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### Disclaimer:

The Saudi Guidelines on the Prevention and Management of Obesity developed by the Obesity Control Program is not meant to replace clinical judgments of physicians but are only tools to help the practicing doctors to manage obese patients. Although a lot of effort was exerted to ensure the accurate names and doses of medications, the authors encourage the readers to refer to the medications' information for further clarification.

### **CONTENTS:**

ABBREVIATIONS	iii
FORWARD BY THE DIRECTOR GENERAL	iv
WORD FROM SAUDI ARABIAN SOCIETY OF METABOLIC AND BARIATRIC SURGERY	V
ACKNOWLEDGEMENT	vi
INTRODUCTION	1
Magnitude of the problem in the Kingdom of Saudi Arabia (KSA)	1
GUIDELINES DEVELOPMENT PROCESS	2
Scope of guidelines	2
Aim of the guidelines	2
Clinical question to be answered	2
Development process	3
Implementation strategies	4
Update of the guidelines	4
HOW TO USE THE GUIDELINES	5
PRIMARY PREVENTION OF OBESITY IN CHILDREN, ADOLESCENTS AND ADULTS	6
Guidelines for Healthy Eating	7
Birth to five years	7
Children above five years and adults	7
Guidelines for Physical Activity	9
Children	9
Adults	9
WEIGHT MANAGEMENT IN CHILDREN	10
Clinical and laboratory assessment of overweight and obesity in children	12
Devise goals	12
Management of obesity in children and adolescents	12
Referral of children and adolescents to secondary or tertiary care	14
Plan for regular monitoring of weight management in children and adolescents	14

WEIGHT MANAGEMENT IN ADULTS	15
Clinical and laboratory assessment of overweight and obesity	17
Assess for readiness to change lifestyle behaviors'	22
Management of obesity	25
Devise goals	25
Devise life style modification program for weight loss and reduction of risk factors	25
Psychological/behavioral interventions	27
Long-term weight management	28
Referral for specialist support	28
PHARMACOLOGICAL TREATMENT	29
BARIATRIC SURGERY	35
ANNEX 1: KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS	43
ANNEX 2: MEMBERS OF ADOPTION GROUP OF FIRST DRAFT OF THE GUIDELINES	47
ANNEX 3: OBESITY CONTROL PROGRAM SCIENTIFIC COMMITTEE	48
ANNEX 4: GUIDELINES PREPARATION COMMITTEE	49
ANNEX 5: CHARTS FOR BMI TO AGE PERCENTILES AMONG CHILDREN	50

ii

## **ABBREVIATIONS:**

ASBP	American Society of Bariatric Physicians		
ACEI	Angiotensin-converting-enzyme inhibitor		
ARB	Angiotensin receptor blockers		
BMI	Body mass index		
CVD	Cardio-vascular disease		
ССВ	Calcium-channel blocker		
GAG	Guidelines Adoption Group		
HDL	High- density lipoprotein		
ICSI	Institute for Clinical Systems Improvement		
Kcal	Kilo-calorie		
Кд	Kilo-gram		
KSA	Kingdom of Saudi Arabia		
LDL	Low-density lipoprotein		
NICE	National Institute for health and Care Excellence (UK)		
NCD	Non-Communicable Disease		
NHMRC	National Health and Medical Research Council (Australia)		
SAGES	Society of American Gastrointestinal and Endoscopic Surgeons		
SASMBS	Saudi Arabian Society of Metabolic and Bariatric Surgery		
SIGN	Scottish Intercollegiate Guidelines Network		
SHIS	Saudi Health Information Survey		
TSH	Thyroid-stimulating hormone		
WC	Waist circumference		

## **FORWARD**:

The health system in KSA has witnessed enormous development and reforms during the last few decades; however, it continues to face many emerging challenges. The country is already experiencing the demographic and epidemiologic transitions, whereby the health scene is dominated by non-communicable diseases (NCDs).

In the Kingdom of Saudi Arabia, obesity and overweight has become one of the most common public health problems affecting people of both sexes and all age groups. The prevalence is on the rise, which requires prompt actions and efforts from health and related stakeholders.

We are putting forward these evidence based guidelines for obesity to health care workers in the Kingdom of Saudi Arabia. The guidelines have been adapted by national experts who are also users of clinical guidelines in their own practices. They are intended to provide health care professionals with the tools to effectively prevent and manage overweight and obesity.

We are very grateful to H.E. the Minister of Health for his constant support and advice to the General Directorate for Control of Genetic and Chronic Diseases to combat NCDs and its risk factors in the country.

Looking forward to see tangible results of this effort in combating obesity in the country.

Dr. Mohammad Y. Saeedi, General Director General Directorate for Control of Genetic & Chronic Diseases Ministry of Health, Riyadh, Kingdom of Saudi Arabia

# WORD FROM SAUDI ARABIAN SOCIETY OF METABOLIC AND BARIATRIC SURGERY:

Saudi Arabian Society of Metabolic and Bariatric Surgery is one of the growing societies that were established in 2010 under the umbrella of the Saudi Commission for Health Specialties. One of the aims of the society includes publishing and disseminating clinical guidelines on prevention and treatment of obesity in Saudi Arabia.

Overweight and obesity affect more than 60% of the total population in Saudi Arabia. Almost all age groups are affected in general and adults in particularly. In order to introduce high quality health-care for these individual, it is mandatory to establish clinical guidelines that will help health-care providers to manage this common problems at all levels. These guidelines are adapted from Scottish Intercollegiate Guidelines Network (SIGN) for management of obesity after taking permission in this regard. The guidelines will cover preventive and curative aspects of overweight and obesity and could be implemented at primary, secondary, and tertiary care levels in Saudi Arabia.

Finally we thank the Scientific Committee of Saudi Arabian Society of Metabolic and Bariatric Surgery for adapting these guidelines and acknowledge the untiring efforts of our partner; the General Directorate for Control of Genetic and Chronic Diseases, Ministry of Health, Kingdom of Saudi Arabia, for their major contribution in issuing the guidelines. We hope that all health care providers will implement it in order to introduce the best quality health care for our community.

Dr. Waleed S Abu-Melha, President, MBBS/CABFM/Fellowship Obesity, Department of Preventive Medicine, Military Hospital, Khamis Mushyait, KSA

## **ACKNOWLEDGEMENT:**

First and foremost I offer my sincerest gratitude to the Director General of the General Directorate for Control of Genetic and Chronic Diseases, who has supported us throughout preparation process in developing these guidelines. His guidance, enthusiastic encouragement and useful critiques were valuable.

I would also like to thank the Saudi Arabian Society of Metabolic and Bariatric Surgery (SASMBS) where these Guidelines are based on their work which was published in the Saudi Journal of Obesity.

Special thanks are extended to the members of adoption group of first draft of the guidelines of obesity for their unlimited help.

I would like to express my appreciation to obesity control program scientific committee and guidelines preparation committee for their valuable and constructive suggestions during planning and development of this work. Their willingness to give their time so generously has been very much appreciated.

Finally, I would also like to extend my thanks to the obesity program coordinators, doctors and nurses from all the regions of the Kingdom for their dedicated work.

## **INTRODUCTION:**

Obesity results from accumulation of body fats overtime. It occurs when the energy intake exceeds energy requirements. This could occur as a result of many factors including increased food intake, physical inactivity, and genetic factors<sup>1,2</sup>.

Obesity is a key risk factor for many non-communicable diseases (NCDs), including type 2 diabetes, hypertension, heart disease and some cancers. The risk increases with increase in the level of obesity. Obesity and overweight are also strongly associated with mental health and eating disorders<sup>2, 3, 4</sup>.

Obesity and overweight have become the most prevalent nutritional problems in the world putting an increased burden on the health care system. They affect almost one third (2.1 billion people) of the global population and result in five percent of all deaths worldwide<sup>3,4,5</sup>. The magnitude of the problem may reach almost half of the world's adult population by 2030 if the current trend persists<sup>6</sup>.

A comprehensive, systemic multi-sectoral program comprising of multiple interventions involves and includes broad behavioral change component is required to produce positive impact in managing obesity among the population. Physical activity and nutritional behavior are a vital part of any obesity control program. This necessitates the development of multi-setting programs (e.g. schools and work-places). Prevention efforts should also invest in, and target all age groups and individuals with parental and/or family involvement<sup>3,5</sup>.

### Magnitude of the problem in the Kingdom of Saudi Arabia (KSA)

In Saudi Arabia, obesity has become one of the most common public health problems affecting people of both sexes and all age groups. According to Saudi Health Interview Survey (SHIS) conducted in 2013, obesity and overweight affect 28.7% and 30.7% of individuals 15 years and older respectively (collectively overweight and obesity affect 59.4% of the total population). The prevalence of obesity among adult males and females was 24.1% and 33.5% respectively, while 33.4% adult males and 28.0% females were overweight <sup>7</sup>.

## **GUIDELINES DEVELOPMENT PROCESS:**

#### Scope of guidelines:

These guidelines address the following areas:

- Prevention of overweight and obesity in children and adults through education and counseling.
- Prevention of overweight and obesity through screening high-risk individuals.
- Management of overweight and obesity through life-style changes, drugs and surgical interventions.

#### Aim of the guidelines:

The guidelines aim to provide recommendations for the prevention and management of overweight/obesity in children and adults based on current evidence for best practices that is suitable for our target population, culture, health-care system, and resources.

#### Clinical question to be answered:

The following five items (PIPOH) were used to define the health question and cover different aspects 8:

(P) The Population concerned and characteristic of disease condition:

- The target population includes all sex and age groups.

#### (I) The Interventions of interest:

- Screening the population for overweight and obesity.
- Psychological, dietary and physical exercise interventions.
- Referral to secondary and tertiary care for further assessment and management.
- (P) The Professionals to whom the guidelines will be targeted:
  - These guidelines are intended for the use of healthcare professionals at all levels, including physicians, nurses, dietitians, psychologists and physiotherapists.

(O) The expected Outcome including patients, public and system outcome:

- To reduce the prevalence of overweight and obesity and their co-morbidities.
- To reduce the expenditure on the health system.
- To decrease clinical practice variation.
- (H) The Health care setting and context in which the guidelines are to be implemented:
  - PHC centers and Hospitals.

#### **Development process:**

The General Directorate for Control of Genetic and Chronic diseases (NCDs) constituted a team to develop "Saudi Guidelines for the Prevention and Management of Obesity". The team operated under supervision of the Director General of NCDs and headed by the Director of Obesity control Program (members of the team are listed at annex 3). The assistance of the Obesity Control Program's Scientific Committee was available for guidance during the process.

The team reviewed the Clinical Practice Guidelines for the Prevention and Management of Obesity in Saudi Arabia developed by the Saudi Arabian Society of Metabolic and Bariatric Surgery (SASMBS); and also conducted a rigorous review of relevant evidenced based scientific literature. After a thorough assessment, a consensus was reached to use the SIGN guideline as the main guideline based on the work of SASMBS and to fill the gap from the following guidelines<sup>9</sup>:

- Clinical Practice Guidelines for the Management of overweight and obesity in adults, adolescents and children in Australia.
- 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults and children.
- NICE (National Institute for health and Care Excellence) guidelines Obesity: identification, assessment and management of overweight and obesity in children, young people and adults (November 2014).
- Institute for Clinical Systems Improvement (ICSI) guideline for Prevention and Management of Obesity for Children and Adolescents.

To avoid duplication of efforts, the team adopted the grading of evidence used by different guidelines used in this document (annex1).

The updated version was presented in a workshop, involving the Obesity Control Program Scientific Committee, in addition to other relevant stakeholders and the recommendation of the participants were included.

The final draft was distributed for review by Obesity Control Program Scientific Committee and their comments were included (annex 3 lists the membership of the Committee).

#### Implementation strategies:

Obesity Control Program will be responsible for implementation of the guidelines with the support of regional directorates. The printed document will be distributed to all targeted health professionals. Training of Trainers (TOT) will be organized at national level to train regional level trainers.

Wide scale training workshops will be conducted at regional level to train health professionals from primary and secondary level health facilities.

Feedback will be obtained from health professionals trained on the guidelines, and their recommendations will be considered in updating the future edition.

#### Update of the guidelines:

Updating the guidelines will be considered every 5 years.

### HOW TO USE THE GUIDELINES:

The goal of these Guidelines is to provide health care professionals with the tools to effectively prevent and manage overweight and obesity among children and adults. The guidelines are structured as follows:

**Chapter (1)** is on primary prevention of obesity among children, young people and adults; the guidelines provide information on preventing overweight and obesity through lifestyle modification program, focusing on recommendations for healthy diet, physical activity and periodic medical examination.

**Chapters (2&3)** are about weight management in children and adults; where the guidelines introduce two algorithms to be followed for assessment and management of obesity and overweight. The assessment is based on Body Mass Index (BMI) for age percentiles for children and BMI and Waist Circumference (WC) for adult, in addition to a set of laboratory investigation to assess for underlying causes, risk factors and co-morbidities.

**Chapter (4)** explains pharmacological management of obesity; it briefly presents a list of medications used for pharmacological treatment. It provides brief description of each medication including mechanism of action, indications, contraindications, maintenance dosage and mode of administration.

**Chapter (5)** on surgical management of obesity (bariatric surgery); it describes briefly the indications for considering bariatric surgery as part of obesity management pass-way. It describes briefly the common types of bariatric surgery highlighting its potential short term and long term complications.

Different grades are used in the document based on the source of evidence. In order to effectively use the document the reader should refer to annex 1, which summarizes the grade of evidences used by different sources quoted in this document.



Chapter 1

## PRIMARY PREVENTION OF OBESITY IN CHILDREN, ADOLESCENTS AND ADULTS

# PRIMARY PREVENTION OF OBESITY IN CHILDREN, ADOLESCENTS AND ADULTS:

• For all age groups, assess diet, physical activity and sedentary behaviors annually (ICSI, strong recommendation, high quality evidence)<sup>10</sup>.

#### **Guidelines for Healthy Eating:**

#### Birth to five years:

- Recommend exclusive breastfeeding from birth up to the age of six months (ICSI, High Quality Evidence)<sup>11,10</sup>.
- Gradually introduce solid food starting at the age of six months<sup>11</sup>.
- Carefully introduce one at a time- foods which may cause allergies such as milk, eggs, wheat, seeds, nuts, fish and shellfish<sup>11</sup>.
- Provide three meals and two between-meal snacks for children one year old<sup>11</sup>.
- Avoid high fiber foods and large volume of full fat dairy products in below two years children<sup>11</sup>.
- Introduce gradually, low fat dairy products, for normally growing above two years old children<sup>11</sup>.
- Adjust salt intake to the age of the child; (less than 1 g/day up to age 12 months; from 1-3 years no more than 2 g/day and a maximum of 3 g/day for 4-6 year olds) <sup>11</sup>.

#### Children above five years and adults

- Recommend food in accordance with healthy eating guidelines from the age of five years onwards unless there is specific clinical dietary requirement (see table 1). Adjust portion sizes to age, gender, weight and activity level<sup>10,11</sup>:
  - Encourage the child to eat to appetite.
  - Encourage children to eat regular meals including breakfast (ICSI, strong recommendation, high quality evidence)<sup>10</sup>
  - Discourage availing easy access to foods not recommended for the child<sup>11</sup>.
  - Encourage intake of low salt foods and limit the intake of energy-dense foods and fast foods (SIGN, Evidence grade B) <sup>11</sup>.
  - Follow the 5-2-1-0 message every day:

7

- \* **5**= Encourage intake of daily **5** portions of fruits and vegetables (ICSI, strong recommendation, high quality evidence).
- \* **2**= Encourage eating with the child in a sociable atmosphere without distractions, separate eating from other activities and keep recreational screen time to less than **2** hours, (ICSI, strong recommendation, high quality evidence)<sup>10</sup>.
- \* 1= Include at least 1 hour or more of active play every day (see physical activity section below).
- \* **0**= Skip sugar sweetened beverages, drink more water every day.
- Advise patients using medications associated with weight gain on weight management, as shown in table 3 (SIGN, evidence grade B)<sup>11</sup>.

#### Table 1: The eat-well plate guidelines (8)

Food group	Recommendation
Bread, rice, potatoes, pasta, and other starchy foods	Eat plenty, choose whole-grain varieties when you can
Fruits and vegetables	Eat plenty, at least 5 portions of a variety of fruit and vegetables a day
Milk and dairy foods	Eat some, choose lower fat alternatives whenever possible or eat higher fat versions infrequently or in smaller amounts
Meat, fish, eggs, beans, and other non-dairy sources of protein	Eat some, choose lower fat alternatives whenever possible or eat higher fat versions infrequently or in smaller amounts. Aim for at least two portions of fish a week, including a portion of oily fish
Foods and drinks high in fat and/or sugar	Consume just a small amount

Source: SIGN Guidelines

#### **Guidelines for Physical Activity:**

#### **Children:**

- Encourage children gradually to perform at least 60 minutes of moderate to vigorous exercise daily continuous or accumulated in short bouts (ICSI, Moderate Recommendation, High Quality Evidence)<sup>10,11</sup>.
- Encourage children to lead active daily life such as walking, cycling, skipping and using the stairs and support them to practice regular physical activity appropriate to their age and ability such as football and swimming<sup>11</sup>.
- Discourage sedentary behavior of more than two hours for children particularly of screen time, like watching TV, computer use and playing video games (ICSI, strong recommendation, high quality evidence)<sup>10,11</sup>.
- Encourage family approach to physical exercise (e.g. walking and cycling to school and shops, going to the park or for swimming)<sup>11</sup>.

#### Adults:

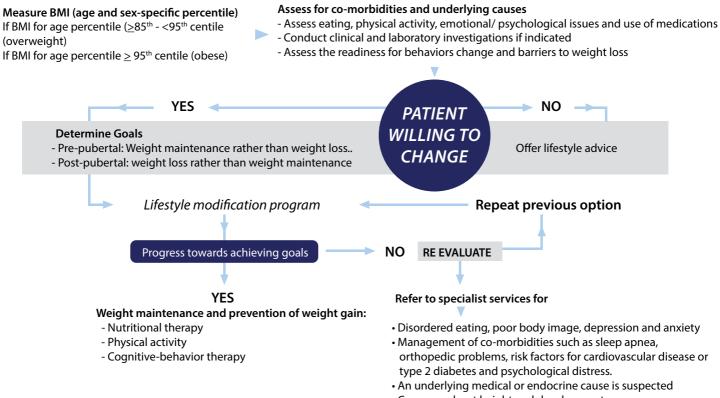
- Provide physical activity advice appropriate to specific individual situation. The focus should be on activities that can fit easily into their everyday lives and are tailored to their individual preferences and circumstances. Attention should be given to pregnant women, those at risk of post-natal weight retention, women reaching the age of menopause, or while quitting smoking<sup>11</sup>.
- Inform the individuals about the benefits of physical activity on reducing the risk of Cardiovascular Disease (CVD) and type 2 diabetes, even without evident weight reduction<sup>11</sup>.
- Encourage adults to do at least 30 minutes of moderate-intensity physical activity on 5 or more days a week. This should be built up over time; start by walking 10 minutes a day on a few days during the first couple of weeks then add more time and days gradually<sup>11</sup>.



Chapter 2

## WEIGHT MANAGEMENT IN CHILDREN

### Algorithm for Managing Overweight and Obesity in Children



- Concerns about height and development
- Pharmacologic or bariatric surgery

### WEIGHT MANAGEMENT IN CHILDREN

#### Clinical and laboratory assessment of overweight and obesity in children:

- Use the Saudi sex-specific BMI for age percentile chart for assessing overweight and obesity in infants and children 0-19 years of age (there are two sets of gender specific charts, Birth to 36 months and 2 to 19 years (see annex 5)). The Growth Chart for Saudi Children and adolescents categorizes overweight as between the 85th and 95th percentile and obesity as above the 95th percentile<sup>12,13,14</sup>.
- Inquire about the presence of parental obesity, type 2 diabetes and CVD which are a strong predictor of a child's weight and co-morbidities (ICSI, Strong Recommendation, High Quality Evidence)<sup>4,10</sup>.
- Assess child developmental history, physical and mental health and assess for current health problems, comorbidities (e.g. raised blood pressure, joint pain, gastrointestinal symptoms, insulin resistance, intertrigo, dental health) and risks for future disease (ICSI, Strong Recommendation, High Quality Evidence) <sup>4,10</sup>.

#### Devise goals:

- In children and pre-pubertal adolescents the goal should be weight maintenance rather than weight loss. Maintaining weight during growth will result in a declining BMI and will prevent potential adverse effects (NHMRC, evidence grade D)<sup>4,5</sup>.
- In post-pubertal adolescents the goal is weight loss rather than weight maintenance<sup>4,5</sup>.

#### Management of obesity in children and adolescents:

- Recommend early start of weight management in children and adolescents with the objectives of preventing adulthood overweight or obesity, reducing risk of co-morbidities and enhancing healthy life style behaviors <sup>4</sup>.
- Target weight management of the child or adolescent through family approach addressing healthy lifestyle behavior of the whole family (ICSI, Strong Recommendation, High Quality Evidence and NHMRC, evidence grade PP<sup>4</sup>.
- Recommend frequent contacts with health professionals for children and adolescents (NHMRC, evidence grade B)<sup>4</sup>.
- Consider child preference, ability and strength when choosing lifestyle activities. It is recommend that the activities

should be fun, recreational and tailored to the relative strengths of child and family (Canadian, evidence grade A, level 2)<sup>3</sup>.

- Lifestyle interventions should focus on changing the health behaviors, consume healthy diet, and perform physical activity<sup>4,10</sup>:
  - Advise the reduction of screen time to less than 2 hours per day (ICSI, Strong Recommendation, High Quality Evidence).
  - Encourage daily 60 minutes of moderate and vigorous exercise, e.g. household tasks, walking to school, sports clubs, swimming pool, walking tracks. etc (ICSI, Strong Recommendation, moderate Quality Evidence).
  - Encourage children to have regular meals in a sociable atmosphere (ICSI, Strong Recommendation, High Quality Evidence).
  - Encourage children to eat a nutrient-dense breakfast daily (ICSI, High Quality Evidence).
  - Discourage eating energy-dense food, like fast food (ICSI, High Quality Evidence).
  - Encourage children to eat to appetite (ICSI, Moderate Quality Evidence).
  - Advice on availing healthy food choices.
  - Encourage drinking water instead of sugary drinks and energy drinks (ICSI, Strong Recommendation, High Quality Evidence).
  - Advice on separating eating from other activities, e.g. watching TV (ICSI, Moderate Quality Evidence).
- Weight management of obese child should include a family based behavior change components targeting lifestyle change of the whole family (SIGN, evidence grade B)<sup>11</sup>.
- Sustained behavioral changes are essential to achieve weight maintenance and/or weight loss in children (SIGN, evidence grade D)<sup>11</sup>.

#### *Referral of children and adolescents to secondary or tertiary care:*

- Specialist services may be required for the following (NHMRC, evidence grade D) <sup>4</sup>:
  - Disordered eating,
  - Poor body image,
  - Depression and anxiety,
  - Presence of co-morbidities (e.g. sleep apnea, orthopedic problems, risk factors for cardiovascular disease or type 2 diabetes and psychological distress),
  - Suspected underlying medical or endocrine cause, and
  - Concerns about height and development.
- Referral for pharmacologic or bariatric surgery may be considered in post-pubertal adolescents, with severe obesity (a BMI > 40 kg/m<sup>2</sup> or > 35 kg/m<sup>2</sup> with obesity-related complications), who failed to respond to lifestyle interventions (NHMRC, evidence grade D)<sup>4</sup>.

#### Plan for regular monitoring of weight management in children and adolescents:

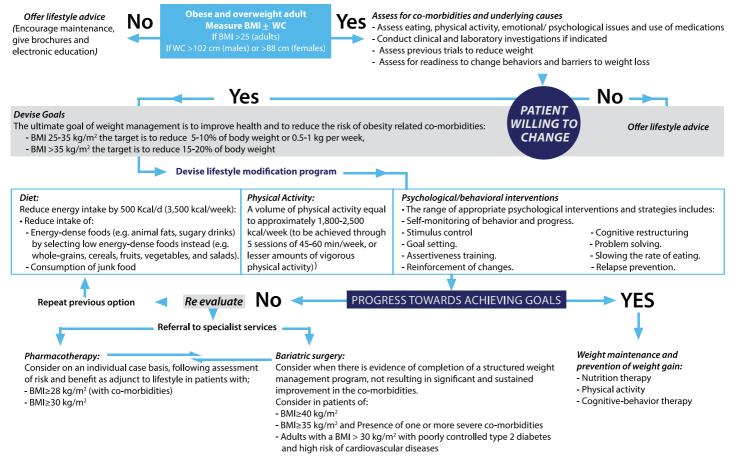
• Follow-up the cases regularly every 3 months (NHMRC, evidence grade PP)<sup>4</sup>.



Chapter 3

## **WEIGHT MANAGEMENT IN ADULTS**

## ALGORITHM FOR ASSESSMENT & STEPWISE MANAGEMENT OF OVERWEIGHT AND OBESITY IN ADULTS



Adapted from 2006 Canadian clinical practice guidelines & SIGN Guideline

### WEIGHT MANAGEMENT IN ADULTS

#### Clinical and laboratory assessment of overweight and obesity:

- Obtain a thorough history and a general physical examination to assess obesity, overweight and obesity related risks and to exclude secondary causes of obesity (Canadian, evidence grade A, level 3)<sup>3,4</sup>. See tables 2 to 9 for details.
- Measure body mass index (BMI) (weight in kilograms divided by height in meters squared) to assess overweight or obesity in adults (Canadian, evidence grade A, level 3)<sup>3,4</sup>. Table 2 provides the reference for different BMI categories.
- Measure the waist circumference (WC) in addition to BMI to assess for abdominal fat and risk of obesity-related comorbidities particularly cardiovascular disease and diabetes (Canadian, evidence grade A, level 3)<sup>3</sup>. Males with WC ≥ 102 cm and females with WC ≥88 cm are at high-risk of the above mentioned complications, see Table 3 <sup>11</sup>.
- Request/ Conduct laboratory tests when appropriate to assess for co-morbidities. Recommended tests include:

   Fasting plasma glucose level, lipid profile, including total cholesterol, triglycerides, low-density lipoprotein cholesterol (LDL), high-density lipoprotein (HDL) and ratio of total cholesterol to HDL (Canadian, evidence grade A, level 3)<sup>3</sup>.
- Liver enzyme tests, urinalysis and sleep studies (Canadian, evidence grade B, level 3)<sup>3</sup>.
- Refer for professional assessment as appropriate for eating disorders, depression and psychiatric disorders (Canadian, evidence grade B, level 3)<sup>3</sup>.

#### Table 2: Classification of Obesity<sup>2</sup>

BMI	Class
<18.5	Underweight
18.5-24.9	Normal
25-29.9	Overweight
30-34.9	Obesity class I (mild)
35-39.9	Obesity class II (moderate)
≥40	Obesity class III (morbid obesity)

#### Table 3: Measuring Waist Circumference<sup>4</sup>

- Use a measuring tape that is checked monthly for stretching (replace if stretched).
- Ask the person to remove heavy outer garments, loosen any belt and empty pockets.
- Ask the person to stand with their feet fairly close together (about 12–15 cm) with their weight equally distributed and to breathe normally.
- Holding the measuring tape firmly, wrap it horizontally at a level midway between the lower rib margin and iliac crest (approximately in line with the umbilicus). The tape should be loose enough to allow the measure to place one finger between the tape and the person's body.
- · Record the measurement taken on an exhalation

#### Table4: Risk factors of obesity 15

Evidence has shown that individuals with following conditions are at high-risk of becoming overweight or obese.

- After smoking cessation.
- On certain medications (see table 5)
- Polycystic ovarian syndrome
- Hypothyroidism and pseudo-hypoparathyroidism
- Hypogonadism
- Cushing syndrome
- Hypothalamic Obesity
- Genetic Syndromes (e.g. Prader-Willi syndrome, Alstrom syndrome, Bardet-Biedl syndrome, Cohen syndrome, Borjeson-Forssman-Lehmann syndrome, Frohlich syndrome)
- Growth hormone deficiency
- Eating disorders (especially binge-eating disorder, bulimia nervosa, and night eating disorder)
- Dyslipidemia.
- Family history of obesity.
- Pregnancy, post-natal weight retention, and at the menopause

#### Table 5: Medications that interfere with weight loss or induce weight gain<sup>15</sup>

Medication Class	Alternatives
Antipsychotics/ Mood Stabilizers • Phenothiazines • Atypical antipsychotics: Clozapine, olanzapine, risperidone, quetiapine • Lithium	Ziprasidone, Aripiprazole
<ul> <li>Antidepressants:</li> <li>Sedating tricyclics: Amitriptyline &gt; imipramine</li> <li>Monoamine oxidase inhibitors (non-selective): Isocarboxazid, Phenelzine, tranylcypromine</li> <li>Selective serotonin reuptake inhibitors: Paroxetine &gt; citalopram, fluvoxamine, sertraline</li> <li>Mirtazapine</li> </ul>	Nefazodone, Bupropion, Venlafaxine
Antiepileptics: • Gabapentin, Valproate, Carbamazepine, Pregabalin	Lamotrigine, Topiramate
Antiepileptics/antipsychotics used in bipolar disorder • Valproate, Carbamzepine, Clozapine, Olanzapine, Risperidone	Lamotrigine, Topiramate, Ziprasidone
Hormonal contraceptives	Barrier methods
Corticosteroids	NSAIDs
Progestational steroids: • Megestrol acetate	Weight loss Aromatase Inhibitors
Antidiabetic agents: • Insulin • Sulfonylureas • Thiazolidinediones	Metformin, Acarbose
Antihypertensives: • Beta and alpha1- adrenergic blocking agents	ACEI, ARB, Diuretics, CCB
Antihistamines: • Cyproheptadine	Diphenhydramine, Decongestants, inhaler

#### Table 6: Co-morbidities and consequences of obesity<sup>15</sup>

Cardiovascular • Hypertension • Heart failure • Coronary artery diseases • Varicose veins • Pulmonary embolism	Respiratory • Dyspnea • Obstructive sleep apnea • Hyperventilation syndrome • Pick wickian syndrome • Asthma
Endocrine • Metabolic syndrome • Diabetes type 2 • Dyslipidemia • Polycystic ovarian syndrome • Reduced fertility and menstrual disorders • Pregnancy complications	Gastrointestinal • Gastro-esophageal reflux diseases, • Fatty liver disease • Cholelithiasis, • Hernias • Pancreatitis
Genitourinary <ul> <li>Urinary stress incontinence</li> <li>Obesity related glomerulopathy</li> </ul>	Surgical <ul> <li>Increased surgical risk</li> <li>Increased post-operative complications</li> </ul>
Neurologic • Stroke • Idiopathic intracranial hypertension • Meralgia parasthetica • Dementia	Musculoskeletal • Osteoarthritis (knee and hip) • Immobility, • Low back pain • Hyperuricemia and gout
Psychological • Depression/ low self-esteem • Body image disturbances • Social stigmatization	Cutaneous • Stretch marks • Status pigmentation of legs • Lymph edema • Cellulitis
Neoplasms   Breast cancer  Uterine cancer  Colonic cancer	<ul> <li>Intertrigo and carbuncles</li> <li>Acanthosis nigricans</li> <li>Skin tags</li> </ul>

20

#### Table 7: Diagnostic Evaluation of Obese Patient<sup>15</sup>:

All obese\ patients	<ul> <li>BP measurement &amp; heart rate</li> <li>Fasting blood sugar, HbA1c and lipid profile</li> </ul>
Suspected Obstructive Sleep Apnea (daytime sleepiness, loud snoring, gasping or chocking episodes during sleep and awakening headaches )	<ul> <li>Measurement of neck circumference (&gt;17 inches in men, &gt;16 inches in women)</li> <li>Polysomnograpy for oxygen desaturation, apnea and hypo-apneic events</li> <li>ENT examination for upper airway obstruction</li> </ul>
Suspected Alveolar Hyperventilation (Pickwickian) syndrome (hypersomnolence, right sided heart failure including elevated JVP, hepatomegaly and lower limb edema	<ul> <li>Polysomnography (to rule out obstructive sleep apnea)</li> <li>CBC to rule out polycythemia</li> <li>Blood gases (Pco2 often elevated)</li> <li>Chest x-ray (enlarged heart and elevated hemi-diaphragm)</li> <li>ECG: right atrial and right ventricular enlargement</li> <li>Pulmonary function test: reduced vital capacity and respiratory reserve volume</li> </ul>
Suspected Hypothyroidism	•TSH
Suspected Cushing's syndrome (moon face, thin skin that bruise easily, severe fatigue, striae	<ul> <li>Elevated late night salivary cortisol level (&gt;7 nmol/l diagnostic, 3-7 nmol/l equivocal)</li> <li>Repeatedly elevated measurements of cortisol secretion (late night salivary cortisol or urine free cortisol, upper normal 110-138 nmol/l)</li> </ul>
Suspected Polycystic Ovarian Syndrome (oligomenorrhea, hirsutism, enlarged ovaries may be palpable, hypercholesterolemia, impaired glucose tolerance, persistent acne and androgenic alopecia	<ul> <li>Morning blood draw for total testosterone, free and weakly testosterone, DHEAS, prolactin, TSH and early morning 17-hydroxyprogesteron</li> </ul>

#### Table 8 : The following questions can help in discussing readiness to change lifestyle behaviors:

- How important do you think it is for you to make changes at the moment?
- How confident are you that you can change your eating patterns and increase your physical activity to improve health?
- Are there any stressful events in your life now that might get in the way?
- Do you feel you can succeed in changing health behaviors', and how much do you believe it is worth the effort?
- Can you picture yourself changing health behaviors? How do you think your friends and family will react to your efforts?
- Are there people who can support you to change health behaviors'? Do you think they will help you in your efforts?

21

### Assess for readiness to change lifestyle behaviors

- Assess readiness for change in adults who are overweight or obese (NHMRC, evidence grade D)<sup>4</sup>.
- Inform all obese or overweight adults that modest or even minor weight reduction could bring health benefits (NHMRC, evidence grade -D) including:
  - Decreasing cardiovascular risk (reduced blood pressure and improved lipid profiles (NHMRC, evidence grade A)<sup>4</sup>.
  - Preventing, delaying progression of, or improving control of type 2 diabetes (NHMRC, evidence grade A), kidney disease, sleep apnea, musculoskeletal problems (NHMRC, evidence grade B), gastro-esophageal reflux or urinary incontinence (NHMRC, evidence grade C)<sup>4</sup>.
  - Improving quality of life, self-esteem and depression (NHMRC, evidence grade C)<sup>4</sup>.
- Life style modification e.g. physical exercise and reduced energy intake is likely to produce some health benefits even without actual weight loss (NHMRC, evidence grade C)<sup>4</sup>.

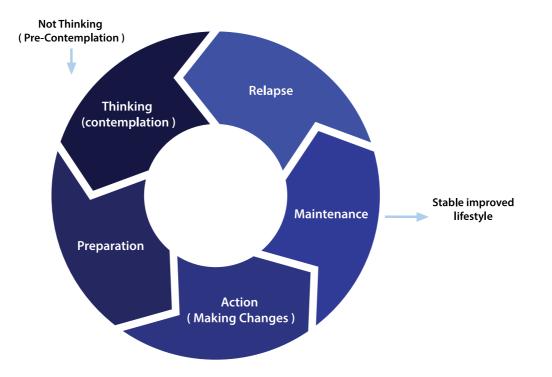
#### Table 9: Assessment of overweight/obese patients<sup>12</sup>

#### (Assessment helps to find answers to the following questions):

- 1-What is the class of obesity?
- 2- Is there any co-morbid condition? e.g. depression, eating disorders, sleep apnea, arthritis, or use of medications
- 3- Is it secondary obesity?
- 4- How much does the obesity affect the individual/s quality of life? e.g. mobility, self-esteem, socializing.
- 5- Is the individual aware of the health consequences of obesity, and benefit of treatment?
- 6- Has there been any attempt to lose weight? If so, why was it not effective?
- 7- Is the individual ready to start changing?
- 8- Is the individual a candidate for medication therapy or surgical interventions?
- 9- Is there any indication for specialist referral?



Figure 1: Stages of Change Model to Assess Readiness to Lose Weight<sup>15</sup>



#### Table 10: Applying the Stages of Change Model to Assess Readiness to Lose Weight<sup>15</sup>

Stages	Characteristics	Patient verbal cues	Appropriate intervention	Sample dialogue
Pre-contemplation	Unaware of problem; no interest in change	l am not really interested in weight loss. It is not a problem	Provide information about the health aspects of obesity	Would you like to read some information about the health aspects of obesity
Contemplation	Aware of problem, beginning to think of changing	l know I need to lose weight, but with all that's going on in my life right now, I am not sure I can	Help resolve ambivalence, discuss barriers	Let's look at the benefit of weight loss, as well as what you may need to change
Preparation	Realizes benefits of making changes and thinking about how to change	I have to lose weight and I am planning to do that	Teach behavior modification; provide education	Let's take a closer look at how you can reduce some of the calories you eat
Action	Actively taking steps toward change	I am doing my best; this is harder than I thought	Provide support and guidance, with a focus on the long term	It is terrific that you are working so hard. What problems have you had so far? How have you solved them?
Maintenance	Initial treatment goals reached	l've learned a lot through this process	Relapse control	What situations continue to tempt you to over eat? What can be helpful for the next time you face such a situation?

## **Management of obesity**

#### Devise goals:

- The ultimate goal of weight management is to improve health and to reduce the risk of obesity related comorbidities <sup>11</sup>.
  - For adults with BMI 25-35 kg/m<sup>2</sup> the target is to lose 5-10% of body weight (0.5-1 kg per week)<sup>3,11</sup>.
  - For adults with BMI>35 kg/m<sup>2</sup> and obesity-related co-morbidities the target is to lose a greater than 15-20% of body weight <sup>11</sup>.

#### Devise life style modification program for weight loss and reduction of risk factors:

- The focus of life style modification goals should be on improving health rather than reducing weight 4.
- Lifestyle modification should target at reducing energy intake, increasing energy expenditure and assisting in behavioral change (NHMRC, evidence grade A)<sup>4</sup>.
- Optimal dietary plan for achieving healthy body weight should be developed with a qualified and experienced health professional team together with the individual and family <sup>11</sup>.
- On discussing weight management with the patient and family, health professionals are encouraged to create a nonjudgmental atmosphere and to address barriers to weight management (Canadian, evidence grade C, level 4)<sup>3</sup>.

#### **Dietary interventions**

- Target energy deficit of 500-1000 kilo-calorie per day (3,500 kcal/week). Attention should be given to the dietary preferences of the individual (NHMRC, evidence grade A)<sup>4</sup>.
- Provide advice on dietary modification appropriate to the patient condition (type, quantity and/or frequency) to achieve and maintain a hypo-caloric intake (a high-protein or a low-fat diet with acceptable macronutrient distribution range). Patients should be advised to:

- choose low energy-dense foods (e.g. whole-grains, cereals, fruits, vegetables, and salads) and reduce intake of energy-dense foods (e.g. animal fats, sugary drinks (SIGN, evidence grade B) <sup>11</sup>.
- reduce consumption of junk food <sup>11</sup>.
- undertake regular self-weighing (SIGN, evidence grade B) <sup>11</sup>.
- Strictly supervise patients on very low calorie diets prescribed for rapid weight loss, (SIGN, evidence grade D) <sup>11</sup>.

#### Physical activity in adults

- Encourage overweight or obese individuals to be physically active and to avoid sedentary behavior (SIGN, evidence grade B) <sup>11</sup>.
- Prescribe a volume of physical activity that produce energy deficit of approximately 1,800-2,500 kcal/week. This could be achieved through 5 sessions of 45-60 min/week of moderate intensity physical activity, or lesser amounts of vigorous physical activity (SIGN, evidence grade B) <sup>11</sup>, however, the individuals can perform multiple small sessions of at least 10 minutes duration during the day to accumulate the required physical activity volume <sup>11</sup>.
- Clinically assess the individual physical fitness to perform the required physical exercise <sup>11</sup>.
- Build up the pace of physical activity gradually over time. The volume of physical exercise should be sustainable and tailored to the individual condition (Canadian, evidence grade A, level 2)<sup>3</sup>:
  - sedentary individuals should start with 10-20 min of physical activity every other day during the first 2 weeks <sup>11</sup>.
  - vigorous intensity activity should be introduced gradually after an initial 4-12 week period of moderate intensity activity <sup>11</sup>.
  - encourage non-weight-bearing moderate intensity physical activities (e.g. cycling, swimming, water aerobics) for obese patients suffering from joint problems (BMI over 35 kg/m2)<sup>11</sup>.
  - brisk walking can be classified as moderate intensity physical activity in obese individuals. Walking one km (0.62 miles) on flat ground burns approximately 60 kcal for a 70 kg person and 90 kcal for a 100 kg person<sup>11</sup>.

#### *Psychological/behavioral interventions*

- Psychological interventions should be part of any weight management program (SIGN, evidence grade A)<sup>11</sup>.
- It should be adjusted to circumstances of the individuals or their families. The objectives are to decrease dietary energy intake, increasing physical activity, and decreasing sedentary behaviors (SIGN, evidence grade B) <sup>11</sup>.

#### Table 11: Psychological Interventions & Strategies

#### • The range of appropriate psychological interventions and strategies includes:

- Self-monitoring of behavior and progress.
- Stimulus control (where the patient is taught how to recognize and avoid triggers that prompt unplanned eating).
- Cognitive restructuring (modifying unhelpful thoughts/thinking patterns).
- Goal setting.
- Problem solving.
- Assertiveness training.
- Slowing the rate of eating.
- Reinforcement of changes.
- Relapse prevention.
- Strategies for dealing with weight regain.

### Long-term weight management:

- Devise strategies appropriate to specific individual situations to prevent or minimize weight regain in adults who successfully achieved weight loss (NHMRC, evidence grade A)<sup>4</sup>.
- Advise the adults who successfully achieved weight loss, to consult health professionals if they observed small amount of weight regain (approximately 3 kg). Health professionals should reassess the lifestyle modification maintenance program for the individual (NHMRC, evidence grade PP) <sup>4</sup>.
- Encourage motivation for long-term weight management through approaches including self-management (e.g. manage hunger, reviewing goals, and regular self-weighing), continuing contact with health professionals and behavioral strategies (NHMRC, evidence grade PP)<sup>4</sup>.

## **Referral for specialist support:**

- Pharmacologic treatment may be considered as an adjunct to lifestyle interventions in individuals with BMI  $\geq$  30 kg/m<sup>2</sup> or BMI  $\geq$  28 kg/m<sup>2</sup> with co-morbidities or in adults who are not attaining, or who are unable to maintain clinically important weight loss with dietary and exercise therapy (Canadian, evidence grade B, level 2, SIGN evidence grade A) <sup>3,4</sup>.
- Refer for specialist services if needed for co-morbidities such as musculoskeletal, physiological, endocrinological, sleep apnea and type 2 diabetes (NHMRC, evidence grade D) or when a very low-energy diet is recommended <sup>4</sup>.
- Refer when bariatric surgery is a consideration <sup>4</sup>:
  - Adults with  $BMI > 40 \text{ kg/m}^2$ .
  - Adults with BMI > 35 kg/m<sup>2</sup> and co-morbidities not adequately improved with the lifestyle intervention.
  - Adults with a BMI >  $30 \text{ kg/m}^2$  with poorly controlled type 2 diabetes and high risk of cardiovascular diseases.



Chapter 4

### PHARMACOLOGICAL TREATMENT

#### PHARMACOLOGICAL TREATMENT:

Currently there is a list of medications used for pharmacological treatment (see table 12), however, there is no enough evidence regarding the efficacy of different drugs, the benefit of combination therapy, weight regain after withdrawal of medications or the benefits of continuing treatment beyond 1 year. However, the following are recommended <sup>11,16</sup>:

- Consider adding pharmacologic agent with lifestyle interventions on an individual case basis after assessment of risks and benefits:
  - In obese adults (BMI  $\ge$  30 kg/m<sup>2</sup>) who failed to achieve or maintain weight loss with lifestyle modification program, (Canadian, evidence grade B level 23 and SIGN, Evidence grade A) <sup>11</sup>.
  - In obese or overweight individuals (BMI ≥28 kg/m<sup>2</sup> with co-morbidities) to assist in reducing obesity-related co-morbidities, like type 2 diabetes, impaired glucose tolerance or the risk factors for type 2 diabetes (Canadian, evidence grade B level 23 and SIGN, Evidence grade A) <sup>11</sup>.
  - In pre-pubertal obese children Pharmacological therapy is generally not recommended, however, it can be considered only (treatment with Orlistat) under supervision of specialized team, if severe co-morbidities are present, e.g. orthopedic problems, sleep apnea, severe psychological disease or within the context of a supervised clinical trial (Canadian, evidence grade C, level 4 and NICE, 2006, amended 2014) <sup>3,17</sup>.
- Discuss with the patient the potential benefits, limitations, drug's side effects, and the temporary nature of the weight loss achieved with medications before initiating therapy (NICE, 2006, amended 2014)<sup>17</sup>.
- Discontinue use if the drug is ineffective, or if there are serious adverse effects <sup>18</sup>.

#### Table 12: Characteristics of Anti-Obesity Medications <sup>19-25</sup>

Active Ingredient	Lorcaserin HCI	Naltrexone HCl and buproprion HCl extended release	Phentermine and topiramate extended-release	Extended-release Liraglutide*	Orlistat*
Class	Serotonin 2C receptor agonist	Opioid antagonist and amino ketone antidepressant	Sympathomimetic amine anorectic and anti epileptic drug	GLP-1 receptor agonist	Reversible gastrointestinal lipase inhibitor
Mechanism of Action	Selective activation of 5-HT2C receptors on anorexigenic pro- opiomelanocortin neurons in the hypothalamus to decrease food consumption and promote satiety	Regulation of food intake through effect on hypothalamus and mesolimbic dopamine circuit.	Likely mediated by release of catecholamines in the hypothalamus, resulting in reduced appetite and decreased food consumption. Exact mechanism is unknown(phentermine)Potential effect on appetite suppression and satiety enhancement, induced by a combination of augmenting activity of gamma aminobutyrate, modulation of voltage-gated ion channels, inhibition of AMPA/kainite excitatory glutamate receptors, or inhibition of carbonic anhydrase. Exact mechanism known(topiramate)	Directly activates GLP- 1 receptors to mimic the action of native GLP-1. Regulates appetite and decreases caloric intake	Exerts activity in the lumen of the stomach and small intestine by forming a covalent bond with the active serine residue site of gastric and pancreatic lipases. The inactivated enzymes become unavailable to hydrolyze dietary fat in the form of triglycerides into absorbable free fatty acids and mono- glycerides
Half-Life	~11 hours	~5 hours (naltrexone)~21 hours (buproprion)	~20 hours (phentermine)~65 hours (topiramate)	13 hours	1-2 hours (parent drug)~3 hours (M1 metabolite)~13.5 hours (M3metabolite)
Metabolism	Extensive hepatic metabolism by multiple enzymatic pathways	Metabolism to active metabolite 6-beta- naltrexol(naltrexone). Extensive metabolism to three active metabolites: hydroxybupropion (viaCYP2B6), threohydrobupropion, and erythrohydrobupropion (bupropion)	p-hydroxylation on the aromatic ring and Noxidationon the aliphatic chain. Primarily CYP3A4 but not extensively metabolized (phentermine). Not extensively metabolized. Metabolism to 6 metabolites via hydroxylation, hydrolysis, and glucuronidation (topiramate)	Metabolized by endogenous peptidases in a similar way to large proteins	Two main metabolites, M1(hydrolyzed β-lactone ring product) and M3 (sequential metabolite after M1'scleavage of the N-formylleucine side- chain)

31

Active Ingredient	Lorcaserin HCI	Naltrexone HCl and buproprion HCl extended release	Phentermine and topiramate extended-release	Extended-release Liraglutide*	Orlistat*
Route of Elimination	Primarily renal	Primarily renal	Primarily renal	No single organ as major route of elimination	Primarily fecal excretion of unabsorbed drug
Limitations of Use	<ul> <li>Safety and efficacy of co- administration with other products for weightloss have not been established</li> <li>Effect on CV morbidity and mortality has not been established</li> </ul>	<ul> <li>Effect on CV morbidity and mortality has not been established</li> <li>Safety and effectivenessin combination with other products for weight loss, including prescription and OTC drugs, and herbal preparations have not been established</li> </ul>	<ul> <li>Effect on CV morbidity andmortality has not beenestablished</li> <li>Safety and effectiveness in combination with other products for weight loss, including prescription and OTC drugs, and herbal preparations have not been established</li> </ul>	<ul> <li>Should not be used in combination with any otherGLP1- receptor agonist</li> <li>Should not be used with insulin</li> <li>Effect on CV morbidity and mortality have not been established</li> <li>Safety and efficacy of co- administration with other products for weight loss have not been established</li> <li>Not been studied in patients with a history of pancreatitis</li> </ul>	
Contraindications	Pregnancy	<ul> <li>Uncontrolled hypertension</li> <li>Seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs</li> <li>Use of other bupropion containing products</li> <li>Chronic opioid use</li> <li>During or within 14 days of taking MAOIs</li> <li>Known allergy to any ingredients in the product</li> <li>Pregnancy</li> </ul>	<ul> <li>Pregnancy</li> <li>Glaucoma</li> <li>Hyperthyroidism</li> <li>during or within 14 days of taking MAOls</li> <li>known hypersensitivity or idiosyncrasy to sympathomimetic amines</li> </ul>	Personal or family history of MTC or MEN2,hypersensitivity to liraglutide or any product components, pregnancy	Pregnancy, chronic mal- absorption syndrome, cholestasis, known hypersensitivity to the medication or to any product components

Active Ingredient	Lorcaserin HCI	Naltrexone HCl and buproprion HCl extended release	Phentermine and topiramate extended-release	Extended-release Liraglutide*	Orlistat*
Maintenance Dosage and Administration	10 mg oral BID, with or without food. Discontinue if patient has not lost ≥5% of baseline body weight by week 12	The dose should be escalated starting with 1tablet in the morning. A total dosage of two 8mg/90 mg tablets oral BID in the morning and evening is reached at the start of Week 4. Should not be taken with a high fat meal. Discontinue if patient has not lost $\geq$ 5% of baseline body weight by week 12	7.5 mg/46 mg oral QD every morning with or without food Maximum dose is 15 mg/92 Mg Discontinue or escalate the dose if the patient has not lost $\geq$ 3% of baseline body weight by week 12 on 7.5mg/46 mg dosage, If the patient has not lost $\geq$ 5% of baseline body weight on 15 mg/92 mg dosage after an additional 12 weeks discontinue treatment	3 mg SC QD at any time of the day, independent of meals. Discontinue if patient has not lost ≥4% of baseline bodyweight by week 16	120 mg oral TID with each main meal containing fat(during or up to 1 hour after the meal)
Warnings and Precautions	Serotonin syndrome or neuroleptic malignant syndrome-like reactions • Valvular heart disease • Cognitive impairment • Psychiatric disorders, including euphoria and dissociation • Monitor for depression or suicidal thoughts • Use of anti- diabetic medications • Priapism	<ul> <li>Suicidal behavior and thoughts</li> <li>Risk of seizure may be minimized by adhering to recommended dosing schedule and avoiding co-administration with high-fat meal</li> <li>Increase in BP and HR</li> <li>Hepato-toxicity</li> <li>Angle-closure glaucoma</li> <li>Use of anti-diabetic medications</li> </ul>	<ul> <li>Fetal toxicity</li> <li>Increase in HR</li> <li>Suicidal behavior and thoughts</li> <li>Acute myopia and secondary angle closure glaucoma</li> <li>Mood and sleep disorders</li> <li>Cognitive impairment</li> <li>Metabolic acidosis</li> <li>Elevated creatinine</li> <li>Use of anti-diabetic medications</li> </ul>	<ul> <li>Risk of thyroid C-cell tumors</li> <li>Acute pancreatitis</li> <li>Acute gallbladder disease</li> <li>Risk of hypoglycemia with concomitant use of anti- diabetic therapy</li> <li>Heart rate increase</li> <li>Renal impairment</li> <li>Hypersensitivity reactions</li> <li>Suicidal behavior and thoughts</li> </ul>	<ul> <li>Can decrease cyclosporine exposure</li> <li>Patient should be strongly encouraged to take multivitamin supplement that contains fat-soluble vitamins</li> <li>Rare cases of severe liver injury with hepatocellular necrosis or acute hepatic failure have been reported</li> <li>Patients may develop increased levels of urinary oxalate following treatment. Monitor renal function in patients at risk for renal insufficiency</li> <li>Substantial weight loss can increase risk of cholelithiasis</li> <li>Exclude organic causes of obesity before prescribing</li> <li>Gi events may increase when orlistat is taken with a high at diet (&gt;30% total daily calories from fat)</li> </ul>

Active Ingredient	Lorcaserin HCI	Naltrexone HCl and buproprion HCl extended release	Phentermine and topiramate extended-release	Extended-release Liraglutide*	Orlistat*
Common Adverse Reactions	Non-diabetic patients: Headache, dizziness, fatigue, nausea, dry mouth, and constipation Diabetic patients: Hypoglycemia, headache, back pain, cough, and fatigue	Nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth, and diarrhea	Paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth	Nausea, hypoglycemia, diarrhea, constipation, vomiting, headache, decreased appetite, dyspepsia, fatigue, dizziness, abdominal pain	Oily spotting, flatus with discharge, fecal urgency fatty/ oil stool, oily evacuation, increased defecation and fecal incontinence
How Supplied	10 mg tablets	8 mg/90 mg tablets	3.75 mg/23 mg, 7.5 mg/46 mg, 11.25 mg/69 mg and 15mg/92 mg capsules	Disposable, pre-filled, multi- dose pen that delivers 0.6mg, 1.2 mg, 1.8 mg, 2.4 mg or 3 mg (6 mg/mL, 3mL).	120 mg capsules
Storage	Store at 77°F (25°C), with permitted excursions of 59-86°F (15-30°C)	Store at 77°F (25°C), with permitted excursions of 59-86°F (15-30°C)	Store at 59-77°F (15-25°C)	Unopened pens: store in the refrigerator between $36-6^{\circ}F$ ( $2-8^{\circ}C$ ) In-use pens: store in the refrigerator $36-46^{\circ}F$ ( $2-8^{\circ}C$ ) OR at room temperature between $59-86^{\circ}F$ ( $15-30^{\circ}C$ ) After initial use, the Liraglutide 3mg pen must be used within 30 days	Store at 77°F (25°C),with permitted excursions of59- 86°F (15-30°C)

GLP-1: glucagon-like peptide-1; AMPA: a-amino-3-hydroxyl-5-methyl-4-isoxazole-propionate; BMI: body mass index; HTN: hypertension; CV: cardiovascular; OTC: over-the-counter; MAOI: monoamine oxidase inhibitors; MTC: medullary thyroid carcinoma; MEN2: Multiple Endocrine Neoplasia syndrome type 2; BID: twice daily; QD: once daily; SC: subcutaneously; TID: three times daily; BP: blood pressure; HR: heart rate; GI: gastrointestinal

\*Only Orlistat and Liraglutide are the only registered drugs in the Saudi Food & Drug Authority



Chapter 5

## **BARIATRIC SURGERY**

#### **BARIATRIC SURGERY:**

- Consider Bariatric surgery as part of an overall clinical pathway for adult weight management.(SAGES evidence level I, grade A) <sup>26</sup>.
- Consider bariatric surgery on an individual case basis after assessing the risks and benefits (SIGN, evidence grade C)<sup>11</sup>.
- Consider bariatric surgery:
  - In adults with clinically severe obesity (BMI > 40 kg/m<sup>2</sup>). It is the most effective treatment for morbid obesity, it leads to durable weight loss and improvement of co-morbidities (SAGES evidence level I, grade A) <sup>26</sup>.
  - In adults with BMI  $\ge$  35 kg/m<sup>2</sup> and severe co-morbidities (SIGN, evidence grade C<sup>3</sup> and Canadian, evidence grade B, level 2)<sup>11</sup>.
  - In adults with BMI > 30 kg/m<sup>2</sup> who have poorly controlled type 2 diabetes and are at increased cardiovascular risk (NHMRC, evidence grade PP) <sup>4</sup>.
  - In post pubertal adolescents with very severe to extreme obesity and severe co-morbidities (SIGN, evidence grade D)<sup>11</sup>. Bariatric surgery in adolescents is to be limited to exceptional cases and performed only by experienced teams (Canadian, evidence grade C, level 4) <sup>3</sup>.
- It should be performed by an experienced and well trained multidisciplinary team, including surgeons, anesthetists, dietitians, nurses, psychologists and physicians (SAGES evidence level III, grade C). However, types of surgery, anesthetic practice and immediate post-operative care are out of the scope of these guidelines <sup>26</sup>.
- Assess for psychological disorders preoperatively (SAGES evidence level III, grade C). Treated psychopathology does not prevent patients to undergo bariatric surgery (SAGES evidence level II, grade B) <sup>26</sup>.
- Intra-gastric balloon is a safe and effective procedure in weight reduction, but, unfortunately, the results are temporal and almost all patients return to their initial weights after balloon removal <sup>27,28</sup>.

#### Table 13: Common types of bariatric surgery <sup>29</sup>

Treatment	General	Potential acute complications	Potential chronic complications
Sleeve Gastrectomy	<ul> <li>Hospital stay 1-2 days</li> <li>Recovery 1-2 weeks</li> <li>Contraindications <ul> <li>Poor surgical candidates</li> <li>Sever psychiatric disorder</li> <li>Intolerance to general anesthesia</li> <li>Pregnancy</li> <li>Drug or alcohol addiction</li> <li>Untreated or sever esophagitis</li> <li>Barrett&gt;s esophagus</li> <li>Sever gastroparesis</li> <li>Achalasia</li> <li>Previous gastrectomy</li> </ul> </li> <li>Sometimes used as staged approach to gastric by-pass</li> </ul>	<ul> <li>Postoperative complications are rare</li> <li>Hemorrhage</li> <li>Anastomotic staple line leak</li> <li>Deep vein thrombosis</li> <li>Pulmonary emboli</li> <li>Dehydration</li> <li>Death</li> </ul>	<ul> <li>Weight regain</li> <li>Marginal ulcer</li> <li>Dumping syndrome with reactive hypoglycemia</li> <li>Luminal stenoses (stomal narrowing)</li> <li>Anastomotic staple line leak</li> <li>Fistula formation</li> <li>Iron deficiency</li> <li>Protein malnutrition</li> <li>Other nutritional and mineral deficiencies (e.g. deficiencies of vitamins A, C, D, E, B and K, folate, zinc, magnesium, thiamine, etc.)</li> <li>Anemia (often related to mineral and nutrition deficiencies)</li> <li>Neuropathies (resulting from nutritional deficiencies)</li> <li>Osteoporosis (often caused by calcium deficiencies and chronically elevated parathyroid hormone levels)</li> <li>Potential need to re-operate</li> </ul>
Laparoscopic adjustable gastric banding	<ul> <li>Outpatient procedure</li> <li>Recovery usually one week</li> <li>Contraindications <ul> <li>Poor surgical candidates</li> <li>Sever psychiatric disorder</li> <li>Intolerance to general anesthesia</li> <li>Pregnancy</li> <li>Drug or alcohol addiction</li> <li>Untreated or sever esophagitis</li> </ul> </li> </ul>	<ul> <li>Band too tight with gastrointestinal obstructive symptoms (e.g. dysphagia)</li> <li>Leakage of gastric content into abdomen</li> <li>Hemorrhage</li> <li>Deep vein thrombosis</li> <li>Death</li> </ul>	<ul> <li>Weight regain</li> <li>Band slippage, erosion ulceration, port infection, disconnection and displacement</li> <li>Esophageal dilation</li> <li>Rare nutrient deficiencies if persistent vomiting or marked and sustained decrease in nutritional intake</li> <li>Depression</li> <li>Potential need to re-operate</li> <li>GERD</li> </ul>

37

Treatment	General	Potential acute complications	Potential chronic complications
Gastric bypass	<ul> <li>Hospital stay 2-4 days</li> <li>Recovery 2-4 weeks</li> <li>Contraindications <ul> <li>Poor surgical candidates</li> <li>Sever psychiatric disorder</li> <li>Intolerance to general anesthesia</li> <li>Pregnancy</li> <li>Drug or alcohol addiction</li> <li>Untreated esophagitis</li> <li>Unwillingness or an inability for appropriate long-term follow-up</li> </ul> </li> </ul>	<ul> <li>Gastrointestinal obstruction</li> <li>Hemorrhage</li> <li>Anastomotic leaks</li> <li>Deep vein thrombosis</li> <li>Pulmonary emboli</li> <li>Dehydration</li> <li>Death</li> </ul>	<ul> <li>Weight regain</li> <li>Marginal ulcer</li> <li>Esophageal dilation</li> <li>Dumping syndrome with reactive hypoglycemia</li> <li>Small bowel obstruction caused by internal hernias or adhesions</li> <li>Anastomotic stenoses (stomal narrowing)</li> <li>Calcium deficiency</li> <li>Secondary hyperparathyroidism</li> <li>Iron deficiency</li> <li>Protein malnutrition</li> <li>Other nutritional and mineral deficiencies (e.g. deficiencies of vitamins A,C,D,E,B and K, folate, zinc, magnesium, thiamine, etc.)</li> <li>Anemia (often related to mineral and nutrition deficiencies)</li> <li>Metabolic acidosis</li> <li>Bacterial overgrowth</li> <li>Kidney stones (oxalosis)</li> <li>Neuropathies (resulting from nutritional deficiencies)</li> <li>Osteoporosis (often caused by calcium deficiencies and chronically elevated parathyroid hormone levels)</li> <li>Depression Potential need to re-operate</li> </ul>

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#### ANNEX 1: KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS:

1 - Level of evidence and grade of recommendations used by Scottish Intercollegiate Guidelines Network (SIGN).

	Levels of evidence
1++	High quality meta-analyses, systematic reviews of RCTs or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies/high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high-risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g., case reports, case series
4	Expert opinion
	Grades of recommendation
A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
В	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+
С	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+

2 - Grade of recommendations used by National Health and Medical Research Council (NHMRC) - Australia

Grade	Description
А	Body of evidence can be trusted to guide the practice
В	Body of evidence can be trusted to guide the practice in most situations
С	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution
CBR	Consensus-based recommendation formulated in the absence of quality evidence
PP	Developed by the Obesity Guidelines Development Committee for areas beyond the scope of the systematic review.

3 - Classification of evidence used in the 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults and children

Level of evidence	Criteria
1	Randomized controlled trials (or meta-analyses) without important limitations
2	<ul> <li>Randomized controlled trials (or meta-analyses) with important limitations</li> <li>Observational studies (nonrandomized clinical trials or cohort studies) with overwhelming evidence</li> </ul>
3	Other observational studies (prospective cohort studies, case–control studies, case series)
4	<ul> <li>Inadequate or no data in population of interest</li> <li>Anecdotal evidence or clinical experience</li> </ul>



#### Criteria for assigning a grade to recommendations

Grade	Criteria
A	<ul> <li>Strong recommendation (action can apply to most individuals in most circumstances)</li> <li>benefits clearly outweigh risks (or vice versa)</li> <li>evidence is level 1, 2 or 3</li> </ul>
В	Intermediate recommendation (action may vary depending on the person's characteristics or other circumstances) • unclear whether benefits outweigh risks • evidence is level 1, 2 or 3
С	Consensus (weak) recommendation (alternative actions may be equally reasonable) • unclear whether benefits outweigh risks • evidence is level 3 or 4

4 - Definition of grades of recommendations used by Institute for Clinical Systems Improvement (ICSI), Minnesota (USA)

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change our confidence in the estimate of effect	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefits, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
Low Quality Evidence	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

5 - Definition of grades of recommendations used by the Society of American Gastrointestinal and Endoscopic Surgeons(SAGES)

Level of evidence	Criteria
Level I	Evidence from properly conducted randomized controlled trials
Level II	Evidence from controlled trials without randomization Or Cohort or case-control studies Or Multiple time series, dramatic uncontrolled experiments
Level III	Descriptive case series, opinions of expert panels

#### Scale used for recommendation grading

Grade	Description
Grade A	Based on high-level (level I or II), well performed studies with uniform interpretation and conclusions by expert panel
Grade B	Based on high-level, well-performed studies with varying interpretation and conclusion by the expert panel
Grade C	Based on lower-level evidence (level II or less) with inconsistent findings and/or varying interpretations or conclusions by the expert panel

#### ANNEX 2: MEMBERS OF ADOPTION GROUP OF FIRST DRAFT OF THE GUIDELINES:

The members of the adoption group of first version of the Clinical Saudi Obesity Guidelines.

- Fahad S. Al-Shehri, Consultant of Family Medicine, Department of Family Medicine and Research, Health Affairs, Aseer Region,
- Mohammed M. Moqbel, Consultant of family medicine, Department of Family Medicine and Research, Health Affairs, Aseer Region,
- Abdullah M. Al-Shahrani, Departments of Family Medicine and Public Health, Ministry of Health Affairs, Southern Region
- Yahia M. Al-Khaldi, Department of Family Medicine and Research, Health Affairs, Aseer Region,
- Waleed S. Abu-Melha, Department of Preventive Medicine, Armed Forced Hospital, Southern Region, Saudi Arabia

#### ANNEX 3: OBESITY CONTROL PROGRAM SCIENTIFIC COMMITTEE:

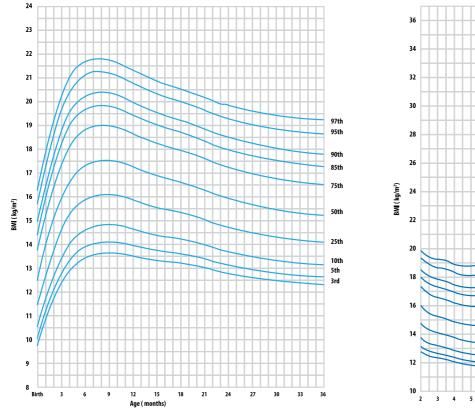
- Prof. Aayed R. Alqahtani MD, FRCSC, FACS, Director of KSU Obesity Chair, Professor of Bariatric and MIS Surgery, College of Medicine, King Saud University
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- Dr. Alhasan M. Alkaud -Family and Bariatric Medical Consultant
- Dr Fahad Shar Alshehri Consultant of family medicine and diabetes, Member of Saudi Arabian Society of Metabolic & Bariatric Surgery (SASMBS)
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- Dr. Mohammad Y. Saeedi -Consultant Family and Community Medicine -Director General for Genetic and Chronic Diseases , MOH , KSA
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- Muteb Z. Almalki-Nutrition technician
- Talal F. Almoreished- Puplic Health Specialist

#### **ANNEX 5: CHARTS FOR BMI TO AGE PERCENTILES AMONG CHILDREN**



BMI for age-percentiles: boys, birth to 36 months 43 x 55 mm

11 Age (years) BMI for age-percentiles: boys, 2 to 19 years 43 x 55 mm

6 7 8 9 10 12 13 14 15 16 17

Source: AI Herbish AS, El Mouzan MI, Al Salloum AA, Al Qureshi MM, Al Omar AA, Foster PJ, Kecojevic T. Body mass index in Saudi Arabian children and adolescents: a national reference and comparison with international standards.

97th

95th

90th

85th

75th

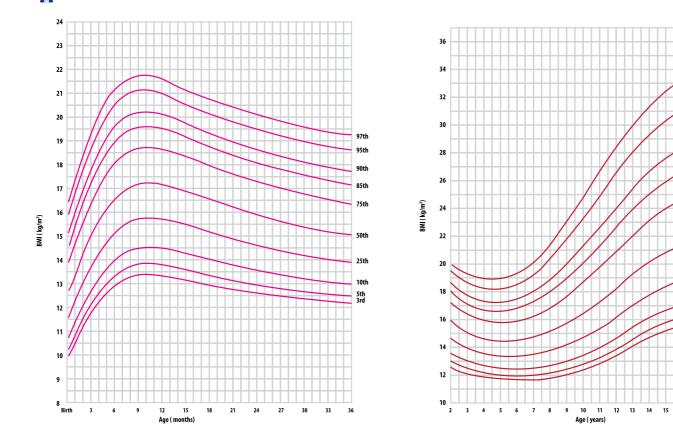
50th

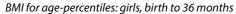
25th

10th

5th 3rd

SAUDI GUIDELINES ON THE PREVENTION AND MANAGEMENT OF OBESITY







Source: AI Herbish AS, El Mouzan MI, Al Salloum AA, Al Qureshi MM, Al Omar AA, Foster PJ, Kecojevic T. Body mass index in Saudi Arabian children and adolescents: a national reference and comparison with international standards.

97th

95th

90th

85th

75th

50th

25th

10th

5th 3rd

17 18



For any inquiries or suggestions please feel free to contact us at: OCP@moh.gov.sa