



NATIONAL STANDARDS ON BARIATRIC AND METABOLIC SURGERY



FOREWORD

Bariatric and Metabolic Surgery has risen to popularity in Malaysia largely due to the growing prevalence of obesity in the country. The National Standards on Bariatric and Metabolic Surgery seeks to address this problem by providing a safe and precise guideline to determine which patients are suitable for this procedure.

This document is a result of numerous meetings held with key stakeholders, including surgeons, endocrinologists, physiotherapists, and dieticians. We have also endeavored to ensure that all parties, specifically from the public, private, and academic sectors, are well-represented. It is encouraging to see everyone coming together to produce this vital guideline.

It is hoped that the National Standards for Bariatric and Metabolic Surgery will serve as a manual for physicians and surgeons alike who intend to offer this service in their facilities. I would like to thank the working committee as well as the societies that have come together to see this through, including SELSMA and MyMBS.

I would also like to congratulate the Medical Development Division of the Ministry of Health, Malaysia for their tireless efforts in achieving the completion of this document.



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“Reflect upon your present blessings, of which every man has plenty; not on your past misfortunes, of which all men have some.” — *Charles Dickens*

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SECTION 1

INTRODUCTION

SECTION 1: INTRODUCTION

This National Standards guidelines is essentially a guide for surgeons and centres that are starting and performing Bariatric Surgery as one of their services. Initially, the focus was to provide a guide for Ministry of Health Malaysia (hereafter MOH) facilities only; the scope was then expanded to cover the entire health framework of the country.

Obesity is fast becoming a global pandemic, with over one million people affected [1]. Malaysia is not an exception. Approximately 45.3% of our population has been identified as either overweight or obese [2]. The westernization of food, the increased popularity of “fast food”, the adoption of a more sedentary lifestyle, and the mechanisation of transportation modalities are among the factors that have led to this major health dilemma. The increasing prevalence of obesity in Malaysia is seen to go hand-in-hand with the rise in Type 2 Diabetes Mellitus (T2DM), which was reported to affect 3.5 million (17.5%) individuals in 2015 [3]. The occurrence of obesity and T2DM has been observed to be higher among women and Malaysians of Indian ethnicity compared to men and Malaysians of various other ethnic backgrounds [3-5].

An obvious concern and a major public health challenge, obesity and its associated comorbidities can diminish the productivity of the working class and threaten future economic development plans, besides acting as a major driver of rising healthcare costs. In 2010 alone, the global expenditure on diabetes was estimated to be approximately \$376 billion (USD), forcing member states of the World Health Organisation (WHO) to take immediate notice and introduce plans to combat the rise of obesity and diabetes by 2025. This commitment was made during the Sixty-Sixth World Health Assembly in Geneva [1,6].

Weight loss drugs and lifestyle modification aside, bariatric surgery (obesity and metabolic) has gained tremendous popularity in recent years and received multilateral validation as an effective treatment option for obesity and obesity-

related T2DM from surgeons and endocrinologists alike. Numerous studies have been published on the superiority of bariatric surgery over medical treatment among the obese population as well as on the sustainability of bariatric surgery over time in terms of weight loss and comorbidity resolution [7-9].

1.1 RATIONALE FOR NATIONAL STANDARDS ON BARIATRIC AND METABOLIC SURGERY

A revised consensus is urgently needed in view of the increasing prevalence of obesity in Malaysia and the numerous advancements in the field of weight and weight-associated comorbidity management. This national consensus aims to: (i) provide an overview of available surgical treatment options for obesity; (ii) offer an understanding of its indication as well as contraindications; and (iii) aid primary care physicians in referrals to appropriate specialists for obesity and obesity-related comorbidities that are resistant to initial diet/lifestyle modification techniques.

1.2 METHODOLOGY FOR CONSENSUS DEVELOPMENT

This consensus was developed by a multidisciplinary workgroup consisting of experts in bariatric surgery, endocrinology (including a paediatric endocrinologist), anaesthesia, psychiatry, sports medicine, and primary care, as well as representatives from dietetics, psychology, and physiotherapy. Published scientific literature and existing international guidelines on this subject matter, especially guidelines emerging from the Asia Pacific region, were referred to extensively and exhaustively during the formulation of this consensus. The heterogeneity of the Malaysian population as well as various other factors were taken into consideration throughout the consensus development process. The time taken to develop it was three (3) years starting from the year 2016. The efforts were initially

spearheaded by the Bariatric and Metabolic Surgery Working Group and later taken up by the National Bariatric Surgery Framework Committee based on a letter of authorisation from the MOH in November 2018.

1.3 OBJECTIVES

This Committee aimed to address the aforementioned issues in two (2) parts:

Part 1

1. To establish a guideline that can be expanded into a clinical practice guideline (CPG) in a year's time. The initial guideline aimed to initiate the practice of bariatric and metabolic surgery by outlining the policies, training pathways, and centres that provide bariatric and metabolic surgery services as identified within the framework of the MOH.
2. To plan a strategy to implement the above guidelines to lead to the registration of morbid obesity as a recognised disease under the MOH and Malaysian Medical Council (MMC).
3. To establish governance for the practice of bariatric and metabolic surgery by implementing audits, mortality meetings, and root cause analysis meetings at least once a year to identify areas for improvement.

Part 2

To propose a plan for a National Bariatric Service Framework for Malaysia, which should encompass the following:

1. Centres must be sustainable as well as flexible to cater to the needs of the country, taking into consideration services that had been running but have now ceased.

2. Continuation of care is maintained, taking into account manpower and resource utilisation.
3. The problem of budget and “patient pay scheme” must be overcome, particularly for bariatric and metabolic surgery in Malaysia.
4. Safe, equitable, and fair access to services in Malaysia must be ensured.
5. Medical tourism must be catered to, particularly through low volume centres, for the purpose of performing bariatric and metabolic procedures.

Following the meeting held on the 9th of November 2018 and the formation of the National Bariatric Framework Committee, the MOH members of the committee endeavoured to optimise the previous recommendations via the following actions:

1. Engaged international reviewers for ideas and input on the proposed guidelines. Among the reviewers were Professor CK Huang (Taiwan), Professor Kasama Kazunori (Japan), and Professor Dr Lee Wei Jei (Taiwan).
2. Reviewed previous audits performed in bariatric centres in Malaysia and assimilated the lessons learnt as an addendum in the policy guidelines.
3. Conducted regular discussions among members to review the current criteria and proposed ideas of implementation.
4. Engaged partners in Thailand and Singapore to solicit their feedback on the guidelines and protocols for surgeons performing the procedure.

1.4 BARIATRIC AND METABOLIC SURGERY

Bariatric surgery is the field of surgery that assists patients in losing weight. The growing prevalence of obesity and obesity-related disease has driven the development of this area of surgery. Apart from weight loss, bariatric surgery has also been proven to assist in metabolic

syndromes, particularly Diabetes Mellitus. This has prompted the expansion of the field into bariatric and metabolic surgery.

A surgeon performing bariatric surgery has to be, first, formally trained in its technique, process, and outcome, and second, proficient in managing complications if and when they may arise. Currently, in Malaysia, three (3) different branches of surgeons perform this procedure, namely general surgeons with training in bariatric surgery, upper GI surgeons, and endocrine surgeons.

1.5 ABBREVIATIONS

ASA	American Society of Anaesthesiologists
BMI	Body Mass Index
BPD/DS	Biliopancreatic Diversion/ Duodenal Switch
COS	College of Surgeons
CPG	Clinical Practice Guidelines
CPD	Continuous Professional Development
CV	Cardiovascular
DVT	Deep Vein Thromboses
ECG	Electrocardiography
ICU	Intensive Care Unit
FBC	Full Blood Count
FBS	Fasting Blood Sugar
FSL	Fasting Serum Lipid
HBa1C	Glycated Haemoglobin Test
MGB	Mini Gastric Bypass

LCD	Low Calorie Diet
LFT	Liver Function test
MMC	Malaysia Medical Council
MO	Medical Officer
OGDS	Oesophagogastroduodenoscopy
Gastro	Duodenoscopy
OSA	Obstructive Sleep Apnoea
OT	Operating Theatre
PACU	Post Anaesthesia Care Unit
RP	Renal Profile
SG	Sleeve Gastrectomy
T2DM	Type 2 Diabetes Mellitus
TFT	Thyroid Function Test
WHO	World Health Organisation
VLCD	Very Low Calorie Diet
MOH	Ministry of Health Malaysia

SECTION 2

INDICATION FOR SURGERY

SECTION 2: INDICATION FOR SURGERY

2.1. A-INDICATION

For this guideline, the aim was to merge the best of readily available guidelines and adapt them to the local setting in consideration of the current manpower, resources, and logistics in Malaysia. The objective was also to provide a comprehensive management plan for obesity and obesity-related diseases in keeping with safety, governance, and accountability.

2.2. INDICATION FOR BARIATRIC SURGERY

2.2.1. Morbid obesity without comorbidity:

Bariatric surgery should be considered for the treatment of obesity in suitable patients with $BMI \geq 37.5 \text{ kg/m}^2$ who fulfil selection criteria.

2.2.2. Morbid obesity with comorbidities:

The surgical approach may be considered as a non-primary alternative to treat obesity in suitable patients with $BMI \geq 32.5 \text{ kg/m}^2$ with obesity-related comorbidity (e.g., subfertility, obesity-related spine and joint disorders) following inadequate weight loss by virtue of medical therapy and lifestyle modifications.

2.2.3. Morbid obesity with metabolic syndrome:

The surgical approach may be considered as a non-primary alternative to treat obesity in suitable patients with $BMI \geq 32.5 \text{ kg/m}^2$ with metabolic syndrome/CV risk following inadequate weight loss by virtue of medical therapy and lifestyle modifications.

2.2.4. Low BMI with or without comorbidities:

Any surgery for metabolic syndrome or obesity-related comorbidity in patients with a $BMI \leq 32.5 \text{ kg/m}^2$ should **not** be a routine clinical practice and should be strictly performed only under clinical study protocol with informed consent from the patient and prior approval from the ethics committee.

2.2.5. Age restriction:

Bariatric surgery is generally recommended for patients within the age range of 18 to 65.

2.2.6. Special circumstances:

In consultation with a physician, paediatrician, orthopaedic surgeon, clinical psychologist, and surgeon, bariatric surgery may be applied in morbidly obese adolescent patients, provided they have attained the physiological bone maturity of Tanner Stage 4.

SECTION 3

BARIATRIC TEAM/PERSONNEL

SECTION 3: BARIATRIC TEAM/PERSONNEL

3.1 BARIATRIC AND METABOLIC SURGEON AND MEDICAL OFFICER

1. Heads the bariatric team and runs day-to-day operations
2. Ensures patient safety is always the priority
3. Adheres to audit, compliance, and reporting

3.2 ENDOCRINOLOGIST/PHYSICIAN (WITH INTEREST IN OBESITY, DM, AND METABOLIC DISORDERS)

1. Runs a combine clinic or sees bariatric patients as required pre- and post-operation
2. Requests additional investigations and manages post-op requirements as needed, including giving appointments to respective clinics

3.3 NURSE COORDINATOR AND BARIATRIC NURSE (DEDICATED IF POSSIBLE)

1. Familiar with the physical and psychological characteristics of the morbidly obese patient
2. Facilitates interactions between the patient and other staff members
3. Communicates with hospital staff regarding specific patient requirements
4. Manages the logistics of equipment (i.e., staplers, energy devices, and trocars) to ensure it is available for surgery

3.4 DIETITIAN

1. Has an understanding of the special feeding characteristics of morbidly obese patients and the nutritional challenges they face
2. Evaluates the patient's eating habits and meal proportions to develop a preoperative dietary plan
3. Counsels postoperative patients regarding the quality and quantity of food consumption

3.5 CLINICAL PSYCHOLOGIST/PSYCHIATRIST/COUNSELLOR

1. Assesses the mental condition of the patient
2. Counsels patients to withstand lifelong changes associated with surgical weight loss procedures
3. Guides patients to have realistic expectations of the rate of weight loss
4. Behavior modification

3.6 PHYSIOTHERAPIST

1. Assists dietician in planning a suitable regime to optimise patients' weight loss
2. Works in tandem with the combine clinic to ensure patient is well-educated about exercise and knows how to formulate a routine, particularly post-operatively after the patient is discharged.

SECTION 4

TYPES OF BARIATRIC SURGERY

SECTION 4: TYPES OF BARIATRIC SURGERY

This consensus recommends four (4) procedures under the two (2) categories listed below, in line with recommendations from international guidelines for bariatric surgery.

1. Restriction

- i. Gastric Band
- ii. Sleeve Gastrectomy

2. Malabsorption

- i. Biliopancreatic Diversion/ Duodenal Switch (BPD/DS)
- ii. Roux-en-Y Gastric Bypass

Although novel bariatric surgical procedures (outside the scope of the four mentioned above) have shown promising results for Asians, such procedures should only be carried out by surgeons with experience.

SECTION 5

SELECTION CRITERIA AND CONTRAINDICATIONS

SECTION 5: SELECTION CRITERIA AND CONTRAINDICATIONS

5.1 SELECTION CRITERIA FOR BARIATRIC SURGERY

Patients who fulfil the indications above SHOULD fulfil the criteria below:

1. Weight loss history:

- i. Previous nonsurgical attempts at weight reduction for at least six (6) months.

2. Patient commitment:

Patient is required to comply to the programme, which includes:

- i. Follow up visits with healthcare team, willingness to follow support group, and other recommendations made by healthcare team.
- ii. Recommended medical management, including use of dietary supplements and exercise routine.
- iii. Compliance with instructions regarding any recommended procedures or tests.
- iv. Smoking cessation for a minimum of eight (8) weeks prior to surgery.²²

5.2 CONTRAINDICATIONS TO BARIATRIC SURGERY

1. Patient who is unable to comply to continuous medical follow up as required.
2. Pregnancy
3. Non-stabilised psychotic disorders, severe depression, or personality and eating disorders, unless specifically advised by a psychiatrist/psychologist.
4. Reversible endocrine disorders that can cause obesity.
5. Alcohol abuse and/or drug dependencies.
6. Diseases threatening life in the short term (ASA-4).
7. Patients who are unable to care for themselves and have no long-term family or social support that warrants such care.

SECTION 6

PREOPERATIVE, OPERATIVE, & FOLLOW-UP CONSIDERATIONS

SECTION 6: PREOPERATIVE, OPERATIVE, & FOLLOW-UP CONSIDERATIONS

A bariatric surgery referral centre should possess multidisciplinary team members as discussed earlier, along with adequate facilities and resources to support the service.

The centre should be able to manage all facades of bariatric surgery from primary to revision bariatric procedures. The team should also be able to perform both diagnostic as well as therapeutic endoscopy.

This segment highlights the facilities and equipment needed to set up a bariatric surgery referral centre. Perioperative investigations and management, including recommended post-procedural follow-up protocols, are also discussed.

6.1 HOSPITAL FACILITIES

1. Suitable operating theatre equipped with laparoscopic camera system and adequate equipment including instruments, trocars, retractors, needle drivers, energy devices, and any other equipment deemed vital for these types of procedures.
2. ICU/High Dependency Unit Services/PACU
3. Blood bank
4. Radiology department with imaging facilities
5. Endoscopy unit

6. Ward and clinic facilities that are suitable for bariatric patients, including adequate chairs, toilets, trolleys, and operation beds to accommodate patients if and when required.

6.2 PERIOPERATIVE MANAGEMENT

6.2.1 General consultation on:

1. Dietary changes required before and after surgery.
2. Optimising treatment of comorbidities to reduce the risks of the surgical procedure.
3. Patient motivation and willingness to adhere to further follow-up visits.
4. Comprehensive explanation on benefits, consequences, outcomes, and risks of the surgical options and the necessity for lifelong follow-up.
5. Ability to provide informed consent.
6. Contraception must be discussed. Patients should be advised to avoid pregnancy for a minimum of 18 months post-surgery.

6.2.2 Information booklet/brochure for patients

1. Preoperative investigations
2. FBC, RP, Calcium, LFT, FBS, FSL, HbA1c, TFT, Serum cortisol (6-8am), Urine 24h cortisol
3. ECG

4. STOP-BANG Questionnaire and quantification of risk of OSA/sleep study/Edwards sleeping score
5. Chest radiograph
6. Ultrasound hepatobiliary system
7. OGDS

6.2.3 Desirable investigations (as required/optional)

1. Body composition index
2. Overnight dexamethasone suppression test
3. Sleep study

6.3 PRE-OPERATIVE ANAESTHETIC ASSESSMENT

Patients to be referred to Anaesthesiology Clinic for pre-op assessment prior to surgery.

6.4. PRE-OPERATIVE CALORIC RESTRICTION

1. Pre-operative caloric restriction may be recommended for selected patients prior to bariatric/metabolic surgery.
2. Low calorie dietary restriction (LCD) at 1200 calories/day or very low calorie dietary restriction (VLCD) at 800 calories/day.
3. Admission for these protocols may be considered.

6.5. PRE-OPERATIVE DVT PROPHYLAXIS

Refer to existing national guidelines.

6.6. AUDIT AND GOVERNANCE

All bariatric surgery procedures must be documented using standard notifications. These forms should be kept by the bariatric nurse or case manager and dispatched for audit on a yearly basis upon request. Mortality from bariatric surgery should be reported and POMR forms are to be adequately filled and submitted.

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STOP-BANG QUESTIONNAIRE

Updated STOP-Bang Questionnaire

Snororing?
Yes No
 Do you **Snore Loudly** (loud enough to be heard through closed doors or your bed-partner elbows you for snoring at night)?

Tired?
Yes No
 Do you often feel **Tired, Fatigued, or Sleepy** during the daytime (such as falling asleep during driving or talking to someone)?

Observed?
Yes No
 Has anyone **Observed** you **Stop Breathing** or **Choking/Gasping** during your sleep?

Pressure?
Yes No
 Do you have or are being treated for **High Blood Pressure**?

Body Mass Index more than 35 kg/m²?
Yes No

Age older than 50 year old?
Yes No

Neck size large? (Measured around Adams apple)
For male, is your shirt collar 17 inches/43 cm or larger?
For female, is your shirt collar 16 inches/41 cm or larger?
Yes No

Gender = Male?
Yes No

Scoring Criteria:

For general population

Low risk of OSA: Yes to 0-2 questions

Intermediate risk of OSA: Yes to 3-4 questions

High risk of OSA: Yes to 5-8 questions

or Yes to 2 or more of 4 STOP questions + male gender

or Yes to 2 or more of 4 STOP questions + BMI > 35 kg/m²

or Yes to 2 or more of 4 STOP questions + neck circumference

(17"/43cm in male, 16"/41cm in female)

Proprietary to University Health Network. www.stopbang.ca

Modified from: Chung F et al. Anesthesiology 2008; 108:812-21; Chung F et al. Br J Anaesth 2012, 108:768-75; Chung F et al. J Clin Sleep Med 2014;10:951-8.

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