therapy that prevents the development of co-morbidities.

Bariatric surgery was recommended by NICE as a first-line option for adults with a BMI of more than 50kg/m^2, in whom surgical intervention is considered appropriate. However, it will be required that these patients also fulfil the criteria below. For patients with BMI > 50 attending a specialist bariatric service, this period may include the stabilisation and assessment period prior to bariatric surgery. Selection criteria of patients for bariatric surgery should prevent perverse incentives for example patients should not become more eligible for surgery by increasing their body weight. Similarly the selection criteria should not forbid bariatric surgery for patients who have lost weight with non-surgical methods.

2. Scope

2.1 Aims and objectives of service

The main clinical aim of a Tier 4 specialised complex obesity service is to achieve a significant reduction in the burden of obesity-related co-morbidities, where all other services have been unable to achieve this. This will be achieved by facilitating a significant, and sustained, weight reduction in the patient.

The provider of a complex obesity service will, as part of a continuous pathway of care include the patient's GP (Primary Care); local (to the patient) services commissioned by local authority (LA) or clinical commissioning group (CCG) and local district general hospital/tertiary care based interventions which may include private sector providers (e.g. those commercial slimming clubs with scientific directors), deliver a service providing specialised care, including both non- surgical interventions and surgical and interventions, for patients who have been unable to achieve and/or maintain significant weight-loss. The service will be provided in a complete and reproducible pathway that meets the required standards of care and achieves expected outcomes whilst remaining within

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proper consideration of cost and resource.

Providers will have clinical protocols and programmes of care that deal with the patient journey through assessment, medical or surgical intervention, post surgical care (where appropriate), discharge and long term follow up, including the transition back to a specialist weight management service local to the patient's home, as part of a life-long shared care arrangement of follow-up and surveillance.

Providers will be required to demonstrate that they have multi-disciplinary teams that can provide such assessments and that clinically appropriate referrals to other specialties for further consultation and clinical management will be made.

Whilst bariatric surgery is a last-line intervention, the provision of follow up for complications, nutritional and weight maintenance support for the patient remains a lifetime commitment for the patient.

We describe an ideal service for severe and complex obesity which includes bariatric surgery. Various elements of this pathway will have different commissioning pathways and responsibilities.

2.2 Service description/care pathway

The services provided will cover in secondary and/or tertiary clinical settings:

- Assessment and diagnosis of underlying causes of overweight and obesity where this cannot be identified or managed in primary care or community based medical obesity services. Including but not limited to rare genetic syndromes, endocrine disturbances and abnormalities.
- Assessment and treatment using non-surgical methods, or onward referral to other specialties, of those with complex disease states and/or comorbidities that cannot be managed adequately in either primary or secondary care.
- These will include:
  - Treatment for those using non-surgical modalities where conventional treatment has failed in primary or secondary care;
  - Treatment for those where drug therapy is being considered for a person with a BMI more than 50 kg/m2;
  - Specialist interventions (such as a very-low-calorie diet for extended periods),
  - Pre-operative preparation, surgical intervention and immediate post-operative follow-up.
  - Life-long post-operative follow-up and specialist surveillance, in conjunction with community based medical obesity services, and primary care.

The Multi-Disciplinary Team (MDT)

The provider will have two pathways of care available for each patient;

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non-surgical and surgical. These pathways will be sequential, not parallel.
At referral a non-surgical team will assess the patient to determine:

- the cause of obesity,
- the presence and severity of co-morbidities,
- to stratify/score risk (Obesity Surgery Mortality Risk Score (OS-MRS) (see appendix 3)),
- to evaluate the modalities of weight loss that have been explored,
- to detect other diseases and
- to optimise their medical condition.

The non-surgical MDT will include, as a minimum;

- Bariatric dietitian
- Bariatric physician
- Bariatric specialist nurse
- Psychotherapist / psychologist / psychiatrist - with an interest in obesity
- Other relevant medical specialist for referral and consultation e.g. endocrinologist/diabetologist/cardiologist/anaesthetist (unless already in the non-surgical MDT)

Following assessment, patients will be reviewed by a combined non- surgical and surgical MDT to consider the optimal therapy for individual patients. If the team feels that the patient fulfils the surgical selection criteria they will be referred onward to the bariatric surgery team. If non- surgical therapies are considered optimal the non-surgical team will recommend, and provide treatment. Depending on local arrangements, the non-surgical and/or surgical MDT will undertake the counselling and preparation of patients assessed as appropriate for bariatric surgery.

The multi-disciplinary team will work, in conjunction with local commissioners and providers, within integrated care pathways and shared care protocols to ensure patients are receiving appropriate pre- and post- operative care and long term follow-up regardless of location.

The provider will be able to offer support to the patients through a designated contact person and in the form of a clear and comprehensive information pack in appropriate formats to comply with equality and diversity legislation.

The requirement for a surgical provider based non-surgical MDT is not essential if there is a primary care based multi-disciplinary weight management team that provides these functions. However, in these circumstances the surgical provider must demonstrate the systems that are in place to ensure that appropriate patient assessment and preparative care is implemented. This will address psychological and medical co- morbidities and the weight management of patients for whom surgery is not the most appropriate form of therapy. There will be formalized links in place (backed up by protocols)to refer and re-refer patients both pre and post-surgery.

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Surgery

The specialist surgical MDT should include as a minimum:

- Bariatric surgeon
- Bariatric dietitian
- Specialist anaesthetist
- *Relevant medical specialist with an interest in obesity e.g. endocrinologist/diabetologist
- *Psychotherapist / Psychologist / Psychiatrist with an interest in obesity
- *Ideally on site access to other relevant medical specialists for the diagnosis and management of co-morbidities.
  *not necessary if part of the non-surgical MDT
  (This list is not exhaustive and the MDT should have access to/include the most appropriate group of health care professionals required to make a comprehensive and appropriate decision).

The surgical MDT will be supported by a radiologist and radiographer with a special interest in obesity. Patients will also have access to physiotherapy and occupational health professionals to assess and manage their levels of physical activity.

Specialised complex obesity services will deliver primary bariatric surgery for all patients deemed clinically appropriate, and within the criteria defined in the commissioning policy.

The bariatric surgery MDT will satisfy itself that:

- bariatric surgery is in accordance with relevant guidelines
- there are no specific clinical or psychological contraindications to this type of surgery
- the individual is aged 18 years or above.
- the patient has engaged with non-surgical Tier3/4 Services.
- the anaesthetic and other peri-operative risks have been appropriately minimised
- the patient has engaged in appropriate support or education groups/schemes to understand the benefits and risks of the intended surgical procedure. This should be provided by the Tier 4 service, following referral, should the patient be assessed by the MDT as having not engaged prior to referral. However the expectation is clearly that the patient has accessed services prior to referral to Tier 4.
- the patient is likely to engage in the follow up programme that is required after any bariatric surgical procedure to ensure:
  - safety of the patient,
  - best clinical outcome is obtained and then maintained.
  - change in eating behaviour
  - change in physical behaviour
  - change in health promoting lifestyle
- The overall risk:benefit evaluation favours bariatric surgery

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- The MDT will meet physically (not virtually) and minutes will be recorded of the patient management decisions.

Specialised complex obesity services will be able to provide the full range of routine bariatric procedures, including laparoscopic and open procedures and revisional procedures (a national policy for revisional procedures will be developed in 2013). Providers will not restrict practice to one single method of operation.

It is expected that laparoscopic surgery will be the normal operating method used.

Specialised severe and complex obesity Services will be able to provide 24-hour emergency management of post-surgical complications, including the availability of 24-hour consultant bariatric surgeon cover or joint cover with upper GI surgeons. In some models of care the surgical bariatric service is part of the wider general surgery division and is clinically integrated with the upper GI surgical service. The critical factor is rapid access to bariatric surgery advice and attendance. Services will also have appropriate on-site arrangements for critical care of the morbidly obese together with suitably trained and qualified staff to support this area.

In order to allow for progression of Specialised Complex Obesity Services, it is anticipated that there will be a need for two levels of service in the future (Units and Centres of Excellence - see International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) guidelines appendix 2 - units correspond to Institutions in IFSO). These levels will work as a clinical network between themselves as part of the wider obesity care pathway, and cover the full range of surgical procedures and case complexity, education and training of post graduates and less experienced bariatric surgeons as well as multi-disciplinary training of other professionals (e.g. psychologists, dietitians etc) with an interest in severe and complex obesity and bariatric surgery.

However, at present, bariatric units will have a minimum of 2 consultant surgeons. Each surgeon will perform at least 50 procedures per annum and the provider unit will perform a minimum of 100 procedures per annum. Units will carry out all types of surgical procedure but will be restricted to an upper BMI/Weight and complexity limit. Thresholds will be agreed in conjunction with the Commissioner and the Clinical network.

The surgeons in the multidisciplinary team should have undertaken a relevant supervised training programme and have specialist experience in bariatric surgery (see International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) guidelines – appendix 2).

Specialised complex obesity services will submit data on all patients treated to the National Bariatric Surgery Registry, using their standard protocols for data compliance.

Patients must be appropriately supported. Support will vary between units, but it is essential that specialist dietetics as well as nursing is provided, due to the specific issues that this work presents. Therefore a mix of specialism should be provided to

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match local requirements which will typically be ~1.5 wte per 100 patients with arrangements for annual leave.

Non-surgical management

It is anticipated that patients will be referred from areas with and without developed weight management services. Therefore, there will need to be pathways for the management of:

- patients who have not yet engaged with weight management services or who do not wish to undergo bariatric surgery and need non-surgical therapies
- patients who require preparative therapy prior to bariatric surgery
- patients who have been assessed and found to be unsuitable for bariatric surgery.

These patients may need to be managed within the non-surgical MDT as described above for a period of up to 2 years.

Patient Support

The Tier 4 provider will be able to offer support to the patients through a designated contact person and in the form of a clear and comprehensive information pack in appropriate formats to comply with equality and diversity legislation.

The provider will set up and maintain patient support groups and also to sign post patients to other patient support groups facilitated by different organisations or charities. Such groups are a vital source of peer support, advice and information for patients. They may also be able, depending on their stage of development, to form an advocacy role, either at group or individual level, or as agents for change or service development.

Follow Up

The provision of after-care and weight management support for the patient remains a lifetime commitment. Structured, systematic and team based follow up should be organised by the Tier 4 provider for 2 years after surgery. Lifelong specialist follow up is also advocated – a policy for this will be developed in 2013.

Patients will continue to receive dietetic, clinical behavioural and, psychological advice and support to help them modify their lifestyle to maintain weight loss/reduction and to prevent or minimise complications.

Long term follow-up and supervision will be on a 'shared care' basis with community based medical obesity services commissioned by Local Authorities (LAs), Clinical Commissioning Groups (CCGs). The patient's GP will provide additional support. The Commissioners intend that the transfer of care from the surgical provider to local services would take place no more than 24-months post-operatively. Follow up arrangements will however be procedure specific (e.g. gastric band adjustment may need to take place at the surgical provider, unless local services are appropriately

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trained, or as outreach services) and for certain procedures there will always be a need for specialist follow up by the specialised services provider (this needs to be expressly defined). The specialised service will at all times maintain links with patient's local services ensuring that they are aware of the patients' ongoing progress. The "loss to follow-up" across the whole pathway will be minimal.

It is the responsibility of the bariatric team to develop clear protocols for the required monitoring with local community based medical obesity services, including a robust mechanism ensuring early identification of post-operative problems. Rapid access to the specialised complex obesity MDT will be available for assessment of complications. In some cases this will available as self-referral; the circumstances under which this is necessary will be included in the protocols and also patient discharge information. Post-operative care will be available to manage complications as they occur, including revisional procedures. Failure to lose "sufficient" weight is not deemed a complication.

Protocols for follow up from the bariatric provider will be provided to primary care for shared care before and long term care after discharge from the bariatric provider.

General Paediatric care

When treating children, the service will additionally follow the standards and criteria outlined in the Specification for Children's' Services (attached as Appendix 1 to this specification)

2.3 Population covered

The service described in this specification is for patients ordinarily resident in England (Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP practice in England); or otherwise the commissioning responsibility of the NHS in England (as defined in *Who Pays?; Establishing the responsible commissioner* and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

Specifically, this service is for adults (aged 18 and over) with complex obesity requiring specialised interventions and management as outlined in this specification and in the Specialised Complex Obesity commissioning policy.

2.4 Any acceptance and exclusion criteria

Acceptance Criteria

Referrals will only be considered for patients who are adults (aged 18 and over) as a treatment option for people with morbid obesity providing the patient fulfils all

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of the criteria laid out in the commissioning policy;

Paediatric Complex Obesity

Services for children and adolescents (aged up to and including 17 yrs and 11 months) with complex obesity are considered to be highly specialised and will be delivered from very few centres dedicated to the provision of Paediatric obesity services, and co-ordinated under the supervision of a national clinical supervisory programme.

Bariatric surgery is not routinely undertaken on children and adolescents. Where it is indicated in exceptional cases, and only at highly specialised centres surgery will be undertaken through this service using this service specification. Prior approval must be sought before surgery.

When treating children, the service will additionally follow the criteria outlined in the specification for Children and Adolescent services (attached as Appendix 1 to this specification - a final version of this specification will be provided shortly).

This specification does not cover:

- Patients with a BMI under 35 kg/m2. There may be rare occasions when special factors (e.g. prior to renal transplant or fertility treatment) necessitate referral to a specialised complex obesity service; these will be treated as exceptional cases and managed through the individual funding processes.
- Ethnic groups with increased risk of obesity related co-morbidities at lower BMI than Caucasians
- Children and adolescents
- Revisional surgery
- Follow-up after 2 years

2.5 Interdependencies with other services

Facilities:

Providers of complex obesity services will be able to demonstrate that they have suitably equipped facilities and appropriately trained specialist staff to provide assessment; pre-operative; operative; and post-operative care for patients. Ideally, facilities for the complex obesity service will be separate from those for other patients in order to maintain the focus of the service on the special needs of the patients. However, irrespective of whether there are dedicated facilities, providers will ensure that privacy and dignity of patients is maintained at all times.

Consideration will be given to the services being delivered on the ground floor of the provider. Where this is not possible the commissioner will seek written assurances regarding access to lifts, including compliance with current legislation; emergency protocols for the event of power failure or rapid evacuation of patients in relation to other emergencies. Where this is not possible, the commissioner will seek written

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assurance regarding the physical structure of the relevant building and its load-bearing capabilities.

The service should have a physical environment that meets the needs of patient attending the service: toilet seats, grab rails, shower chairs, commodes, chairs, beds, lifting equipment etc. will be suitable for use by patients who are morbidly obese. The provider will make appropriate beds and scales available for obese patients and ensure that suitable imaging equipment is available for obese patients.

The surgical service should have demonstrable arrangements for:

- access to in-patient beds for post-operative recovery;
- access to critical care facilities 24 hours a day, to at least high dependency (HDU) Level 2, and located on the same site at which surgical procedures are undertaken;
- access to Intensive care unit (ITU) Level 3 facilities on sites where surgical procedures are undertaken that are available 24 hours a day. Where this is not the case providers will have robust plans and procedures in place for patient transfers to local ITU level 3 critical care facilities that are available 24 hours a day. Procedures will include details of arrangements that the provider has with the receiving hospital for clinical liaison hand-over during the patient transfer and post transfer/re-admittance to their surgical unit;
- access to suitably qualified doctor with sufficient training and experience in bariatric surgery 24 hours a day for advice and treatment as necessary;
- the emergency assessment and treatment of post-operative complications;
- provision for revisional procedures following assessment of previous outcomes for primary bariatric surgery;
- the training and education of all staff involved in the care and management of morbidly obese patients.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

Core Standards: to be in place at commencement of the contract

- NICE Clinical Guideline 43: Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children
- National Bariatric Surgery Registry data standards and requirements http://hostn3.e-dendrite.com/csp/bariatric/FrontPages/nbsrfront.csp accessed 26 Aug 2012 http://www.bomss.org.uk/pdf/Pages_from_NBSR_2010.pdf accessed 26 Aug 2012
- Safeguarding Adults: the Role of Health Service practitioners (Department of

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Health, 2011)

- British Obesity and Metabolic Surgery Society Commissioning Standards
- Association of Upper Gastro-intestinal Surgeons: Provision of Services (2011)
- International Federation for the Surgery of Obesity: Guidelines for Safety, Quality, and Excellence in Bariatric Surgery (2008) – see Appendix 2 http://www.eac-bs.com/eacbs/en/4/58.html accessed 26 Aug 2012.

4. Key Service Outcomes

Commissioning Data and minimum data sets

The Commissioners require data on the services in order to benchmark the service against this specification and provide assurance on the expected service and clinical outcomes, together with information required to monitor and manage the contractual agreement. This data will be provided through national and local information collection.

Providers shall comply with guidance relating to clinical coding as published by the NHS Classification Services and with the definitions of activity maintained under the NHS Data Model and Dictionary.

Providers shall collect and provide national datasets within the timescales set out in the relevant Information Centre guidance and all applicable Information Standards Notice(s) and submit coded data to SUS.

Providers shall ensure that all patients seen within the service are entered onto the National Bariatric Surgery Registry, and comply with a the data requirements of the registry.

Providers shall comply with all local information collection requirements as listed in this service specification and in the contractual agreement with the commissioner.

The outcome measures listed below will be derived from information collected at individual patient level. The outcome measures are to be collected for all patients.

Outcome Measures

For all patients referred to the secondary care provider, there should be documentation of weight management trajectory in non-surgical services, information about reasons for referral for bariatric surgery, or not, and notes of any exceptional aspects of care. At least 90% of patients going for bariatric surgery should comply with all criteria as given in Policy document.

Co-morbidity improvement

Reduction in objective measures of identified co-morbidities.

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To be monitored at 6-months, 12-months, 18-months and 24-months post-surgery. Split by co-morbidity, e.g. type 2 diabetes.

Weight Loss

Weight should be recorded at onset of engagement with weight management programme (whether it be in a community or secondary care centre). Weight should be recorded at the time of assessment at surgical MDT.

Weight loss (WL): at 2 years post-operatively, by type of surgery. WL to be monitored at 6-months, 12-months, 18-months and 24- months post-surgery.

Weight Loss (WL): at 2 years post referral, for non-surgical interventions (for patients clinically unsuitable for surgery). WL to be monitored at 6-months, 12-months, 18-months and 24-months post intervention.

100% **data submission to National Bariatric Surgery Registry**: all procedures carried out will be entered into the NBSR as per Dendrite data entry criteria.

% patients lost to follow-up: 6-months; 12-months; 24-months. It is the responsibility of the bariatric provider to ensure follow up to 2 years. There is an expectation of zero loss to follow-up.

% patients within 18-weeks; the percentage of patients achieving a maximum wait of 18-weeks between referral and first definitive treatment/clock-stop on both admitted and non-admitted pathways. Minimum expectations of 90% admitted patients and 95% non- admitted patients within 18-weeks. (Please be aware that this does not mean surgery within 18-weeks of referral, first definitive treatment might be any non-surgical intervention deemed clinically necessary).

Morbidity and Mortality

Post-operative complication rates by operation type: leak rate, early obstruction, deep vein thrombosis, pulmonary embolism, chest infection, bleeding or other.

In-hospital mortality rates: classified by operation type, BMI band and surgical risk score; separate data to be recorded for revisional procedures).

Post-discharge mortality rate: All deaths that occur post-discharge, reporting at 6-months and 12-months following primary or revisional surgery.

Surgical complication requiring HDU: Observed admissions post operatively into ITU/HDU.

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ANNEX 1 TO SERVICE SPECIFICATION:

PROVISION OF SERVICES TO CHILDREN

Aims and objectives of service

This specification annex applies to all children's services and outlines generic standards and outcomes that would fundamental to all services.

The generic aspects of care:
The Care of Children in Hospital (Health Service Circular (HSC) 1998/238) requires that:

- Children are admitted to hospital only if the care they require cannot be as well provided at home, in a day clinic or on a day basis in hospital.
- Children requiring admission to hospital are provided with a high standard of medical, nursing and therapeutic care to facilitate speedy recovery and minimize complications and mortality.
- Families with children have easy access to hospital facilities for children without needing to travel significantly further than to other similar amenities.
- Children are discharged from hospital as soon as socially and clinically appropriate and full support provided for subsequent home or day care.
- Good child health care is shared with parents/carers and they are closely involved in the care of their children at all times unless, exceptionally, this is not in the best interest of the child; Accommodation is provided for them to remain with their children overnight if they so wish.

Service description/care pathway

All paediatric specialised services have a component of primary, secondary, tertiary and even quaternary elements.

The efficient and effective delivery of services requires children to receive their care as close to home as possible dependent on the phase of their disease.

Services should therefore be organised and delivered through "integrated pathways of care" (*National Service Framework for children, young people and maternity services* (Department of Health (DOH) & Department for Education and Skills, London 2004

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Interdependencies with other services

All services will comply with Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Inter-Dependencies – DOH

Imaging

All services will be supported by a 3 tier imaging network (‘Delivering quality imaging

services for children’ DOH 13732 March2010). Within the network;

- It will be clearly defined which imaging test or interventional procedure can be performed and reported at each site
- Robust procedures will be in place for image transfer for review by a specialist radiologist, these will be supported by appropriate contractual and information governance arrangements
- Robust arrangements will be in place for patient transfer if more complex imaging or intervention is required
- Common standards, protocols and governance procedures will exist throughout the network.
- All radiologists, and radiographers will have appropriate training, supervision and access to Continuing Professional Development (CPD)
- All equipment will be optimised for paediatric use and use specific paediatric software

Specialist Paediatric Anaesthesia

Wherever and whenever children undergo anaesthesia and surgery, their particular needs must be recognised and they should be managed in separate facilities, and looked after by staff with appropriate experience and training.[1] All UK anaesthetists undergo training which provides them with the competencies to care for older babies and children with relatively straightforward surgical conditions and without major co-morbidity. However those working in specialist centres must have undergone additional (specialist) training[2] and should maintain the competencies so acquired[3] *. These competencies include the care of very young/premature babies, the care of babies and children undergoing complex surgery and/or those with major/complex co-morbidity (including those already requiring intensive care support).

As well as providing an essential co-dependent service for surgery, specialist anaesthesia and sedation services may be required to facilitate radiological procedures and interventions (for example MRI scans and percutaneous nephrostomy) and medical interventions (for example joint injection and intrathecal chemotherapy), and for assistance with vascular access in babies and children with complex needs such as intravenous feeding.

Specialist acute pain services for babies and children are organised within existing departments of paediatric anaesthesia and include the provision of agreed (hospital wide) guidance for acute pain, the safe administration of complex analgesia regimes

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including epidural analgesia, and the daily input of specialist anaesthetists and acute pain nurses with expertise in paediatrics.

*The Safe and Sustainable reviews of paediatric cardiac and neuro- sciences in England have noted the need for additional training and maintenance of competencies by specialist anaesthetists in both fields of practice.

References

1. Guidelines on the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. Royal College of Anaesthetists (RCoA) 2010 www.rcoa.ac.uk
2. Certificate of Completion of Training (CCT) in Anaesthesia 2010
3. CPD matrix level 3

Specialised Child and Adolescent Mental Health Services (CAMHS)

The age profile of children and young people admitted to specialised CAMHS day/in-patient settings is different to the age profile for paediatric units in that it is predominantly adolescents who are admitted to specialised CAMHS in-patient settings, including over-16s. The average length of stay is longer for admissions to mental health units. Children and young people in specialised CAMHS day/in-patient settings generally participate in a structured programme of education and therapeutic activities during their admission.

Taking account of the differences in patient profiles the principles and standards set out in this specification apply with modifications to the recommendations regarding the following:

- Facilities and environment – essential Quality Network for In-patient CAMHS (QNIC) standards should apply (http://www.rcpsych.ac.uk/quality/quality,accreditationaudit/qnic1.aspx)
- Staffing profiles and training - essential QNIC standards should apply.
- The child/ young person's family are allowed to visit at any time of day taking account of the child / young persons need to participate in therapeutic activities and education as well as any safeguarding concerns.
- Children and young people are offered appropriate education from the point of admission.
- Parents/carers are involved in the child/young persons care except where this is not in the best interests of the child / young person and in the case of young people who have the capacity to make their own decisions is subject to their consent.
- Parents/carers who wish to stay overnight are provided with accessible accommodation unless there are safeguarding concerns or this is not in the best interests of the child/ young person.

Applicable national standards e.g. NICE, Royal College

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Children and young people must receive care, treatment and support by staff registered by the Nursing and Midwifery Council on the parts of their register that permit a nurse to work with children (Outcome 14h *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010):

- There must be at least two Registered Children's Nurses (RCNs) on duty 24 hours a day in all hospital children's departments and wards.
- There must be an Registered Children's Nurse available 24 hours a day to advise on the nursing of children in other departments (this post is included in the staff establishment of 2RCNs in total).

Accommodation, facilities and staffing must be appropriate to the needs of children and separate from those provided for adults. All facilities for children and young people must comply with the Hospital Build Notes *HBN 23 Hospital Accommodation for Children and Young People* NHS Estates, The Stationary Office 2004.

All staff who work with children and young people must be appropriately trained to provide care, treatment and support for children, including Children's Workforce Development Council Induction standards (Outcome 14b *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010).

Each hospital who admits inpatients must have appropriate medical cover at all times taking account of guidance from relevant expert or professional bodies (National Minimum Standards for Providers of Independent Healthcare, Department of Health, London 2002)."Facing the Future" Standards, Royal College of Paediatrics and Child Health.

Staff must carry out sufficient levels of activity to maintain their competence in caring for children and young people, including in relation to specific anaesthetic and surgical procedures for children, taking account of guidance from relevant expert or professional bodies (Outcome 14g *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010).

Providers must have systems in place to gain and review consent from people who use services, and act on them (Outcome 2a *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010). These must include specific arrangements for seeking valid consent from children while respecting their human rights and confidentiality and ensure that where the person using the service lacks capacity, best interest meetings are held with people who know and understand the person using the service. Staff should be able to show that they know how to take appropriate consent from children, young people and those with learning disabilities (Outcome 2b) (*Seeking Consent: working with children* Department of Health, London 2001).

Children and young people must only receive a service from a provider who takes steps to prevent abuse and does not tolerate any abusive practice should it occur (Outcome 7 *Essential Standards of Quality and Safety*, Care Quality Commission,

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London 2010 defines the standards and evidence required from providers in this regard). Providers minimise the risk and likelihood of abuse occurring by:

- Ensuring that staff and people who use services understand the aspects of the safeguarding processes that are relevant to them.
- Ensuring that staff understand the signs of abuse and raise this with the right person when those signs are noticed.
- Ensuring that people who use services are aware of how to raise concerns of abuse.
- Having effective means to monitor and review incidents, concerns and complaints that have the potential to become an abuse or safeguarding concern.
- Having effective means of receiving and acting upon feedback from people who use services and any other person.
- Taking action immediately to ensure that any abuse identified is stopped and suspected abuse is addressed by:
  - having clear procedures followed in practice, monitored and reviewed that take account of relevant legislation and guidance for the management of alleged abuse
  - separating the alleged abuser from the person who uses services and others who may be at risk or managing the risk by removing the opportunity for abuse to occur, where this is within the control of the provider
  - reporting the alleged abuse to the appropriate authority
  - reviewing the person's plan of care to ensure that they are properly supported following the alleged abuse incident.
- Using information from safeguarding concerns to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.
- Working collaboratively with other services, teams, individuals and agencies in relation to all safeguarding matters and has safeguarding policies that link with local authority policies.
- Participates in local safeguarding children boards where required and understand their responsibilities and the responsibilities of others in line with the Children Act 2004.
- Having clear procedures followed in practice, monitored and reviewed in place about the use of restraint and safeguarding.
- Taking into account relevant guidance set out in the Care Quality Commission's Schedule of Applicable Publications
- Ensuring that those working with children must wait for a full CRB disclosure before starting work.
- Training and supervising staff in safeguarding to ensure they can demonstrate the competences listed in Outcome 7E of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010

All children and young people who use services must be fully informed of their care, treatment and support.

- Able to take part in decision making to the fullest extent that is possible.
- Asked if they agree for their parents or guardians to be involved in decisions

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they need to make.

(Outcome 4I *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010)

Key Service Outcomes

Evidence is increasing that implementation of the national *Quality Criteria for Young People Friendly Services* (Department of Health, London 2011) have the potential to greatly improve patient experience, leading to better health outcomes for young people and increasing socially responsible life-long use of the NHS.

Implementation is also expected to contribute to improvements in health inequalities and public health outcomes e.g. reduced teenage pregnancy and STIs, and increased smoking cessation. All providers delivering services to young people should be implementing the good practice guidance which delivers compliance with the quality criteria.

Poorly planned transition from young people's to adult-oriented health services can be associated with increased risk of non adherence to treatment and loss to follow-up, which can have serious consequences. There are measurable adverse consequences in terms of morbidity and mortality as well as in social and educational outcomes. When children and young people who use paediatric services are moving to access adult services (for example, during transition for those with long term conditions), these should be organised so that:

- All those involved in the care, treatment and support cooperate with the planning and provision to ensure that the services provided continue to be appropriate to the age and needs of the person who uses services.

The National Minimum Standards for Providers of Independent Healthcare, (Department of Health, London 2002) require the following standards:

- **A16.1** Children are seen in a separate out-patient area, or where the hospital does not have a separate outpatient area for children, they are seen promptly.
- **A16.3** Toys and/or books suitable to the child's age are provided.
- **A16.8** There are segregated areas for the reception of children and adolescents into theatre and for recovery, to screen the children and adolescents from adult patients; the segregated areas contain all necessary equipment for the care of children.
- **A16.9** A parent is to be actively encouraged to stay at all times, with accommodation made available for the adult in the child's room or close by.
- **A16.10** The child's family is allowed to visit him/her at any time of the day, except where safeguarding procedures do not allow this
- **A16.13** When a child is in hospital for more than five days, play is managed and supervised by a qualified Hospital Play Specialist.
- **A16.14** Children are required to receive education when in hospital for more than five days; the Local Education Authority has an obligation to meet this need and are contacted if necessary.
- **A18.10** There are written procedures for the assessment of pain in children and

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the provision of appropriate control.

All hospital settings should meet the *Standards for the Care of Critically Ill Children* (Paediatric Intensive Care Society, London 2010).

There should be age specific arrangements for meeting Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These require:

- A choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users' needs;
- Food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background
- Support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs.
- For the purposes of this regulation, "food and hydration" includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed.
- Providers must have access to facilities for infant feeding, including facilities to support breastfeeding (Outcome 5E, of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

All paediatric patients should have access to appropriately trained paediatric trained dieticians, physiotherapists, occupational therapists, speech and language therapy, psychology, social work and CAMHS services within nationally defined access standards.

All children and young people should have access to a professional who can undertake an assessment using the Common Assessment Framework and access support from social care, housing, education and other agencies as appropriate

All registered providers must ensure safe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines (Outcome 9 *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010). For children, these should include specific arrangements that:

- Ensures the medicines given are appropriate and person-centred by taking account of their age, weight and any learning disability
- Ensuring that staff handling medicines have the competency and skillsneeded for children and young people's medicines management
- Ensures that wherever possible, age specific information is available for people about the medicines they are taking, including the risks, including information about the use of unlicensed medicine in paediatrics.

Many children with long term illnesses have a learning or physical disability. Providers should ensure that:

- They are supported to have a health action plan

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- Facilities meet the appropriate requirements of the Disability Discrimination Act 1995
- They meet the standards set out in Transition: getting it right for young people. Improving the transition of young people with long-term conditions from children's to adult health services. Department of Health Publications, 2006, London

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Appendix 2

IFSO Guidelines for Safety, Quality, and Excellence in Bariatric Surgery

A. IFSO Guidelines for Primary Bariatric Institutions (PBIs)

(i) Institutional requirements

For any medical institution considering the surgical management of morbidly obese patients, it would be necessary to:

1. Ensure that surgeons performing bariatric surgery have the appropriate certification, training, and experience to treat severely obese patients as described in the surgeon's credentials.

2. Ensure that individuals who provide services in the bariatric surgery programme are adequately qualified to provide such services.

3. Provide ancillary services such as specialised nursing care, dietary instruction, counselling, and psychological assistance if and when needed.

4. Have readily available consultants in cardiology, pulmonology, psychiatry, and rehabilitation with previous experience in treating bariatric surgery patients.

5. Have trained anaesthesiologists with experience in treating bariatric surgery patients.

6. Keep records of the adverse events that occur during the management of the patients.

7. Ensure that basic equipment necessary for the treatment of obese patients is available e.g. scales, operating room tables, instruments, supplies specifically designed for bariatric laparoscopic and open surgery, laparoscopic towers, wheelchairs, various other articles of furniture and lifts that can accommodate stretchers are available. There should also be available a recovery room capable of providing critical care to morbidly obese patients and an intensive care unit with similar capacity.

8. Ensure that radiology department facilities can perform emergency chest x-rays with portable machinery, abdominal ultrasonography, and upper GI series.

9. Ensure that blood tests can be performed on a 24hr basis.

10. Ensure that blood bank facilities are available and blood transfusion can be carried out at any time.

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(ii) Surgeon's credentials

1. Appropriate certification to perform general surgery.

2. Training and experience in gastrointestinal open and/or laparoscopic surgery.

3. Successful completion of a training course in an existing Bariatric Institution or at least a minimum of two days on a bariatric training course including live demonstrations and laboratory hands-on training.

4. Testimonials by mentors (proctors) of satisfactory Bariatric surgical ability.

5. Careful maintenance of a database of all Bariatric cases, including outcomes, which can be audited by the appropriate national authorities.

6. Commitment to postoperative lifetime follow-up of the patients.

7. Carrying out of operations in approved facilities as described above.

Primary Bariatric Institutions (PBIs) should not accept super obese patients for the first one to two years of their practice.

During the early period of service development the management of morbidly obese patients should be confined to more simple bariatric procedures. PBIs may proceed to more complex bariatric techniques and to treat super obese patients only when significant experience has been gained (i.e. after performing a minimum of 50 cases). More technically demanding procedures requiring stapling and division of the stomach and gut and revisional surgery should not be carried out until the conditions described for existing Bariatric Institutions (BI)are completely reached.

B. IFSO Guidelines for Bariatric Institutions (BIs)

(i) Institutional Requirements

Any medical institution undertaking the management of morbidly obese, super obese, and super-super obese patients with laparosscopically adjustable gastric banding (LAGB) and/or procedures requiring stapling of the stomach and the gut, such as sleeve gastrectomy, roux-en-y gastric bypass (RYGBP) and biliopancreatic diversion (BPD)/duodenal switch (DS)* or revisional cases should, apart from points described in guidelines for PBIs, ensure that they fulfil the following additional conditions:

1. Ensure that the director of bariatric surgery has at least five years' experience in the field and is capable of performing advanced bariatric procedures successfully.

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2. Have comprehensive and full in-house consultative services required for the care of Bariatric surgical patients, including critical care services.

3. Have the complete range of necessary equipment, instruments, items of furniture, wheel chairs, operating room tables, beds, radiology facilities such as CT scan and other facilities specially designed and suitable for morbidly and super obese patients.

4. Have a written informed consent process that informs each patient of the surgical procedure, the risk for complications and mortality rate, alternative treatments, the possibility of failure to lose weight and his/her right to refuse treatment.

5. Maintain details of the treatment and outcome of each patient in a digital database.

6. Provide all necessary assistance and advise the staff to attend relevant meetings, subscribe to international journals and become members of a national Bariatric Society.

7. Have experienced interventional radiologists available to take over the non- surgical management of possible anastomotic leaks and strictures.

* Duodenal switch is associated with high morbidity and will normally be reserved for extreme cases.

(ii) Surgeon's credentials

Each interested surgeon should:

1. Have performed at least 50 bariatric cases per year.

2. Be able to perform revisional surgery by open and/or laparoscopic approach.

3. Be committed to a long-term (lifetime) follow up of his patients.

4. Attend bariatric meetings regularly, subscribe to at least one ariatric journal, and report his/her experience by presenting at local or international congresses or by publishing articles in peer-reviewed journals.

5. Perform advanced bariatric surgery at the appropriate facilities.

C. IFSO Guidelines for Centre of Excellence Bariatric Institution (COEBI)

(i) Institutional requirements

Apart from the described requirements for BIs, every medical centre willing

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to be evaluated and approved as an IFSO Centre of Excellence Bariatric Institution, should prove to the IFSO authorised Review Committee that:

1. It is committed to the highest level of excellence in bariatric surgical patient care and maintains a regular programme of education for medical, nursing, administrative and allied health staff in bariatric surgery.

2. Performs at least 100 bariatric surgical cases per year including revisional cases. The perioperative care and the surgical procedures have to be standardised for each surgeon.

3. Has a bariatric surgeon who spends the main portion of his or her effort in the field of bariatric surgery.

4. Has supervised support groups for bariatric patients.

5. Provides lifetime follow up for the majority and not less than 75% of all bariatric surgical patients. Details of the patients' outcome should be included in a digital database and confidential information should be available on request by IFSO authorities.

(ii) Surgeon's credentials

Each surgeon in addition to the above described BIs credentials should:

1. Perform at least 50 bariatric cases per year including a number of revisional cases among them.

2. Be involved in the training and the accreditation of less-experienced bariatric surgeons.

3. Be committed to complete life time follow up of his/her patients and prove that his/her follow up is for at least five or more years.

4. Report his/her results in international conferences and publish articles in international peer-reviewed journals.

Obesity Surgery Mortality Risk Score

Risk Factor	Points
Age>45 years	1
Hypertension	1
Male sex	1
Risk factors for pulmonary embolism	1
Body mass index ≥ 50 kg per m2	1

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Risk Group	Points
Low	0 or 1 points
Medium	2 or 3 points
High	4 or 5 points

DeMaria EJ, Portenier D, Wolfe L. Obesity surgery mortality risk score: proposal for a clinically useful score to predict mortality risk in patients undergoing gastric bypass. Surg Obes Relat Dis 2007;3:134-40.

Demaria EJ, Murr M, Byrne TK, Blackstone R, Grant JP, Budak A Wolfe L. Validation of the Obesity Surgery Mortality Risk Score in a multicenter study proves it stratifies mortality risk in patients undergoing gastric bypass for morbid obesity. Ann Surg 2007;246:578–582

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Appendix 3

Person specifications of specialists comprising multi-disciplinary team (MDT)

Bariatric Surgeons

The surgeons in the multidisciplinary team should hold GMC (General Medical Council) registration, be on the specialist register for general surgery and have undertaken a relevant supervised training programme and have specialist experience in bariatric surgery. See IFSO guidelines appendix 2. They should be members of The British Obesity & Metabolic Surgery Society (BOMMS).

Bariatric Physicians

The physicians in the multidisciplinary team should hold GMC registration, be on the specialist register and have undertaken a relevant supervised training programme and have specialist experience in bariatric medicine. Formal training in obesity is a component of the training requirement for diabetes & endocrinology and metabolic medicine

Primary Care Bariatric Specialists

The primary care specialists in the community based multidisciplinary team should hold GMC registration, be on the GP register and be a member of SCOPE and/or be a GP with a special interest in obesity. They should have undertaken a relevant supervised training programme.

Dietitians

All dietitians should be HPC (Health profession Council) registered and have undergone appropriate training in the management of obesity. Junior dietitians should have the support of a senior colleague with appropriate experience. Training should include both an understanding of psychological factors and readiness to change and motivational interviewing and counselling skills. They should be a member of BOMMS.

Psychologists

All psychologists should have HPC registration and be chartered with British Psychological Society. Psychologists should be sufficiently experienced in weight loss surgery, mental health and disordered eating behaviour. Ability to conduct an assessment to establish the individual's ability to implement necessary health behaviour changes for weight loss post-surgery through therapeutic approaches such as Motivational Interviewing and Stages of Changes. Experienced in identifying the individual emotional, cognitive and behavioural factors that may

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influence weight loss and be able to provide individual recommendations to improve weight loss and QoL outcomes. Ability to make recommendations for more complex patients that potentially may require psychological intervention pre and/or post-surgery for anxiety, depression and binge-eating. Able to train other health professionals in facilitation of health behaviour change.

Specialist nurses

All nurses should hold state registration, have undergone appropriate training within their specialist field and attended an obesity training course. Nurses involved in obesity management should have attended an obesity training course.

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