Alberta STE Report

Bariatric treatments for adult obesity

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Alberta STE Report: Policy-driven Health Technology Assessment reports that include an analysis of the social and system demographics, technological effectiveness and economic implications of a health technology. The reports are written under contract with the Alberta Health Technologies Decision Process and contextualized for use in Alberta.

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EXECUTIVE SUMMARY

Social and System Demographics

Adult obesity has emerged as a chronic medical condition characterized by an accumulation of excess body fat caused by a long-term energy imbalance that mainly results from complex interactions of biological, environmental, and behavioural factors. In practice, it is defined according to body mass index (BMI), categorized as follows:

BMI Range	Type of Obesity	Obesity Class
30 kg/m² to 34.9 kg/m²	mild obesity	Class I obesity
35 kg/m² to 39.9 kg/m²	moderate obesity	Class II obesity
40 kg/m² or greater	severe/extreme/morbid obesity	Class III obesity

Adult obesity is associated with multiple organ-specific and psychosocial consequences that may result in reduced quality of life and increased morbidity and premature mortality. The most serious adverse health risks and consequences are associated with severe (class III) obesity.

In Canada, as in other countries, the prevalence of obesity during the past 30 years has increased progressively within all demographic groups and continues to rise. This increase is influenced by numerous individual-level and environmental factors.

Among Alberta's 2007 population of adults (aged 18 years and over), 17.7% were classified as obese, with 12.5% in class I, 3.7% in class II, and 1.5% in class III. These rates were based on self-reported data from the 2007 Canadian Community Health Survey (CCHS). They are considerably lower than the latest available directly measured rates from the 2004 CCHS data, where the measured adult obesity rate was 25.2% and the rates for classes I, II, and III obesity were 15.4%, 6.7%, and 3.2%, respectively.

According to evidence-based recommendations, when addressing adult obesity, both prevention strategies (to keep more individuals from becoming obese) and bariatric therapy (to assist those diagnosed with obesity in managing their weight problems) should be considered. A comprehensive and multisectoral approach to adult obesity prevention is recommended. Lifestyle and behavioural modification, based on intensive patient education and counseling, is recommended as an essential part of effective adult obesity management. Pharmacotherapy may be added if lifestyle and behavioural modification interventions alone are insufficient. For severe and moderate obesity (BMI $\geq$ 40 kg/m^2 and BMI $\geq$ 35 kg/m^2 with comorbidities) refractory to appropriate non-surgical treatments, bariatric surgery may be an appropriate option when combined with long-term lifestyle modifications.

Bariatric treatment options should be stratified according to BMI and waist circumference measurements, the presence of associated health risks and consequences, readiness for change and willingness to comply with an individualized treatment plan, and failure of previous bariatric treatments. Key components of quality bariatric care include:

- appropriate selection of patients for each treatment strategy;
- the availability of a multidisciplinary team that includes dedicated and appropriately trained and credentialed personnel;

- facilities with specialized technical and equipment capacity;
- an environment free of bias toward obesity;
- the availability of long-term monitoring and follow-up mechanisms.

In Alberta there are five publicly funded weight management programs: a number of private clinics that provide non-surgical bariatric care and four tertiary healthcare centres that provide bariatric surgery. Access to non-surgical bariatric care programs varies by program and a referral by a family physician is required for access to the centres that offer bariatric surgery. Although the various centres measure bariatric surgery waiting times differently, it can take between 2 and 5 years from referral to completion of surgery.

Technological Effects and Effectiveness

The objectives of the technology section of this report are:

- to perform a systematic review and critical appraisal of the available evidence on the safety and efficacy or effectiveness of various bariatric treatment strategies, including dietary therapy, physical exercise, behavioural therapy, pharmacotherapy, and surgical therapy;
- to determine the comparative safety of various bariatric treatment strategies for adults with obesity and the comparative efficacy/effectiveness of various bariatric treatment strategies for overweight (defined as BMI $\geq$ 25 kg/m^2) or obese (defined as BMI $\geq$ 30 kg/m^2) adults.

A comprehensive literature search for publications released between 2000 and April 2010 identified 14 systematic reviews/health technology assessments (SRs/HTAs) that met the predefined inclusion criteria. All had average or good methodological quality ratings. Of these 14 SRs/HTAs, three reviews focused on dietary therapy/physical exercise, one on behavioural therapy, three on weight loss medications, and two on bariatric surgery. Four other reviews assessed the safety and efficacy of multiple treatment strategies and one other review examined the long-term effects of bariatric treatment strategies on mortality. Search dates and selection criteria varied across the reviews and a great deal of overlap was evident in the primary studies included within these reviews.

In general, randomized controlled trials (RCTs) assessed in the included SRs/HTAs suffer from severe methodological limitations. Few studies described the randomization process adequately or provided sufficient information about the blinding process. High attrition rates were common in the trials and an intention-to-treat analysis was conducted very rarely. Follow-up periods in the RCTs were usually short-term, thus data on long-term outcomes is very limited.

Information is lacking on the adverse events associated with the use of dietary therapy, physical exercise, and behavioural therapy. Adverse events associated with weight loss medications were common and sometimes led to discontinuation of the drugs. Two drugs, orlistat and sibutramine, were approved by Health Canada for long-term use. Gastrointestinal side effects were predominant in patients treated with orlistat. Increases in blood pressure and heart rate were serious safety concerns with the use of sibutramine, particularly in patients with pre-existing cardiovascular diseases. These concerns resulted in the suspension of this drug from the European drug market and the United States Food and Drug Administration (US FDA) noted additional contraindications. While not approved by Health Canada and the US FDA, another new antiobesity drug, rimonabant, was withdrawn from the European drug market in 2008 because of its serious psychiatric side effects.

Three surgical procedures—adjustable gastric banding (AGB), sleeve gastrectomy, and Roux-en-Y gastric bypass (RYGB)—are currently performed in Alberta. Compared to RYGB, AGB required significantly shorter hospital stays and resulted in fewer late ulcers and lower levels of late stenosis, late hernia, and early wound infection, but had more late failed surgeries and higher risks of late slippage or dilatation. Information is limited about the safety profile for sleeve gastrectomy.

Compared to those who had open surgery, patients who received laparoscopic surgery had significantly shorter hospital stays and fewer incidents of early wound infections and late hernias, but had significantly higher incidents of late luminal stenosis. No difference was found in reoperation and revision rates between laparoscopic and open surgery**.** No trials reported on the comparative incidence of myocardial infarction following bariatric surgeries.

Evidence from RCTs assessed in the 14 SRs/HTAs suggests that all dietary therapy, physical exercise, behavioural therapy, pharmacological therapy, and bariatric surgery are effective, to varying degrees, in reducing weight in the short term in people who are overweight or obese.

Compared with standard care, dietary therapy significantly reduced body weight, BMI, waist circumference, blood pressure, blood lipids, and blood glucose levels in overweight and obese people. There appeared to be no differences between the different types of diets.

Physical exercise appeared to be effective in weight loss, particularly when combined with dietary interventions. Dietary therapy appeared to be more effective in weight loss than exercise alone; however, exercise is an effective intervention for improving risk factors even when weight loss does not occur.

Overweight or obese adults appeared to benefit from behavioural and cognitive-behavioural therapies intended to enhance weight reduction. Behavioural therapy is particularly useful when combined with dietary and exercise strategies.

Evidence from placebo-controlled clinical trials suggests that three antiobesity drugs—orlistat, sibutramine, and rimonabant—are modestly effective in reducing weight and have different effects on cardiovascular risk. Because the SRs/HTAs assessed in this report did not include primary studies on head-to-head comparisons of the three drugs, the superiority of one particular drug over another remains to be determined.

Bariatric surgery appeared to be more effective than dietary therapy with or without physical exercise in treating severely obese adults. Diversionary procedures resulted in the greatest weight loss and restrictive procedures (such as AGB) resulted in loss of the least weight, while the effectiveness of hybrid procedures (such as RYGB) was in between. The evidence base was limited for sleeve gastrectomy.

Currently available evidence is far from clear about the comparative efficacy/effectiveness of different treatment strategies. Dietary therapy, physical exercise, and behavioural/cognitive-behavioural therapies should be the cornerstone of any program; based on these foundational strategies, pharmacotherapy and bariatric surgery can be provided for appropriate individuals with different degrees of overweight, obesity, pre-existing diseases, and obesity-related co-morbidities. Collaborations among dieticians, physical therapists, psychologists, medical doctors/nurses, and bariatric surgeons, and efforts to enhance patients' adherence to weight management programs, are essential for long-term success.

Economics Section

The objectives of the economic analysis are:

- to determine the comparative cost-effectiveness of various bariatric treatment strategies for obesity in adults;
- to estimate the direct health services cost associated with bariatric surgery in Alberta;
- to assess the economic burden of obesity.

A literature review was conducted to examine the cost-effectiveness of alternative bariatric interventions, while an analysis of provincial health utilization data was conducted to inform both the cost of bariatric surgeries—including its impact on inpatient, outpatient, and physician services—and the economic burden of obesity in Alberta.

Literature Review of Economic Studies

Twenty-nine studies that met the final inclusion criteria for the literature review were classified into four categories:

- bariatric surgical procedures;
- pharmacotherapy;
- weight management programs;
- lifestyle modification.

A Canadian study showed the cost per quality-adjusted life year (QALY) gained was $9398 for RYGB and $12,212 for LAGB, as compared to lifestyle modification. This study suggested bariatric surgical procedures were cost-effective for patients with a BMI $\geq$ 40 kg/m^2 or a BMI $\geq$ 35 kg/m^2 with obesity-related comorbidities. For patients with obesity-related morbidity, bariatric surgery was more attractive. This conclusion is consistent with those reported in the other nine studies. Within bariatric surgical interventions, studies did not identify which type of bariatric surgery was the most cost-effective.

Pharmacotherapy, as compared to lifestyle modification or no intervention, was associated with an improvement in health benefits for patients with a BMI $\geq$ 30 kg/m^2 or with a BMI $\geq$ 27 kg/m^2 with obesity-related morbidity. Medication treatment was shown to be cost-effective for obese patients with obesity-related comorbidities. The cost of the treatment was $18,881 per QALY gained for patients with type 2 diabetes as compared to no treatment and $28,631 per QALY gained for patients with impaired glucose tolerance as compared to lifestyle modification. However, the evidence in the economic literature is less consistent with reference to cost-effectiveness for the treatment of obese patients without comorbidity.

Compared to no intervention, weight management programs or lifestyle modification were found to be cost-effective. However, significant variation can exist in the specific characteristics included in either weight management programs or lifestyle modification, which limits the generalizability of this finding.

Costs of Bariatric Surgery and Potential Impact on Health Service Utilization

In Alberta, the mean cost of inpatient and physician services associated with bariatric surgery in 2006 was estimated to be $12,176. The health service utilization and costs for the 2 years following surgery were greater than for the 2 years preceding surgery. An upward trend was found in health service utilization and costs in the 2 years preceding surgery and a downward trend in health service utilization and costs in the 2 years following surgery. Although this may suggest that bariatric surgery may alter the upward trajectory of health service utilization for severely obese patients who have undergone surgery, it is important to note that the value in 2008 was still greater than that observed in 2005. Hence, it is unclear whether the decrease is simply a return to pre-surgical levels.

Economic Burden of Obesity in Alberta

Compared to normal weight, obesity, overweight, and underweight are associated with cost increases of $217, $65, and $44, respectively. Based on the 2007 CCHS survey, 463,000, 843,000, and 58,000 Alberta residents were obese, overweight, and underweight, respectively.

When including both physician and outpatient services, in Alberta:

- the economic burden associated with obesity was estimated at $100 million;
- the economic burden associated with overweight was estimated at $55 million;
- the economic burden associated with underweight was estimated at $2.5 million.

TABLE OF CONTENTS

TABLES AND FIGURES

Section One: Social and System Demographics

Section Two: Technology Effects and Effectiveness

ABBREVIATIONS

All abbreviations that have been used in this report are listed below unless the abbreviation is well known, or it has been used only once, or it is a non-standard abbreviation used only in figures, tables, or appendices, in which case the abbreviation is defined in the figure legend or at the end of the table.

ACS	American College of Surgeons
AE	adverse event
AETMIS	Agence d'évaluation des technologies et des modes d'intervention en santé
AGB	adjustable gastric banding
AHS	Alberta Health Services
AORN	Association of periOperative Registered Nurses
ASMBS	American Society for Metabolic and Bariatric Surgery
AWMC	Adult Weight Management Clinic
BDD	balanced deficit diet
BIA	bioelectrical impedance analysis
BMI	body mass index
BP	blood pressure
BPD	biliopancreatic diversion
BT	behavioural therapy
BW	body weight
CAD	coronary artery disease
CADTH	Canadian Agency for Drugs and Technologies in Health
CBT	cognitive behavioural therapy
CCHS	Canadian Community Health Survey
CCI	Canadian Classification of Health Interventions
CDC	Centers for Disease Control and Prevention
CEA	cost-effectiveness analysis
CHD	coronary heart disease
CHF	congestive heart failure
CI	confidence interval
CPG	clinical practice guideline
CPI	Consumer Price Index

CrI	credible interval
CUA	cost-utility analysis
CVA	cerebrovascular accident
D	diet
DBP	diastolic blood pressure
DM	diabetes mellitus
DS	duodenal switch
E	exercise
EWL	excess weight loss
F	female
FDA	Food and Drug Administration
GB	gastric banding
GBP	gastric bypass (open procedure)
GI	glycemic index
HbA1c	glycesylated glucose
HBG	horizontal banded gastroplasty
HDL	high-density lipoprotein
HG	horizontal gastroplasty
HTA	health technology assessment
HrQoL	health-related quality of life
ICER	incremental cost-effectiveness ratio
IFSO	International Federation for the Surgery of Obesity
IGT	impaired glucose tolerance
JB	jejunoileal bypass
kg	kilogram
L	litre
LAGB	laparoscopic adjustable gastric banding
LCD	low-calorie diet
LDL	low-density lipoprotein
LGBP	laparoscopic gastric bypass
LM	lifestyle modification
LRYGB	laparoscopic Roux-en-Y gastric bypass

LY	life year
M	male
m	metre
MA	meta-analysis
MD	mean difference
MUHC	McGill University Health Centre
NA	data not available
NHLBI	National Heart, Lung, and Blood Institute
NHS	National Health System
NICE	National Institute for Clinical Excellence
NIH	National Institutes of Health
NNH	number needed for harm
NPHS	National Population Health Survey
NS	difference not significant
NSS	not statistically significant
OHTAC	Ontario Health Technology Advisory Committee
OR	odds ratio
QALY	quality-adjusted life year
QoL	quality of life
RCT	randomized controlled trial
RD	risk difference
RR	risk ratio
RYGB	Roux-en-Y gastric bypass
RR	relative risk
SD	standard deviation
SOS	Swedish obesity subjects
TC	total cholesterol
T2DM	Type 2 diabetes mellitus
TG	triglycerides
UK	United Kingdom
US, USA	United States of America
VLCD	very-low-calorie diet

VBG	vertical banded gastroplasty
WC	waist circumference
WHO	World Health Organization
WHR	waist-to-hip ratio
WL	weight loss
WMP	weight management program(s)

GLOSSARY/DICTIONARY

The glossary terms listed below were obtained and adapted from the following sources:

Hassen-Khodja R, Lance JMR. Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). Surgical treatment of morbid obesity; An update. Montréal (QC): AETMIS; 2006. Available from: www.aetmis.gouv.qc.ca/site/download.php?f=d76d1f910aff4f2e92bcbe0520e21bd8) (accessed 2010 June 18).

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www.bmimedical.ca.html

www.bariatricedge.com/dtcf/pages/GlossaryTerms.htm

www.docshop.com/education/bariatrics/glossary

Abdominal obesity: the presence of excess fat in the abdominal area. It is typically measured by waist circumference; a measurement of 40 inches or more in men and 35 inches or more in women indicates abdominal obesity. Excess fat in the abdomen is considered an independent predictor of risk and morbidity, meaning the likelihood for developing diseases is higher for those with abdominal obesity.

Absorption: the process in which digested food is absorbed by the lower part of the small intestine into the bloodstream.

Adipose tissue: connective tissue made up of adipocyte (fat) cells, in which the body stores fat in the form of triglycerides.

Amino Acids: the building blocks of protein. The human body uses 11 non-essential amino acids (produced by the human body) and nine essential amino acids (found in the diet; the human body cannot produce them).

Balanced Deficit Diet (BDD): a diet that subtracts a set number of calories from a person's daily expenditures. BDDs are individualized diets and vary in their total calories.

Bariatric: pertaining to bariatrics, which is the field of medicine concerned with weight loss.

Bariatric physician: a licensed Doctor of Medicine or Doctor of Osteopathy who has received specialized training in the field of bariatric medicine (medical weight management). Bariatric physicians may treat overweight and obese patients with diet, nutrition, exercise, behavioural therapy, appropriate medications, or any combination of these treatments. Someone who has repeatedly and unsuccessfully attempted to lose weight on his or her own may benefit from treatment under the care of a bariatric physician.

Bariatric surgery: surgery on the stomach and/or intestines, to help a person with extreme obesity lose weight.

Baseline: refers to the initial time point in a clinical trial, just before a participant starts to receive the experimental intervention. At this reference point, measurable values are gathered from which variations found in the study are determined.

Bioelectrical impedance analysis (BIA): a way of estimating per cent of body fat by measuring the flow of a harmless electrical current through the body.

Body fat: a compound which is an energy source for the human body, comprised of glycerol—a substance formed by fatty acids—and fatty acids.

Body mass index (BMI): a key index for relating a person's body weight to their height. The BMI is a person's weight in kilograms divided by their height measured in metres squared.

Calorie: a unit of food energy. The common use of the term "calorie" of food energy is understood to refer to a kilocalorie and actually represents 1000 true calories of energy. A calorie is also known as a cal, a gram calorie, or a small calorie.

Cardiovascular: the circulatory system comprising the heart and blood vessels, which carries nutrients and oxygen to the tissues of the body and removes carbon dioxide and other wastes.

Cardiovascular disease: any disease of the heart or blood vessels.

Cholesterol: an important component of the human body's hormones, cell membranes, and bile. Although most cholesterol is synthesized by the liver, some is absorbed from diet. The different components of cholesterol include high-density lipoproteins, low-density lipoproteins, and triglycerides.

Clinical trials: scientific studies conducted to evaluate the effectiveness and safety of healthcare interventions by monitoring the effects of those interventions on groups of people.

Comorbidities: medical problems that coexist with the diagnosis of a separate, primary medical issue, such as obesity.

Congestive heart failure (CHF): specifically, the inability of the human body's heart to pump blood with normal efficiency and to provide adequate blood flow to other organs. CHF may be due to failure of the right, left, or both ventricles.

Coronary artery disease (CAD): a condition that begins when hard cholesterol substances (plaques) are deposited within a coronary artery.

Depression: an illness involving the body, mood, and thoughts, which affects: the way one eats and sleeps; the way one feels about oneself; and the way one thinks about things.

Diabetes mellitus: a chronic disease associated with the presence of abnormally high levels of glucose in the blood caused by inadequate production of insulin or inadequate sensitivity of cells to

the action of insulin. The two main types of diabetes correspond to these two mechanisms and are called type 1 diabetes and type 2 diabetes.

Diet: what a person eats and drinks, or any type of eating plan.

Digestive system: includes the organs (that is: salivary glands, mouth, esophagus, stomach, small intestine, liver, gallbladder, pancreas, colon, rectum, and anus) that are responsible for getting food into and out of the body and for making use of it.

Dumping syndrome: an adverse event caused by eating refined sugar, symptoms of which include rapid heart rate, nausea, tremor, faintness, and diarrhea.

Endocrinology: the study of hormones, their receptors, the intracellular signaling pathways they invoke, and the diseases and conditions associated with them.

Epidemic: a sudden severe outbreak of a disease (the occurrence of more cases of a disease than would be expected in a community or region during a given time period).

Excess weight: the difference between one's actual weight and a healthy weight.

Excess weight loss (EWL): surplus weight loss achieved through diet or through medical or surgical treatment. EWL is measured by weight units (pounds or kilograms) or by a percentage (initial weight – current weight)/(initial weight – ideal weight).

Fat: a building block of human bodies and a major source of energy in the diet. Fat helps the human body absorb fat-soluble vitamins (such as vitamins A, D, E, and K) and carotenoids. Fats that are in food/diet are combinations of monounsaturated, polyunsaturated, and saturated fatty acids. All dietary fats contain nine calories per gram, more than twice the number provided by carbohydrates or protein.

Gastrointestinal: a term that describes the entire digestive tract, referring collectively to the stomach and the small and large intestines.

Gastrointestinal tract: the tube that extends from the mouth to the anus, in which food is digested through the movement of muscles and the release of hormones and enzymes. It is also called the alimentary canal, the digestive tract, and the GI tract.

Genes: the basic biological units of heredity.

Genetic: pertaining to inherited characteristics.

Glucose: the simple sugar (monosaccharide) that serves as the main source of energy in the body. The body makes glucose from proteins, fats, and, in largest part, carbohydrates. Glucose is carried to each cell through the bloodstream. Cells cannot use glucose without the help of insulin. Glucose is also known as dextrose.

Glycemic Index (GI): an index that ranks foods based on their effect on blood sugar in the human body. Each food on the Glycemic Index receives a "score" according to how much the blood sugar level increases within a few hours of eating that food.

Gout: a condition characterized by abnormally elevated levels of uric acid in the blood, recurring attacks of joint inflammation (arthritis), deposits of hard lumps of uric acid in and around the joints, decreased kidney function, and kidney stones. Uric acid is a breakdown product of purines, which are found in many foods we eat.

High-density lipoprotein (HDL): a form of cholesterol that circulates in the blood, commonly called "good" cholesterol. An HDL of 60 mg/dl or greater is considered high and is protective against heart disease. An HDL of less than 40 mg/dl is considered low and increases the risk for developing heart disease.

Healthy weight: a body weight that is less likely to be linked with any weight-related health problems (such as type 2 diabetes, heart disease, high blood pressure, high blood cholesterol, or other problems). A BMI between 18.5 kg/m^2 and 25 kg/m^2 is associated with a healthy weight, although not all individuals with a BMI in this range may be at a healthy level of body fat (they may, for example, have more body fat and less muscle tissue).

Heart attack: the death of heart muscle due to the loss of blood supply. Loss of blood supply is usually caused by a complete blockage of a coronary artery, one of the arteries that supplies blood to the heart muscle. Death of the heart muscle, in turn, causes chest pain and electrical instability of heart muscle tissue.

Heart disease: any disorder that affects the heart. Heart disease is synonymous with cardiac disease but not with cardiovascular disease, which is any disease of the heart or blood vessels. Types of heart disease include angina, arrhythmia, congenital heart disease (CHD), coronary artery disease (CAD), dilated cardiomyopathy, heart attack (myocardial infarction), heart failure, hypertrophic cardiomyopathy, mitral regurgitation, mitral valve prolapse, and pulmonary stenosis.

Herbal: a term referring to herbs, and which may reflect the botanical or medicinal aspects of herbs.

Hormone: a chemical substance produced in the body. Hormones control and regulate the activity of certain cells or organs.

Hypertension: repeatedly or consistently elevated blood pressure, characterized by a blood pressure measurement exceeding 140 over 90 mmHg.

Hypothyroid: a deficiency of thyroid hormone (the hormone normally produced by the thyroid gland).

Incidence: the frequency with which a disease appears in a particular population or area, defined as the number of cases newly diagnosed during a specific time period.

Incoherence statistic: the difference between direct and indirect evidence.

Insulin: a natural hormone made by the pancreas that controls the level of the glucose in the blood. Insulin permits cells to use glucose for energy. Cells cannot use glucose without insulin.

Insulin resistance: the diminished ability of cells to respond to the action of insulin in transporting glucose (sugar) from the bloodstream into muscle and other tissues. Insulin resistance typically heralds the onset of type 2 diabetes.

Laparoscopy: direct visual examination for diagnostic or therapeutic purposes of the abdominal cavity, where the abdominal cavity has been previously distended by means of an endoscope introduced through the abdominal wall.

Laparotomy: (also called *open surgery*) surgical incision through the abdominal wall and peritoneum.

Lean body mass: the mass of the body minus the fat (storage lipid). A number of methods exist for determining lean body mass, including underwater weighing (hydrostatic weighing), dual-energy X-ray absorptiometry, and bioelectric impedance analysis.

Leptin: a hormone that has a central role in fat metabolism.

Lipids: a generalized term that refers to any type of fat in our bodies, including fat, cholesterol, and phospholipids (which make up the cell membranes). Roughly 95% of the lipids in foods and in our bodies are triglycerides.

Lipoproteins: compounds of protein that carry fats and fat-like substances (such as cholesterol) in the blood.

Low-calorie diet (LCD): a diet that contains between 800 and1200 calories.

Low-density lipoprotein (LDL): a form of cholesterol that circulates in the blood, commonly called "bad" cholesterol. An LDL of less than 100 mg/dl is considered optimal, 100–129 mg/dl is considered near or above optimal, 130–159 mg/dl is considered borderline high, 160–189 mg/dl is considered high, and 190 mg/dl or greater is considered very high.

Metabolism: the whole range of biochemical processes that occur within any living organism. Metabolism consists both of anabolism and catabolism (the buildup and breakdown of substances, respectively). The term is commonly used to refer specifically to the breakdown of food and its transformation into energy.

Network analysis: mixed-treatment comparisons, extends meta-analysis from pooling directly compared treatments to pooling data from studies that are not directly compared but linked via one or more common comparators.

Obesity: the state of being well above a normal body weight. The clinical definition of obesity is having a BMI of 30 kg/m^2or higher.

Overweight: designates a state in between normal weight and obesity.

Physical activity: any form of exercise or movement. It may include planned activity such as walking, running, basketball, or other sports, as well as daily activities such as household chores, yard work, walking the dog, and so on.

Quality-adjusted life year (QALY): a calculation method allowing situations to be compared in relation to two criteria taken into account simultaneously; that is, comparing efficacy (the number of life years gained) to the quality of life of those years.

Resting Metabolic Rate: refers to the number of calories one's body requires on a daily basis to ensure that they have sufficient energy to power all of their body's processes. It is primarily determined by the amount of muscle one's body has.

Sleep apnea: the temporary stoppage of breathing during sleep, often resulting in daytime sleepiness.

Stroke: the sudden death of some brain cells due to a lack of oxygen when the blood flow to the brain is impaired by the blockage or rupture of an artery leading to the brain. A stroke is also called a *cerebrovascular accident* (CVA).

Syndrome: a set of signs and symptoms that tend to occur together and which reflect the presence of a particular disease or an increased chance of developing a particular disease.

Thermogenesis: the process of heat production, caused primarily by the metobalism of fatty acids, which is related to the metabolic rate. The higher the metabolic rate, the more free fatty acids are broken down to produce heat.

Very-low-calorie diet (VLCD): a diet that contains less than 800 calories.

Waist circumference: a measurement of the waist.

Weight cycle: losing and gaining weight over and over again. It is commonly called "yo-yo" dieting (going on a diet to lose weight, going off the diet and gaining weight back again, then repeating the process).

Weight loss: a decrease in body weight, in either voluntary or involuntary circumstances. Most instances of weight loss arise from the loss of body fat, but in cases of extreme or severe weight loss, protein and other substances in the body can also be depleted.

Waist-to-hip ratio (WHR): a measurement that compares the size of your waist in inches to the measurement of your hips. The risk for developing heart disease is typically indicated by the waist-to-hip ratio.

SECTION ONE: SOCIAL AND SYSTEM DEMOGRAPHICS

Paula Corabian, BSc, MPH, Charles Yan, PhD

METHODOLOGY: SOCIAL SYSTEMS AND DEMOGRAPHICS (S) APPROACH

The social systems and demographics approach (SSDA) addresses the following questions:

- What is adult obesity (definition, progression, severity, associated co-morbidities)?
- What are the prevalence and incidence of adult obesity in Alberta and Canada?
- What is the standard of care for adult obesity in Alberta and Canada?
- What patient selection criteria are used for various bariatric treatments (non-surgical and surgical) in adult Albertans and Canadians with obesity?
- How many adults with obesity in Alberta and Canada would benefit from appropriate bariatric treatments?
- What demand exists for bariatric treatments for adult obesity in Alberta and Canada?
- What are the utilization and the discontinuation rates of bariatric treatments in Alberta and Canada?
- What are the barriers to adult obesity management from the perspective of patients and their caregivers? Do any issues exist related to acceptability, adherence/compliance, quality of life, and/or access when using appropriate bariatric treatments for adult obesity in Alberta?
- What are the number and distribution of programs that provide bariatric treatments within clinical settings/facilities for adult obesity in Alberta? How many are primary, how many are secondary, and how many are tertiary care programs?
- Are the available weight management programs accredited for adult obesity management in Alberta and are they all publicly funded?
- What are the number and the distribution of appropriately trained healthcare practitioners and support staff capable of providing bariatric treatments for adult obesity in Alberta?
- What barriers exist to managing adult obesity in Alberta from the perspective of healthcare providers? Do issues exist with relation to training and accreditation, acceptability, quality control, and/or any ethical and legal matters when using appropriate bariatric treatments?
- What are the implications (to society, families/caregivers, and the affected individuals) for the use of multidisciplinary programs providing bariatric treatments for adult obesity in Alberta?

Search strategy

To answer the SSDA questions, the medical literature was searched to identify any relevant articles and documents published between January 2005 and June 2010 using key health information resources, including PubMed/MEDLINE, the Cochrane Database of Systematic Reviews, and the Centre for Reviews and Dissemination (CRD) databases (see Appendix S.A for more details).

Additional Internet searches were conducted to retrieve grey literature. Reference lists of relevant articles were also browsed to identify more studies. Search results were limited to information about humans, published in English. The date restriction was applied to ensure that the evidence collected was current and clinically relevant.

The literature search focused on articles and documents providing information on the profile (definition, etiology, pathogenesis) and epidemiology (incidence and prevalence) of obesity in adults (≥ 18 years, both genders), referred to here as adult obesity. The literature search also focused on articles and documents providing information on the psychosocial impact of adult obesity, patterns of care, types of bariatric services provided (any class/category, duration, or stage), and demand for and usage of bariatric services/treatments in Alberta and in Canada.

The search strategy focused on articles that published findings from secondary research studies reporting on:

- the epidemiology of adult obesity and the demand for and utilization rates of bariatric treatments in Alberta and Canada;
- systematic reviews and health technology assessment studies reporting on quality of life, ethical, and social considerations in adult obesity management;
- evidence-based clinical practice guidelines;
- policy papers;
- overviews, clinical reviews, and/or discussion papers that were conducted or developed in North America (Canada and the United States).

A geographic restriction was applied.

As well, a search was conducted for published local data and information, from sources including the Canadian Institute for Health Information (CIHI), Health Canada, Statistics Canada, the Surveillance Branch of Alberta Health and Wellness, and the Institute of Health Economics' Database of Online Health Statistics.

Healthcare providers from facilities/clinics/programs providing bariatric treatments in Alberta were contacted to provide information on the local context and clinical practice.

Study selection

One reviewer (PC) conducted the initial and final study selection using selection criteria developed a priori. The initial study selection was based on titles and/or abstracts only. Excluded were articles that, on the basis of their abstract, clearly did not meet the inclusion criteria. The final selection was based on review of full text articles.

The study selection process focused on secondary research studies including systematic reviews and health technology assessment studies, evidence-based clinical practice guidelines, policy papers, overviews, clinical reviews, and/or discussion papers on the topic of interest. Primary research studies and/or papers reporting on secondary analyses of research data (such as health surveys and claims data) were included only if they provided information about adult obesity and its management in Alberta and in Canada.

Clinical practice guidelines (CPGs) were included if they provided definitive recommendations specific to the diagnosis and management of adult obesity. An article was deemed to be a CPG if it met all the following criteria:

- It contained the word 'guideline' or 'recommendation' in its title or introduction, or contained specific guidance, in the form of advice or instructions, on how to diagnose and/or manage adults (≥ 18 years, both genders) with obesity (of any duration or stage).
- It was developed by at least two authors.
- It used an evidence-based approach in the process of developing the guidance (recommendations, advice, or instructions were based on a systematic review of the literature, were graded based on the strength of the supporting evidence, and reflected the consensus of the experts involved in the development of the guidance).
- It described the evidence-based approach used for the development of recommendations, advice, or instructions.

Only those publicly available, evidence-based CPGs developed by national bodies in Canada and other countries with developed market economies were considered.

Consensus statements and/or position statements containing recommendations based solely on expert opinion were included only if they were developed in Alberta.

SOCIAL SYSTEMS AND DEMOGRAPHICS APPROACH

The social systems and demographics approach analysis summarizes available key information on the use of bariatric treatments for adult obesity in Alberta and North America (mainly Canada). This analysis was intended to describe the profile of adult obesity (definition, progression, epidemiology, and population dynamics of affected individuals in Alberta and in Canada) and patterns of care for this condition (focusing on bariatric treatments recommended by evidence-based clinical practice guidelines), as well as to identify potential inequities in health status or care across population groups. Also considered were social factors associated with the use of multidisciplinary programs involving bariatric treatments for adult obesity in Alberta.

Profile of Illness

As a medical term, the term "obesity" describes a condition of excess body fat caused by an imbalance between the amount of energy entering the body and the amount of energy leaving it. Obesity is the result of complex interactions between various factors including environmental (social, economic, and cultural), behavioural, hormonal, and genetic factors. It is a health problem, because it is associated with multiple health risks and organ-specific consequences, including type 2 diabetes mellitus (T2DM), cardiovascular disease, musculoskeletal problems, and certain forms of cancer.

Over the past 30 years obesity has become one of the most prevalent conditions in countries with developed market economies, and it is increasingly viewed as a societal issue (www.iotf.org, accessed 23 July 2010; www.who.int/mediacentre/factsheets/fs311/en/index.html, accessed 23 July 2010).[1-15] It affects individuals of all ages (children, adolescents, and adults) and both genders. It is recognized as a major public health problem and has been identified as an epidemic by the World Health Organization (WHO) and medical organizations around the globe.

This report addresses obesity in adults only (≥ 18 years, both genders) and the condition is referred to here as *adult obesity*.

Definition, classification, and description of adult obesity

Obesity is defined as an accumulation of excess body fat (adipose tissue) that may impair one's health and may result in reduced quality of life (QoL) and increased morbidity and premature mortality (www.who.int/mediacentre/factsheets/fs311/en/index.html, accessed 23 July 2010).[1,2,5,6,11,13,14,16-27] A variety of methods have been proposed to measure body fat accurately or reliably, among which the most complex include densitometry, bioelectrical impedance analysis, dual energy x-ray, and computed tomography or magnetic resonance imaging scanning.[1,2,10,13,19,28] However, these methods require expensive equipment and highly trained professionals and their use is not feasible in current practice.

A common alternative is to define obesity as excess body weight rather than excess body fat (www.who.int/mediacentre/factsheets/fs311/en/index.html, accessed 23 July 2010).[1,2,5-7,11,13,14,16-27] International and Canadian guidelines for body weight classification in adults define obesity for both genders and all age groups in relation to body mass index (BMI), which is calculated as weight (expressed in kilograms) divided by height (expressed in meters squared, or kg/m^2). Within this framework, the term obesity applies when the BMI is equal to or greater than (≥) 30 kg/m^2.

As BMI is highly correlated with reference measures of body fat, it is widely used to indicate different levels of health risks associated with obesity and to predict future health status in men and women (www.who.int/mediacentre/factsheets/fs311/en/index.html, accessed 23 July 2010).[1,2,6,9-14,16,17,19-22,24,27,29-31] Because BMI varies greatly among adults, obesity has been divided into three classes (class I or mild obesity; class II or moderate obesity; and class III or severe/extreme/morbid obesity), with successive values representing escalating health risk levels. According to the Canadian guidelines for body weight classification in adults, which are in line with those of the WHO, adults in class I (BMI between 30.0 kg/m^2 and 34.9 kg/m^2) have a high risk of developing health problems.[22] For those in class II (BMI between 35.0 kg/m^2 and 39.9 kg/m^2), the risk is very high. And for those in class III (BMI of 40 kg/m^2 or more), the risk is extremely high.

Assessing body weight using BMI cut-off points is simple and convenient; but it has a number of limitations because it does not take into consideration body composition.[1,2,5,6,9-13,16,17,19,22,24,25,27,30,32] BMI does not measure body fat or the distribution of body fat directly and does not distinguish fat from fat-free mass such as muscle and bone. While it provides a useful surrogate for total adiposity, BMI is influenced by, and needs adjustment for, gender, age, and ethnicity/race. Because of body composition differences, women generally have a higher percentage of body fat than do men and older individuals tend to have a higher percentage of body fat than do younger adults with the same BMI. Furthermore, BMI classifications are based on the body types of those of Caucasian/European descent, which are different than Asian and Aboriginal body types.[1,22,30] For Asian and Aboriginal populations, more research is needed to determine whether current BMI classifications apply.[1,22]

For these reasons, although BMI is a good measure of adult obesity at the population level, it may not be an accurate predictor for obesity-related health risks for certain groups because it does not correspond to the same degree of fatness in different adults.[1,2,5,6,11,16,17,19,22,24,25,30,32] Therefore, BMI-based obesity classification may underestimate or overestimate the effect of excess body weight and fat on health risks for some diseases in specific groups such as:

- young adults who have not reached full growth;
- adults who have a naturally lean body build;
- adults who have a highly muscular body;
- adults who are very tall or very short;
- elderly adults (those aged 65 and over);
- pregnant women;
- certain ethnic groups.

The latest research indicates that, when considering the health risks associated with obesity, it is important to determine both the amount of fat an individual has and the location of fat stores in the body.[1,3,5,6,10,19,20,22,24,25,27,33-35] Excess abdominal fat (also referred to as central adiposity or abdominal obesity) is recognized as an important, independent risk factor that appears to drive many of the endocrine, cardiovascular, and malignant consequences of obesity.

The amount of abdominal fat can be assessed by waist circumference and waist-to-hip ratio measurements.[1-3,5,6,10,19,20,22,24-28,33-35] In clinical practice, waist circumference, which is directly associated with abdominal fat content, is more frequently used as an index of abdominal fat than the waist-to-hip ratio, which is more difficult to measure. Men with waist circumferences equal to or greater than 102 cm (40 inches) and women with a waist circumference equal to or greater than 88 cm (35 inches) are considered at increased risk for cardiovascular disease and a range of other conditions, such as T2DM and sleep disorders.

However, the established waist circumference cut-off points have not been validated for their ability to discriminate clinical events and are likely to differ in various subgroups (men versus women, different adult age groups, and different ethnic populations). Another limitation to using waist circumference measurements is their inability to distinguish visceral adipose tissue from overlying subcutaneous adiposity.[1-3,5,6,13,20,22,24,26,27,34,36] Measuring waist circumference is most useful in individuals with a BMI < 35 kg/m^2.

Pathogenesis of obesity

The cause of obesity is complex and multifactorial and may differ from one individual to another.[1,3,4,6,9,11,15,19,20,23,24,31,32,37-45] At the simplest level, obesity results from long-term energy imbalance and fat stores due to the interaction of energy intake and energy output or expenditure. However, complex interactions between genetics, hormones, and various behavioural, socioeconomic, cultural, and other environmental factors are involved in the regulation of energy balance and fat stores.

It is presumed that 20% to 75% of the variability of body weight and composition within a population is explained by genetics.[23,24,31,42,44-46] Genetic factors can either play a major role in the pathogenesis of obesity or can enhance susceptibility to its development.[23,24,31,38,42] In some populations, such as in the Canadian Aboriginal population, genetics may play a more predominant role in the pathogenesis of obesity and the gene-environment interaction may be particularly strong.[31,38] Although multiple candidate genes have been implicated in the pathogenesis of obesity,[23,24,38,42,44] the findings are inconsistent.[24] The rapidly occurring changes in obesity prevalence over the past 30 years are highly unlikely to be explained only by genetic changes.

Many systemic factors have been identified as forces driving these rapidly occurring changes in obesity prevalence.[1,4,6,16,19,23,24,31,38,41-45,47] These factors include modern lifestyles, work environments, urban design and obesogenic (obesity-producing) environments, transportation systems, food production systems, technological developments, and economic growth itself. High energy-density diets, increased portion sizes, decreased physical activity, and the adoption of a sedentary lifestyle, as well as eating disorders, are considered to be important risk factors in the development of obesity.

However, accurate and reliable data on behavioural, socioeconomic, and other environmental influences on diets and physical activity are still needed for clarifying the complex causes and consequences of obesity.[4,31,32,43] Most of the available data were obtained through survey studies conducted in North America, Europe, and Australia using various data collection strategies to record usual dietary intake and frequency of physical activity. All the survey measures represent short-term measures of dietary intake and physical activity, while obesity is the result of a long-term imbalance between energy intake and expenditure. Although the existing social differences between and within countries constitute evidence that may provide important insights into ways of influencing change to prevent and manage obesity, caution needs to be exercised in generalizing data from different sociopolitical contexts.

The administration of some drugs (such as antidepressants, antiepileptics, antipsychotics, antihypertensive agents, antidiabetic agents, and steroids), and neuroendocrine abnormalities or diseases (such as hypothalamic, pituitary, thyroid, and adrenal diseases) may lead to or are associated with excessive weight gain and may hinder induced weight loss.[1,2,13,19,20,23,24,45,46,48] The hormones that are believed to be involved in the regulation and pathophysiology of obesity include insulin, cholecystokinin, and leptin.[23,24] Lack of sleep may also contribute to excessive weight gain.[19]

Health risks and complications associated with obesity

For many individuals, carrying excess body fat and weight, together with other known and unknown factors, may lead to many cardiovascular and metabolic complications and is associated with many debilitating health problems.[1,6,10,12,16,19,25,26,32,38-40,47-57] Health risks and acute and chronic conditions associated with obesity include the following:

- **metabolic risks and complications:** T2DM, insulin resistance, dyslipidaemia, metabolic syndrome, hyperuricaemia, gout, and low-grade inflammation;
- **cardiovascular system:** hypertension, coronary heart disease, congestive heart failure, and venous thromboembolism;
- **respiratory system:** asthma, hypoxemia, obstructive sleep apnea, obesity hypoventilation syndrome (Pickwickian syndrome), dyspnea, and fatigue;
- **cancers:** esophagus, small intestine, colon, rectum, liver, gallbladder, pancreas, kidney, leukaemia, multiple myeloma, and lymphoma, as well as:
    - in women: endometrial, cervix uteri, ovary, breast cancer after menopause;
    - in men: prostate cancer, colon, rectum cancer;
- **musculoskeletal system:** osteoarthritis (especially knee), immobility, low back pain and pain in the weight-bearing joints, musculoskeletal pain resulting in functional limitations;
- **gastrointestinal system:** gallbladder disease, non-alcoholic fatty liver disease, hepatic steatosis, gastro-esophageal reflux disease, and hernia;

- **genitourinary system:** hypogonadism, urinary incontinence;
- **reproductive complications:** menstrual irregularity, infertility, hirsutism, polycystic ovaries, miscarriage, gestational diabetes, hypertension, preeclampsia, macrosomia, fetal distress, defects, malformation, dystocia, and primary Caesarean section;
- **neurologic system:** idiopathic intracranial hypertension, meralgia paresthetica, and stroke;
- **miscellaneous:** disrupted or inadequate sleep, proteinuria, nephrotic syndrome, skin infection, lymphoedema, complications in surgery, and poor dental health.

The specific levels of health risk associated with obesity vary with BMI level, body fat content and distribution, age, gender, ethnicity, and social conditions.[1,6,29,31,32,38-40,50,53,58]

Growing evidence shows that obesity (as defined by BMI and waist circumference) is not always related to an unfavourable cardiometabolic profile or poor health outcomes.[5,15,26,36,59,60] The existence of cardiometabolically healthy obese individuals (who present a lower prevalence of health risk factors and less disease burden) is referred to as uncomplicated obesity; this has become a distinct clinical entity and is not an uncommon finding in clinical practice.

Obesity is associated with an increased risk of premature death from chronic conditions such as cardiovascular diseases, T2DM, and certain cancers.[1,6,12,25,31,38,50,51,61-65] The association between obesity and mortality weakens with increasing age, especially for those over 75 years of age.[6,63-66] Data from several epidemiological studies suggest an inverse correlation between obesity and mortality, particularly cardiovascular mortality in the elderly, often termed as the obesity paradox.[5,26,36,59,61,63,64]

According to the reviewed evidence, there is an association between the category of obesity and medical complications—the more severe the obesity, the more serious the medical complications.[1,6,12,15,31,39,40,50,51,53,58,67,68] Severe (class III) obesity presents a 13- to 18-fold increased risk of T2DM, a 7-fold increased risk of hypertension, and a 2-fold increased risk of all-cause mortality compared to normal weight.[67,69] Severe obesity can shorten life expectancy by 8 to 13 years.[69]

Psychological and social consequences of obesity

In addition to an increased risk of developing physical morbidity and premature mortality, obesity is associated with debilitating psychological and social consequences.[1,6,15,19,25,39,40,48,52-55,57,58,67,68,70-73] Body image dissatisfaction, low self-esteem, disturbed eating habits, depressive symptoms, mood and anxiety disorders, suicidal ideation, and psychological disturbance are common in individuals who seek bariatric treatment and, as with obesity-related cardiometabolic health risks and complications, tend to cluster in the most susceptible individuals (especially in those with severe obesity and most notably in young women).[25,53-55,57,58]

Psychopathology may be considered a comorbidity of severe obesity, mainly consisting of depression, anxiety disorder, personality disorder, and impaired self-esteem.[15,25,39,40,54,58,71,73,74] Individuals with severe obesity often present with binge eating disorder (BED), night eating syndrome, and frequent snacking or grazing, although there is some discussion concerning the prevalence of these conditions.[39,40,53-55,57,58,73] Although an individual with obesity may not meet strict criteria for the diagnosis of an eating disorder, similar characteristics exist, including dissatisfaction with the body image or negative body view, frequent dieting, and experiences of failure related to eating restraint.[39,40,54,55,57,58] The presence of BED is associated with increased symptoms of depression and the prevalence of mood, anxiety, personality, and substance-use disorders.[39,40,53-55,57,58]

Severe obesity is associated with decreased health-related quality of life (HRQoL), a term that refers to the burden of suffering and the limitations in physical, occupational/vocational, and social functioning associated with illness.[1,6,39,40,52-55,57,67,68,72] Affected individuals frequently report that the pervasiveness and severity of their impairments are their strongest motivators for seeking bariatric treatment. Additionally, impairments in HRQoL may account for increased symptoms of depression.

Persons who have significant limitations in their functional abilities due to obesity could be expected to have impaired occupational function.[39,40,54] Severe obesity has been associated with greater morbidity and a poorer HRQoL than smoking/drinking problems (alcoholism) or poverty.[40]

Emotional suffering may be one of the most painful consequences of obesity.[1,6,12,19,25,39,40,53-55,57,58,60,70,75] Socially, individuals with obesity, particularly those affected by severe obesity, have to deal with stigmatization, prejudice, discrimination, and social rejection/isolation. The prevalence of weight bias and discrimination in the United States has increased by 66% over the past decade and is comparable to rates of racial discrimination, especially among women.[75]

Society emphasizes physical appearance and often equates attractiveness with slimness, especially for women.[19,39,40,53-55,57,58,60,70,75,76] Obesity is often viewed as the physical manifestation of a character flaw, and the psychosocial problems of individuals with obesity are attributed to their character rather than to their condition. Also, weight bias and discrimination translate into inequities in employment settings, health-care facilities, and educational institutions. As a result, obese individuals feel misunderstood and neglected.

Epidemiology of adult obesity and population dynamics of affected individuals

Over the past several decades, the worldwide prevalence of obesity (BMI $\geq$ 30 kg/m^2) has increased steadily among all demographic groups and countries with developed market economies are leading the way.[1,6,7,13,23-25,31,38,42,44,46,56,73,74,77-80] The obesity subgroups experiencing the most rapid growth are the severe/extreme/morbid class and the moderate class (class III and class II, when BMI reaches 40 kg/m^2 or even only 35 kg/m^2 if associated with comorbidities).[11,29,68,73,74,77,81-83]

The latest World Health Organization estimates indicate that globally in 2005 at least 400 million adults were obese and, projecting that, by 2015 more than 700 million adults will be obese (www.who.int/mediacentre/factsheets/fs311/en/index.html, accessed 23 July 2010). According to the WHO, there are 300 million adults with class I or II obesity and 30 million with class III obesity.[79]

The prevalence is rising at an even faster rate among children and adolescents.[2,27,56,61,69] The International Obesity Task Force estimates that more than 155 million children worldwide are overweight or obese.[56] According to the WHO, worldwide, at least 20 million children under the age of 5 were overweight in 2005 (www.who.int/mediacentre/factsheets/fs311/en/index.html, accessed 23 July 2010).

At the same time, the prevalence of obesity is rapidly increasing in the elderly population; this has become a growing concern.[14,15,56,61,63-66,78,84-87]

The reported gap in obesity prevalence between women and men is usually small and the rates increase for both men and women, up to age 60 to 69, and then decline.[6,17,25,28,29,38,43,44,46,61,77,88] Studies in countries with developed market economies have usually noted an inverse relationship between BMI and socioeconomic status, particularly among women.[10,28,43,88,89]

Considerable variation in the prevalence of obesity occurs among and within countries of the Western hemisphere.[9,10,25,28,46,77,78,88,89] However, comparisons of the data collected by/for different countries are complicated by the differences in year of data collection, the age range of the population studied, and the location of data collection (urban, rural, nationally representative).

Adult obesity in the United States

The National Center for Health Statistics at the Centers for Disease Control and Prevention (CDC) in the United States released the 2009 National Health Interview Survey (NHIS) (www.cdc.gov/nchs/nhis/released201006.htm#6) in June 2010. This survey (based on interviews with 88,129 individuals) found that 28% of US adults 20 years and older were considered obese (BMI $\geq$ 30 kg/m^2). This is slightly higher than the 2008 estimate of 27.6%. The annual prevalence of obesity has increased steadily from the 19.4% reported in 1997. Obesity was higher among adults aged 40 to 59 (31.6%) than among adults aged 20 to 39 (24.9%) and those aged 60 years and older (27.0%). There was no significant difference between genders. Non-Hispanic white women and men were less likely than Hispanic women and non-Hispanic black women to be obese. Non-Hispanic white women were less likely than non-Hispanic white men to be obese and non-Hispanic black women were more likely than non-Hispanic black men to be obese.

The prevalence of obesity has increased over the past years among both genders, in all age and ethnic groups, and at all educational levels.[35,44,50,51,57,73,90-93] The most rapid increases in obesity prevalence are in its most severe forms.[44,57,73,90] Approximately 5% of adult Americans suffer from severe obesity,[14,15,57,90] which affects 20% of the obesity-affected US population.[73] Approximately 20 to 25% of children are either overweight or obese and the prevalence is even greater in some minority groups, including Pima Indians, Mexican Americans, and African Americans.[35,44]

Evidence from a meta-regression analysis published in 2007 predicts that 41% of adult Americans will become obese by 2015.[50] If these trends in obesity prevalence continue, by 2030 the number of adults with obesity will be 1.12 billion, representing more than 86% of adults in the US.[90]

Adult obesity in Canada

In Canada, the overall prevalence of obesity has increased over the past several decades among children, adolescents, and adults of both genders, in all areas of the country, and it continues to rise.[1,3,8-12,16,17,24,28,29,31-33,47,68,69,81,88,94-96] Canadian statistics rely upon a number of different surveys of nationally representative samples. These surveys vary in regard to cut-off points, reference populations, and data collection techniques (most used self-reported heights and weights; only some were based on directly measured heights and weights). Regardless of the specific studies or surveys, both self-reported and directly measured data have shown a steady increase in obesity prevalence among adults aged 18 or older since 1970, with the most rapid increase being seen in obesity classes II and III.

An examination of self-reported BMI data from seven surveys, conducted from 1985 through 2003, of nationally representative samples of Canadian adults found that the overall prevalence of self-reported obesity increased from 6.1% in 1985 to 15.7% in 2003.[16,81] The investigators also found that the prevalence of class I obesity increased from 5.1% in 1985 to 11.5% in 2003. The prevalence of class II obesity increased from 0.8% to 3.0%, while class III obesity rates increased from 0.4% to 1.3%.

However, directly measured BMI data are considered more accurate than self-reported data, which may underestimate the actual prevalence of obesity given the tendency of respondents to over-

report their height and under-report their weight.[1,16,17,29,31,88,97] The directly measured weight and height data suggest that in Canada the prevalence of obesity (BMI ≥ 30 kg/m^2) in the household population aged 18 and older (excluding pregnant women) is growing steadily and has almost doubled during the past several decades.[11,16,17,29,47,94] Whereas individuals with obesity accounted for only 13.8% of Canada's adult population in 1978–1979, this figure was 23.1% in 2004.[11,17,29,47] Among men, the rates increased from 7.9% in 1970 to 22.9% in 2004 and for women, the rates increased from 12.9% in 1970 to 22.5% in 2004.[16]

The increase was evident in each of the three obesity categories, especially in classes II and III.[11,29] The proportion of adults in class II increased from 2.3% in 1978–1979 to 5.1% in 2004 and in class III from 0.9% to 2.7%. The obesity rate rose during this period for every age group except among those aged 65 to 74. The most striking increases were among people younger than age 35 and those aged 75 or older. The percentage of obese adults aged 25 to 34 more than doubled (from 8.5% in 1978–1979 to 20.5% in 2004). The increase among people aged 75 or older was about the same: from 10.6% to 23.6%.

Although the difference in the 2004 directly measured obesity rates between men and women was small, it was larger for class III obese adults (1.6% for men and 3.8% for women).[11,16,17,29,47] For both genders, rates were lowest among those aged 18 to 24 (10.7% of men and 12.1% of women) and peaked at around 30% among those aged 45 to 64. The percentage of seniors who were classified as obese was about 25%.

Statistics Canada recently released the latest data from the Canadian Community Health Survey (CCHS), based on a survey of more than 65,000 Canadians, conducted between January 2007 and December 2007 (www.statcan.gc.ca/daily-quotidien/080618/dq080618a-eng.htm).[88,98] Overall, 17% of Canadians aged 18 or older self-reported data on weight and height that classified them as obese (BMI ≥ 30 kg.m^2).[88,98] Although self-reported obesity rates generally changed little between 2005 and 2007, during that period there was a slight increase in the proportion of women aged 18 to 24 who were considered obese. Self-reported obesity rates were generally highest among individuals aged 45 to 64. Twenty per cent of men in this age group were considered obese, as were 18% of women. Men aged 25 to 44 were considerably more likely than their female counterparts to be obese.

Extrapolating from self-reported and directly measured data collected over time, it has been estimated that the actual prevalence of adult obesity is likely closer to 25%.[88] If historical trends remain unchanged, prevalence could reach 27% for men and 24% for women by 2010.[16] The WHO projected that obesity prevalence in Canada will increase between 2005 and 2015 by 4.3% for men and 6.3% for women.[16]

Factors influencing adult obesity prevalence in Canada

Obesity in Canada is influenced by numerous individual-level and environmental factors, such as age, gender, ethnicity, income, and place of residence.[1,11,12,28,29,47,88,89] Directly measured and self-reported obesity rates for both men and women seem to increase until individuals reach the age of 65, after which the rates start to decline.

Canadians are experiencing accelerated weight gain at younger ages[1,8-12,29,31,32,47,94,95] and it seems that obesity among children and adolescents in Canada is advancing at an even more rapid pace than obesity among adults.[1,3,8,47,94] According to directly measured BMI data from the 2004 CCHS, in 2004, among children and adolescents (aged 2 to 17), one in four (26%) were overweight or obese (18.1% were overweight and 8.2% were obese).[1,94] The obesity rate has increased during the past decades

from 2% to 10% among boys and from 2% to 9% among girls.[94] It appears that children living in low-income families are more likely to be overweight than those living in higher-income families.[1] There is evidence to suggest that parental obesity increases the risk of offspring obesity.[8]

In the 2007 CCHS, self-reported rates of obesity among youth aged 12 to 17 were 6.8% for boys and 2.9% for girls.[88] Given the recent obesity trends among children and youth, the prevalence of obesity among adults will likely continue to increase as the current generation of children enter adulthood.[1,3,88,94] Childhood obesity not only increases the risk of obesity in adulthood, it can also contribute to the early development of serious health conditions such as T2DM, heart disease, and high blood pressure, as well as psychosocial problems.[1,16,88,94]

Obesity is an important health issue among Aboriginal populations in Canada.[1,11,29,31,88,95,96,99] Self-reported and directly measured data from the CCHS indicate that, among the major ethnic groups, Aboriginal people (living off reserve) have the highest prevalence of obesity and a significantly higher obesity rate than the national average.[1,11,29,31,99] Ktazmarzyk recently investigated ethnic differences in obesity and physical activity among Canadians aged 2 to 64 using data from the 2004 CCHS and found a higher obesity prevalence among Aboriginals (37.8%) than among non-Aboriginals (22.6%).[99] Data from 2007 CCHS show that obesity rates are higher among off-reserve Aboriginal adults compared to non-Aboriginal people (24.8% versus 16.6%).[88] Other Canadian studies have also documented the high prevalence of obesity among Aboriginal people.[31]

Recent immigrant status appears to be protective against obesity.[52,89,95] Cross-sectional data from the 1994 National Population Health Survey (NPHS) suggest that the length of time since immigration is an important risk factor for excess weight for women, regardless of ethnic origin, and for men of Asian origin after controlling for socio-demographic and lifestyle correlates.[95] These results suggest that the Canadian lifestyle, also imported into Aboriginal communities, could constitute an obesigenic environment for previously healthy immigrants. A 2003 round table meeting highlighted the links between the environment, obesity, and health (www.cihr-irsc.gc.ca/e/21597.html). According to the presentations and discussions of this meeting, during the past decades Canadians have experienced a paradigm shift characterized by fundamental changes in how they live in and construct their environment. This shift has had an impact on both obesity prevalence and the health of Canadians.

Gadalla used self-reported data from the 2005 CCHS to examine a range of socio-demographic, economic, physical health, and behavioural correlates of obesity, as well as the associations between obesity and mood and anxiety disorders.[52] Bivariate chi-square tests revealed a significant association ($p < .0005$) between obesity and gender, age, living arrangement, length of time in Canada, education level, number of chronic physical conditions, limitations in daily living activities, smoking frequency, and level of physical activity.[52] The prevalence of obesity increased steadily with advancing age and the number of chronic physical conditions and decreased steadily with higher education and physical activity levels. The prevalence of obesity among individuals born in Canada was more than double that prevalence among recent immigrants. Findings from this research also revealed significantly elevated levels of obesity in persons living with a partner compared to those not living with a partner, in non-smokers as compared to smokers, and in persons with functional limitations as compared to those with no such limitations. Adjusting for the above-listed variables, the odds of obesity remained significantly higher in individuals with mood disorders (with or without anxiety) than in those with neither mood nor anxiety disorders.

Also using self-reported data from 2005 CCHS, Slater et al.[89] examined how overweight and obesity in Canadian adults were distributed across socio-demographic and geographic groupings. Age, physical inactivity, education, non-immigrant status, white racial status, and moderate food insecurity predicted varying degrees of overweight and obesity in both men and women. The highest obesity rates were observed in older age groups, among those who were physically inactive, white or non-immigrant, with low educational levels, and living in the prairie and east coast regions. The lowest rates of obesity were observed in major urban centers. Although low rates of physical activity were predictive of obesity for both genders, low consumption of fruits and vegetables was not associated with a higher BMI.

Tjepkema analyzed directly measured data from the 2004 CCHS for specific characteristics, including physical activity and fruit and vegetable consumption, for those aged 18 and older, and formal educational attainment for those aged 25 to 64.[29] Obesity was significantly related to diet and physical exercise and it was generally inversely correlated with formal educational attainment. Both men and women whose leisure time activities were largely sedentary were more likely to be obese than those who were more physically active in their leisure time.

Geographical variation in adult obesity in Canada

According to self-reported data from the 2007 CCHS, several provinces, including Alberta, Saskatchewan, Ontario, and Québec, have had an increase in their obesity rates between 2003 and 2007, while rates in other provinces (Manitoba and Prince Edward Island) may be leveling off or may have decreased slightly (British Columbia, New Brunswick, Nova Scotia, and Newfoundland and Labrador) in 2007 (www.statcan.gc.ca/daily-quotidien/080618/dq080618a-eng.htm).[88,98] Rates of obesity were highest in Saskatchewan, Alberta, and Atlantic Canada, ranging from 18% in Alberta to a high of 22% in Newfoundland and Labrador. The lowest rates were in British Columbia where 11% of adults were classified as obese.

Adult obesity in Alberta

Self-reported and directly measured data have shown a steady increase for adult obesity prevalence in Alberta since 1986.[1,9,10,16,28,29,100] Schopflocher examined self-reported data from the 1996 NPHS and the 2001 and 2003 CCHS and reported that in 1996, 10.3% of adults in Alberta (age 20 and over) were classified as obese (BMI 30–39.9 kg/m^2, combined class I and II), and 1.6% as severely obese (BMI ≥ 40 kg/m^2, class III).[28] In 2003, the percentages were 14.3% for adults classified as obese (combined class I and II) and 3.2% for those classified as severely obese (class III). The rates increased with advancing age in both men and women until age 65 (with the highest rates seen in those aged 55 to 64), after which there was a decline. The proportion of adults classified as obese (combined class I and II) and severely obese increased in the lower income classes, although there were differences in these rates between genders and within income groups. Rural obesity rates were higher than urban rates, but the specific data were not given. Albertans without a secondary education had higher levels of obesity than those having secondary education, some postsecondary education, and college or university degrees.

Schopflocher also correlated self-reported BMI in Alberta by health status, prevalence of chronic diseases, and healthcare service utilization, using data from the 1996 NPHS and the 2001 and 2003 CCHS.[28] He found that 12% of adults with obesity (combined classes I and II) and 9% of those with severe obesity (class III) reported having fair or poor health, as compared to 8% of the normal-weight population. The proportion of adults diagnosed with one or more chronic conditions

generally increased with an increasing BMI: 16% of adults with obesity (combined classes I and II) and 22% of adults with severe obesity (class III) reported having two or more chronic diseases, as compared to 14% of those in the normal weight range.

According to Statistics Canada data for Alberta, in 2005 the percentage of self-reported obesity (BMI 30–39.9 kg/m^2, combined classes I and II) was 14.7% and the percentage of severely obese was 1.1% in Alberta.[16] The obesity rates were 17.6% for men and 13.9% for women.

Directly measured Canadian and provincial obesity rates for the adult population aged 18 and over showed that Alberta obesity rates between 1986 and 2004 rose in parallel with rates in Canada, although the Alberta rates were slightly higher.[9,10,16,101] Obesity rates in Alberta increased by nine percentage points (from 16% to 25%) during this period, while the overall Canadian rate rose by eight percentage points (from 15% to 23%).[16]

In 2004, 35.7% of adult Albertans were classified as overweight while an additional 25.2% were classified as obese, compared to the 37.3% who were of a normal weight.[16,101] Among those who were classified as obese, 15.4% fit into class I obesity (BMI 30–34.9 kg/m^2), 6.7% into class II (BMI 35–39.9 kg/m^2), and 3.2% into class III (BMI ≥ 40 kg/m^2). The prevalence was significantly lower in large urban than rural centres (22.6% versus 32.2%).[9] The obesity rate in Calgary (estimated population 765,000) was 25.7% and in Edmonton (estimated population 946,000) the rate was 20.1%.[9]

According to self-reported data from the 2007–2008 CCHS, among 2,619,032 adult (aged 18 and over) Alberta residents in 2007, 17.7% were classified as obese (BMI ≥ 30 kg/m^2) and 32.2% were classified as overweight (BMI 25–29.9 kg/m^2), compared to 42.6% who were of a normal weight.[102] Upon further breaking down the obese category, these same CCHS data indicated that 12.5% fit into obese class I (BMI 30–34.9 kg/m^2), 3.7% into obese class II (BMI 35–39.99 kg/m^2), and 1.5% into obese class III (BMI ≥ 40 kg/m^2).

Table S.1 presents adult obesity by demographic, geographic, and obesity-related comorbidity categories. It shows the proportion of Alberta residents who reported fitting into obese class I, II, or III over the whole population in each category, which was calculated based on the prevalence of Alberta adult residents with obesity (BMI ≥ 30 kg/m^2) in 2007 (see Appendix S.B for the prevalence of adult obesity in Alberta in 2007).

Table S.1 also shows differences in the adult obesity rates in 2007 among the categories by gender, age, education level, marital status/living arrangement, and household annual income. Women were less likely to be classified as obese than men (15.9% versus 19.5%). Education-specific obesity distribution showed that adult Albertans who had graduated from high school were less likely to be classified as obese than those who had not graduated from high school (17.2% versus 22.5%). Obesity rates increased with age, from 8.1% among adults aged 18 to 24 to a peak of 23.5% among individuals aged 55 to 64. The proportion of obesity drops among the elderly (those over age 65). The proportion of obesity also varied by marital status, with a higher rate among married and widowed adults (both at over 19%) than among single persons (12.4%).

The relationship between adult obesity and household annual income did not present in a linear fashion. Obesity rates were lower (approximately 16%) for those in income categories of less than $20,000 or between $40,000 and $59,000 and higher for those with incomes between $20,000 and $39,000 (17.7%) or between $60,000 and $70,000 (19.2%). The highest obesity rate (21.6%) was observed in individuals with incomes of more than $80,000.

An examination of overall obesity distributions by health zones in Alberta (also shown in Table S.1) showed that people in the Edmonton and Calgary zones have lower obesity rates (17.7% and 14.2%, respectively), than those in other health zones in the province (where rates ranged from 20% to 25%).[1]

With reference to the relationship between obesity and obesity-related morbidity, Table S.1 shows that those who reported having been diagnosed with obesity-related morbidity were more likely to report being obese. Obesity rates among those with cancer, diabetes, high blood pressure, and heart disease, were 21%, 44%, 33%, and 28%, respectively, as compared to 18%, 16%, 15%, and 17% among those without comorbidities.

[1] For this analysis it was assumed that the previous nine Alberta health regions (www.health.alberta.ca/services/health-regions.html, accessed 24 August 2010) were represented in the current five health zones (www.albertahealthservices.ca/1532.asp, accessed August 24, 2010) as follows:

- South Zone: formerly the Chinook and Palliser Health Zones
- Calgary Zone: formerly the Calgary Health Zone
- Central Zone: formerly the David Thompson and East Central Health Zones
- Edmonton Zone: formerly the Capital Health Zone
- North Zone: formerly the Aspen, Peace Country, and Northern Lights Health Zones

Table S.1: Percentage of adult obesity by demographic, geographic, and comorbidity groups in Alberta in 2007

By gender	**Male**	**Female**	**Overall**				
%	19.45%	15.88%	17.69%				
By education	**Less than HS**	**HS**	**Overall**				
%	22.47%	17.15%	17.69%				
By marriage	**Married or common law**	**Widowed**	**Single**	**Overall**			
%	19.4%	19.2%	12.4%	17.7%			
By income (per $1,000)	**< 20**	**20–39**	**40–59**	**60–79**	**> 80**	**Overall**	
%	16.43%	17.73%	16.78%	19.22%	21.63%	17.69%	
By health zone	**South zone**	**Calgary zone**	**Central zone**	**Edmonton zone**	**North zone**	**Overall**	
%	20.08%	14.24%	20.30%	17.70%	24.97%	17.69%	
By age (years)	**18 to 24**	**25 to 34**	**35 to 44**	**45 to 54**	**55 to 64**	**65 +**	**Overall**
%	8.13%	16.53%	17.89%	20.79%	23.49%	18.73%	17.69%
By comorbidity							
Cancer	**WO/cancer**	**W/cancer**	**Overall**				
%	17.62%	20.86%	17.67%				
Diabetes	**WO/diabetes**	**W/diabetes**	**Overall**				
%	16.26%	43.93%	17.66%				
HBP	**WO/HBP**	**W/HBP**	**Overall**				
%	14.83%	32.53%	17.65%				
HD	**WO/HD**	**W/HD**	**Overall**				
%	17.31%	27.57%	17.66%				

Abbreviations: HBP = high blood pressure; HD = heart disease; HS = High school; W = with; WO = without

Source: Based on Statistics Canada 2009 Canadian Community Health Survey, Cycle 4.1, 2007–2008 (public use microdata file) [cd-rom]. Statistics Canada (producer). All computations, use, and interpretation of these data are entirely those of the authors of this STE report.

Table S.2 presents the associational relationship between activity limitation levels and obesity in adult Albertans in 2007. The data show that those with obesity experience almost twice as much activity limitation imposed by long-term physical and/or mental health problems or conditions as do adults of normal weight.

Table S.2: Activity limitation levels by BMI category in Alberta in 2007

BMI	Activity limitation		
	Never	Sometimes	Often
Underweight	68.47%	14.62%	16.91%
Normal weight	73.15%	17.01%	9.84%
Overweight	66.36%	20.31%	13.33%
Obese	55.75%	26.90%	17.35%
Overall	67.48%	19.92%	12.59%

Source: Based on the Statistics Canada 2009 Canadian Community Health Survey, Cycle 4.1, 2007–2008 (public use microdata file) [cd-rom]. Statistics Canada [producer]. All computations, use, and interpretation of these data are entirely those of the authors of this STE report.

Burden of adult obesity

Obesity and its associated comorbidities can cause a significant reduction in life expectancy, especially among young adults with severe obesity.[38,40,42,46,69] It is believed that obesity is responsible for more than 2.5 million deaths per year worldwide.[40] According to the 2007 CDC report, obesity is associated with approximately 112,000 deaths each year in the US.[90]

In addition to affecting personal health and well being, the increased risk of health problems and premature mortality associated with obesity translates into an increased burden on the healthcare system and on society.[1,16,25,32,48,50,69,91,101,103,104] The associated healthcare costs of obesity include both direct medical costs (which include expenses associated with preventive, diagnostic, and therapeutic services provided to obese individuals) and indirect personal and societal costs (including expenses associated with decreased productivity, presenteeism, restricted activities, disability, absenteeism, workers' compensation, and premature mortality).[25,32,91,103] Welfare losses resulting from increased pain and suffering, for example, are also considered indirect costs, although they are rarely measured.

Burden of adult obesity in Canada

Adult obesity places a substantial burden on public health in Canada.[1,3,16,17,24,31,47,81,88,94] It is strongly associated with many of the major chronic diseases Canada confronts today, such as cardiovascular diseases, T2DM, and some cancers.[1,11,16,29,31,47,88] In 2004, 39% of T2DM, 23% of coronary artery diseases, 19% of osteoarthritis, 11% of stroke, 22% of endometrial cancer, 12% of postmenopausal breast cancer, and 10% of colon cancer could be attributed to obesity.[47] Approximately 1 in 10 premature deaths in Canadian adults 20 to 64 years of age may be directly attributable to overweight and obesity.[1,3,94]

Using 1997 self-reported data, the total direct cost of obesity (defined as BMI $\geq$ 27 kg/m^2) was estimated at over $1.8 billion, or 2.4% of total health care expenditures for all diseases in Canada.[1,16,17,24,31] In 2004, the total direct and indirect costs associated with obesity (defined as

BMI $\geq$ 30 kg/m^2) were estimated to be $4.3 billion in 2001 dollars, of which $1.6 billion was attributable to direct costs and $2.7 billion to indirect costs.[16,31] Total direct costs represented 2.2% of total healthcare costs in Canada in 2001.

Burden of adult obesity in Alberta

The increasing prevalence of obesity over the past several decades represents a significant public health concern in Alberta.[16,28,101] In 2004, the prevalence of excess weight (overweight and obesity) was 60.9% which, in 2005, translated into substantial costs for the provincial healthcare system in the amount of $1.27 billion (direct and indirect costs contributed nearly equally to this total). This represents 5.6% of the total cost of all health conditions in Alberta (direct costs, indirect costs, and caregiving).[101,104] The cost of obesity (all classes) represented approximately 70% of the total cost of excess weight (overweight and obesity).[104]

Among the health conditions attributable to excessive weight (overweight and obesity), coronary heart disease (CHD) accounted for the greatest proportion of the cost at 28.3% ($307.1 million).[101,104] Osteoarthritis, T2DM, hypertension, and 14 cancers had the next highest costs, all exceeding $100 million. These conditions accounted for 80.5% of the costs of excessive weight (overweight and obesity) that could be attributed to one of the 22 health conditions evaluated. Direct costs contributed the highest proportional costs for hypertension, T2DM, gallbladder disease, depression, and asthma.

The proportion of the cost of excess weight for men was greater than that for women (55.4% or $607.2 million versus 44.6% or $488.7 million). The difference can be explained by the higher obesity-attributable cost of CHD among men.[101,104] With the exception of CHD and T2DM, women had higher costs attributable to excess weight (overweight and obesity) for most of the other health conditions. However, the obesity-attributable costs of all types of cancer combined and for hypertension were comparable between men and women.

Patterns of Care

The impact of obesity points to the importance of its prevention. Healthy lifestyle and behaviours, including increased physical activity and the adoption of a healthy diet beginning early in life and continuing through all stages of life, are important prevention strategies.[1,2,13,36,46,90,105,106] Given that long-term weight loss is difficult to achieve once an individual becomes obese, the prevention of excess weight gain and obesity is an important public health priority worldwide.[1,2,6,7,13,48,80,90,105,106]

However, most of the studies examining interventions used to prevent excess weight gain and obesity showed little long-term effect on BMI and the evidence base for large-scale preventive interventions is limited.[1,31,105,106] The compelling research needs in this area relate to producing and sustaining the lifestyle changes necessary to stop weight gain. This will involve efforts directed not only toward the individual but also efforts directed toward modifying the environment to support and sustain individual behaviour change.[1,2,6,13,105-107]

According to the Public Health Approaches to the Prevention of Obesity Working Group of the International Obesity Task Force, a comprehensive approach to obesity prevention should:[1]

- address both the dietary habits and the physical activity patterns of the population;
- address both societal-level and individual-level factors;
- address both immediate and distant causes;

- have multiple focal points and levels of intervention (that is, at national, regional, community, and individual levels);
- include both policies and programs;
- build links between sectors that may otherwise be viewed as independent.

Although the primary goal should be to prevent obesity, it appears that a large number of adults worldwide could benefit from comprehensive assessments to identify those who are at risk of developing obesity as well as those who are obese and at high risk for associated adverse consequences.

Screening and diagnosis of adult obesity

According to best practice recommendations in cases of overweight and obesity, BMI and waist circumference measurements can function both as screening and as diagnostic tests for weight outside the normal range.[1,2,6,7,13,22,27,80,108]

The diagnostic protocols are composed of physical examination, laboratory tests, psychological assessments, and a comprehensive evaluation of medical history.[1,2,6,7,13,27,108,109] The medical evaluation entails a complete history (eating patterns, behavioural patterns, physical activity, weight history, attempts at weight loss, and obesity-related risk factors and complications) and a physical examination (including BMI and waist circumference measurements), as well as appropriate laboratory and diagnostic testing. During physical examination it is recommended that the presence and impact of obesity-related health risks and diseases be assessed.

The 2006 Canadian guidelines on diagnosis and management of obesity recommend:[1]

- measuring BMI and waist circumference in all adults to assess obesity-related health risks;
- conducting a a clinical evaluation of obese adults that includes a history and a general physical examination to exclude secondary (endocrine or syndrome-related) causes of obesity and obesity-related health risks and complications;
- measuring fasting plasma glucose levels and determining a lipid profile, including total cholesterol, triglycerides, LDL cholesterol, HDL cholesterol, and calculating the ratio of total cholesterol to HDL cholesterol (repeating these tests at regular intervals as needed is suggested);
- conducting a psychological assessment:
    - to determine the person's readiness to change behaviours;
    - to identify barriers to weight loss;
    - to screen for eating and psychiatric disorders.

The guidelines reference the International Diabetes Federation (IDF) cut-off points for waist circumference, given that these measures better reflect the ethnic diversity of Canada.[1,3,94] Using IDF criteria, over 50% of Canadians are considered abdominally obese.

Management of adult obesity

Effective management of adult obesity is multifaceted and complex and involves a range of long-term, if not lifelong, bariatric strategies.[1,2,6,7,13,17,21,27,46,50,56,80,82,83,105,106] The therapeutic approach to long-term weight management requires a specially adapted bariatric treatment structure that is tailored to

the obese individual, as well as the availability of a multidisciplinary team (which may include physicians, nurses, dietitians, physiotherapists, psychologists/psychiatrists, counsellors, aestheticians, and surgeons). The choice of bariatric treatment depends on the individual's age, gender, level of obesity, overall health condition (individual health risks, existing comorbidities, functional limitations and ability to exercise, and psychobehavioural characteristics), and readiness and motivation to make lifestyle and behavioural changes. Long-term, if not lifelong, follow-up and continued supervision are necessary to prevent weight regain, monitor disease risks, and manage co-morbidities.

Current evidence-based clinical practice guidelines (CPGs) recommend measuring an index of abdominal fat (waist circumference) in addition to BMI to identify the obese adults in the highest cardiometabolic risk category and guide the use of bariatric treatment options (see Table S.3) (www.iotf.org, accessed 23 July 2010).[1,2,13,18,21,22]

Table S.3: Classification of body weight and risk of health problems by BMI and waist circumference[1,2,6,13,20-22,27,35]

Measure	Classification	Risk of health problems
BMI, kg/m²		
< 18.5	Underweight	Increased
18.5 – 24.9	Normal weight	Least
25.0 – 29.9	Overweight	Increased
≥ 30	Obese	
30.0 – 34.9	Class I (mild) obesity	Moderate to high
35.0 – 39.9	Class II (moderate) obesity	Very high
≥ 40.0	Class III (severe/extreme or clinical) obesity	Extremely high
Waist circumference		
Men		
< 102 cm (40 in)		Lower
≥ 102 cm (40 in)		Increased
Women		
< 88 cm (35 in)		Lower
> 88 cm (35 in)		Increased

However, the practice of using only BMI and waist circumference measurements to predict an unfavourable cardiometabolic profile has been recently discussed and criticized.[1,5,26,36,106] Current classifications of obesity have limitations when applied in clinical practice because they do not provide information on the presence or extent of obesity-related health risks, comorbidities, or functional limitations that would guide an individual's decisions.[1,5,22,26,30,36] These classifications are derived from health risk assessments performed in large, heterogeneous populations, and the application of BMI and waist circumference measures to predict the development of health

problems in obese individuals varies from person to person and depends on the presence of other factors that may influence the person's health status (such as genetic factors, dietary and physical activity patterns, and environmental factors).[5,22,30,36]

Successful obesity management is a slow process which depends on an individual's readiness for lifestyle and behavioural changes and their realistic weight loss goals and expectations.[1-3,6,8,13,17,21,27,48,50,94,110,111] As most obese individuals face challenges in attaining the level of weight loss that they consider to be esthetically pleasing, incremental progress to achieving weight goals is recommended.[1,2,6,13,21,27,110] A clinically important short-term weight loss goal for mild obesity with associated health risks is a 5% to 15% reduction in the initial body weight (which may be sufficient for favorable modification of waist circumference and result in significant health benefits) at a slow pace, over a 3- to 6-month period.[1-3,6-8,13,21,22,27,34,50,90,94,110-113] For moderate and severe obesity (BMI ≥ 35 kg/m^2, with associated comorbidities), a weight loss greater than 15% to 20% (over 10 kg) is required to obtain and sustain significant health benefits.[2,6,56] Thereafter, the priority becomes one of preventing weight regain and sustaining improvement in health status. Ultimately, the main criteria for weight management success in obese individuals include long-term maintenance of weight loss and the prevention, cure, and improvement of comorbidities.

For some obese individuals, failure to respond to weight loss interventions may have genetic, biological, or behavioural determinants.[1,6,14,45,46,51,114,115] Prevention of further weight gain is then a reasonable objective in these cases, especially when dietary restriction is poorly tolerated or increased physical activity is not possible (for example, in the severely disabled or the elderly).

Specific components of bariatric therapy

In clinical settings, bariatric therapy addressing adult obesity includes lifestyle and behavioural modification interventions (dietary, physical activity or exercise, and behavioural interventions), pharmacotherapy, bariatric surgery, or a combination of these modalities.[1,6,17,19,35,44,50,51]

Lifestyle and behavioural modification interventions

Lifestyle and behavioral modification interventions are based on diet change, increased physical activity, and cognitive and behavioural therapy interventions, usually provided in some combination.[1,2,6,13,35,41,46,50,51,56,111,112,116]

The current diets for weight management are formulated according to energy content and relative macronutrient composition.[1,6,7,35,41,44,46,51,56,90,111,116,117] They include calorie restricted diets (such as low-calorie and very-low-calorie diets), vegetarian diets, and carbohydrate restricted diets, as well as other diets. Although understanding of and knowledge about the safest, most tolerable, and most effective weight management diets continues to grow, the main principle is to induce a state of negative energy balance in order to promote gradual weight loss and prevent weight regain over time. Improved palatability and quality of life are important factors that will likely play a role in long-term adherence to dietary patterns.[41]

Physical activity is currently considered a valuable part of a weight management regimen, particularly when combined with dietary change, as there is strong evidence that this combination is able to produce weight loss and improve a person's cardiometabolic profile.[1,6,7,13,21,27,35,46,51,56,111,118] Physical activity may also be useful in preventing weight regain/maintaining weight loss. Although it is uncertain whether there is an optimal prescription for weight management, duration of physical activity appears to be more important than intensity.

The main problem in any weight management program based on lifestyle modification interventions is compliance.[1,6,35,41,46,48,51,56,67,111,114,116-119] Long-term adherence to dietary and physical activity strategies is often poor and weight regain is common. Adherence to diet and physical activity recommendations can be promoted through various components of cognitive and behavioural therapy, which is also currently considered to be an important element of an effective weight management program.[1,2,6,7,13,21,27,46,51,56,111]

The aim of cognitive and behavioural therapy is to provide obese persons with a set of techniques for identifying and modifying eating and physical activity patterns and lifestyle habits that contribute to the individual's weight problems.[1,6,7,13,27,46,51,56,111] The various components of cognitive and behavioural therapy used to promote adherence to diet and exercise recommendations include:

- self-monitoring (daily records of food intake and physical activity);
- cognitive restructuring (identification and correction of negative thoughts that undermine weight loss efforts);
- stimuli control (limiting the places and activities associated with excess eating and inactivity);
- social support (reinforcement contingencies);
- problem solving skills;
- relapse prevention.

These techniques are usually used in combination and can be offered in individual or group sessions in the clinical setting, as part of commercial weight-loss programs (such as WeightWatchers), or as self-help programs to open groups. In contemporary contexts, behaviour modification techniques are often combined with social support.

Pharmacotherapy

Pharmacotherapy is often considered as an adjunct to lifestyle and behavioural modification interventions when these approaches have failed.[1,2,6,13,27,35,46,48,50,51,56,82,110,111,114] The aim is to facilitate weight loss and prevent or limit weight regain. It can help ameliorate obesity-related health risks and improve quality of life. Medications approved for weight management can be broadly divided into two categories:

- those that decrease food intake by reducing appetite or increasing satiety and energy expenditure (appetite suppressants, such as sibutramine);
- those that decrease nutrient absorption (agents interfering with energy absorption, such as orlistat).

All drugs that are currently approved for weight management in adults are associated with adverse side effects that may result in drug intolerance and none are approved for clinical use for longer than 2 years.[1,2,6,13,27,35,46,48,50,51,56,82,110,111] Long-term compliance with pharmacotherapy is poor, with 1 year persistence rates of 10% and 2 year persistence rates of 2%.[13,48,67] Some people are refractory to drug therapy and do not respond to treatment.[111]

There is little optimism about the long-term maintenance of weight loss that is induced by lifestyle modification interventions (diets and exercise/physical activity) combined with behavioural modification and pharmacotherapy.[1,39,40,46,48,53,55,57,67,82,111] Comprehensive weight management

programs using lifestyle and behaviour modification interventions as well as pharmacotherapy typically produce a 5% to 10% reduction in initial weight at 1 year.[1,42,53,55,57]

These weight loss outcomes may help improve the health and psychosocial status of individuals with mild to moderate obesity without related comorbidity, but probably have little effect on the health status and well being of those with extreme morbidity.[1,2,13,17,39,40,53-55,57,62,74,78,79,82,83] Severely obese individuals typically respond poorly to non-surgical bariatric treatments in terms of achieving clinically significant weight loss.

Bariatric surgery

Surgical treatment of obesity, or bariatric surgery, has emerged as the preferred option for suitable candidates with moderate to severe obesity who are refractory to non-surgical bariatric treatments:

- to facilitate significant and sustained weight loss;
- to resolve or improve associated morbidity;
- to improve QoL.[1,2,6,7,13-15,17,24,27,35,39,40,42,46,50,53-58,68,69,78,82,83,91,120-123]

Bariatric surgery is based on restricting food intake or on reducing nutrient absorption. Various procedures have been developed to alter the anatomic and physiologic function of the stomach to meet therapeutic goals.

Based on their mechanism of action, the available procedures can be broadly categorized into:

- restrictive procedures (such as adjustable gastric banding);
- malabsorptive procedures (such as biliopancreatic diversion);
- hybrid procedures that combine restrictive and malabsorptive procedures (such as Roux-en-Y gastric bypass).

Each of these procedures can be performed using either an open approach or a laparoscopic approach.

Candidates must meet specific criteria and must be motivated and fully informed.[1,2,6,7,13,15,17,24,27,35,39,40,42,46,50,53-58,68,69,78,82,83,91,120] Age and weight criteria for bariatric surgery candidacy have widened in parallel with the growing prevalence of severe obesity in the elderly and the rapid increase in the prevalence of extremely severe obesity (BMI $\geq$ 50 kg/m^2).[14,15,56,78,82,83,120,122,123]

Psychosocial factors of those who undertook bariatric surgery and obtained a poor weight outcome have been studied.[39,40,53-55,57,58,115] In many cases of noncompliance with the rigours of the post-operative regime, the presence of psychological distress or of environmental stressors emerged, which interfered with the adaptability of the patients. As a consequence, there has been a tendency in clinical practice to screen out patients with significant psychological or psychiatric disturbances. Typically cited contraindications include active substance abuse, active psychosis, bulimia nervosa, and severe uncontrolled depression.[55] However, there is no consensus that these disturbances are negative indicators for surgery, especially if adequate management is provided.[39,40,53-55,57,58]

Bariatric surgery does not lead to equal results for every patient and several studies have suggested that the resulting anatomic and physiological changes may have an adverse affect on QoL.[14,15,39,40,53,54,57,71,122,124] After bariatric surgery patients struggle to adhere to the rigours of the post-operative regimens and may suffer from various nutritional deficiencies, psychological battles with

food, and a negative body image. As a direct consequence of successful surgery, 30% to 40% of patients require plastic surgery (known as body contouring surgery) to remove excess skin after weight is lost.[39,40,46,53-55,57,67]

Outcomes vary by surgical procedure and depend on the intrinsic value of each procedure.[14,15,17,39,40,46,53-55,57,58,69,74,82,83,120,122,125] Desired outcomes depend to a great extent on:

- the exclusion of candidates who are at risk for post-operative complications;
- the candidate's pre-operative clinical and psychological preparation;
- the candidate's acceptance of long-term, if not lifelong, follow-up.

Long-term success after bariatric surgery depends on the candidate being well educated about how the procedure will promote weight loss, and on the lifestyle and behavioural changes needed on their part to maintain that weight loss.

Several factors may influence the choice of bariatric surgery procedure, including the patient's and the surgeon's preference.[1,14,15,17,46,69,73,82,83,120] The choice also depends on:

- patient-related factors (including age, personality, eating patterns, BMI level, previous operations, associated morbidities, contraindications, and personal understanding and commitment);
- procedure-related factors (such as reversibility/non-reversibility and associated risks and complications);
- provider-related factors (learning curve, the availability of multidisciplinary care and support, accreditation of the center, and the training, credentials, and experience of the available surgical, medical, psychiatric, nursing, and other healthcare personnel).

The number of competing surgical procedures and their utilization has increased during the past few decades. Both surgeon and institutional volumes have been shown in several large-population-based studies to affect outcomes.[1,14,15,17,120,125-130] As a result, facility and bariatric surgeon accreditation and credentialing standards grounded in evidence-based best practice have been developed by various bodies, including the American College of Surgeons (ACS), the American Society for Metabolic and Bariatric Surgery (ASMBS), and others.[14,15,70,120,123,125,127,129,131-135]

According to best practice recommendations, effective and successful surgical programs require appropriately accredited specialized facilities and multidisciplinary teams with experience in obesity management and surgery (including dedicated and appropriately trained and credentialed physicians, nurses, dietitians, physiotherapists, psychologists/psychiatrists, counsellors, anesthetics, and surgeons).[1,14,15,17,46,70,82,83,120,123,129-134] Substantial pre- and post-operative evaluation of patients, teaching, and monitoring are required to optimize the outcomes. Treated patients should be followed up for at least 5 years to ensure success and appropriate support.[1,15,120] Such specialized, multidisciplinary, long-term care is considered a valid indicator of quality in bariatric surgery programs, along with the development and use of care pathways and the prospective collection of data on thesafety and efficacy of all performed procedures.[70,123,129-134]

Best practice guidelines in bariatric surgery recommend the completion of formal residency training in general surgery and of formal training in open and laparoscopic approaches.[1,14,15,120,127,129-132] To acquire the skills needed to perform laparoscopic bariatric surgery a surgeon must negotiate a relatively steep learning curve (between 75 and 100 cases). Ideal training would include the

acquisition of advanced laparoscopic skills and intra-operative techniques and a knowledge of preoperative and post-operative care.

Currently available training models for laparoscopic bariatric surgery are grouped in several categories:

- no formal training;
- formal courses;
- mini-fellowships;
- fellowships for formal, minimally invasive surgery/bariatric techniques.[1,129,130]

Dedicated fellowships for minimally invasive surgery/bariatric technique were suggested as the best model.[130]

Alternative therapies

The lack of efficacious long-term bariatric treatments for most obese individuals and the rapid increase in the prevalence of obesity has resulted in the increased use of various alternative approaches such as acupuncture, homeopathy, and the use of plant extracts, polymers, and hormones.[1,6,50,110] However, data supporting the claims made for these alternative therapies are often slim and of limited quality.

Maintenance of weight loss and adherence to bariatric treatments

In contrast to the short-term weight loss phase of a weight management regimen, long-term maintenance of weight loss is rarely achieved.[2,13,27,39-41,45,48,51,54,58,111,114,119] Approximately two thirds of individuals who lose weight will regain it within 1 year[45] and approximately 95% will regain the lost weight within 5 to 7 years.[45,111] Complex biological and psychological factors are involved in the long-term regulation of body weight.[14,45,46,51,114,115] Multiple mechanisms exist to modify energy balance in order to re-establish the original body weight, making it very difficult for individuals to maintain weight loss. Weight loss and the subsequent weight regain, known as "weight cycling," may have adverse psychological and medical consequences.[2,6,111]

The National Weight Control Registry (NWCR) in the US, which documents successful individual weight loss measures, revealed several predictors of long-term weight loss maintenance including eating a low-fat and low-calorie diet, frequent self monitoring of body weight and dietary intake, daily physical activity, and consistent eating patterns, including regularly eating breakfast.[41,46,51,114,119]

The concept of adherence is complex.[51,91,115,119,136] Antecedents associated with adherence (related to an individual's ability to adhere to health-promoting behaviours) include self-efficacy, outcome expectation, perceived value, prior relapse, time, social support, knowledge, socioeconomic status, perception of harm or adverse effects, active participation, provider influence, mental status, motivation, and perceived goal attainability. The antecedents are important when developing bariatric strategies aimed at maintaining weight loss over the long-term. According to the Health Belief Model (HBM), if an individual's health beliefs do not support the management of obesity, he/she is less likely to achieve and maintain weight loss.[91,119,136] To comply with the behaviour change required by bariatric treatments, an obese person needs motivation and relevant information, a perception of vulnerability, a belief in efficacy of the intervention, and a belief that there will be no difficulties following the therapy.[91,119,136] It was also suggested that the lasting behaviour change

necessary for weight loss maintenance depends not on complying with demands for change but rather on accepting personal ownership of the regulation for change.[91]

Areas of uncertainty

There is still uncertainty regarding the proper roles of non-surgical and surgical treatment for obesity and regarding what constitutes success for medical bariatric interventions.[5,14,19,31,36,60,83,107,114,115,137-142] This clinical confusion reflects a knowledge gap and is also related to the absence of a triage strategy for patients with obesity.[14] In part, this also reflects the varying patient and clinician perceptions about obesity and the effectiveness and safety of bariatric treatments, and reflects a debate about the cause of obesity and, by extension, the appropriate bariatric treatment.

Varied opinions regarding weight management approaches parallel differing philosophies regarding the obesity problem. These include approaches focusing on:

- weight loss outcomes;
- healthful lifestyle approaches directed toward changing eating behaviours and physical activity patterns with or without weight loss;
- non-dieting and size acceptance approaches where treatment goals include improved self-esteem, fat acceptance, and/or advocacy for decreased weight discrimination.

This context of divergent philosophies has likely created confusion and diversity of practice among healthcare providers.

The obesity classification based on anthropometric measurements and the observed presence of uncomplicated obesity may be part of the barrier for considering patients for various bariatric treatments.[5,14,26,36,51,60] It has been stated that the eligibility criteria based on anthropometric measurements alone might have created a subset of patients who "meet the numbers" but not the clinical threshold for referral.[14] There appears to be a population of individuals classified as obese who do not present with obesity-associated health risks and adverse consequences (the so-called "healthy fat," or metabolically normal).[14,36] Healthcare providers cannot determine which individuals with obesity are at highest risk for functional, social, QoL, and clinical decline, or for premature death without significant weight loss.[14] Sharma and Kushner[5] recently proposed that the current anthropometric definitions of obesity be complemented by a clinical staging system aimed to provide a meaningful framework for medical decision-making, clinical research, and reimbursement policies.

The sources of variability in response to bariatric treatments also remain unclear, because there is no adequate explanation of why some people adopt the attitudes and behaviours needed for long-term weight management while others do not.[14,26,36,46,51,58,77,114,115] Obesity is a heterogeneous condition and, in real life settings for weight management programs, physiological and psychosocial individual factors (some of which may carry genetic influence) interact with environmental factors in a complex manner, producing a wide range of individual responses.[14,58,77,115] Concern has been raised that the psychological, biological, and environmental differences among individuals with obesity are too large for any single obesity treatment to ever be effective in terms of long-term weight control. Any treatment will be useful to some obese persons, but no single treatment will be effective for all, suggesting the need for better matching treatment features with patients' characteristics and needs.

The link between obesity and premature mortality has been debated and it appears that the resolution of this matter cannot be resolved with current data.[1,14,36,59] Obesity very rarely, if ever,

directly causes death.[61] To the extent that it contributes to premature death, it does so by contributing to chronic diseases, such as diabetes, heart disease, and cancer, that generally manifest over years to decades. The causal pathway involved is lengthy and obesity is a distant, "upstream" factor.

Whereas substantial attention has been paid to the role of nutritional and psychobehavioural factors in weight management, the role played by hormonal and hereditary determinants of weight loss and weight loss maintenance has not been well studied.[46]

Evidence-based recommendations

According to evidence-based best practice guidance, the clinical decision on selecting appropriate bariatric treatment strategies is based on BMI and/or waist circumference (WC) and health risks or comorbidity (see Table S.4).[1,2,6,7,13,18,27,108] The majority of the documents used the WHO obesity classification based on BMI. No document has yet been found that used the Edmonton Obesity Staging System.[5]

Table S.4: Bariatric treatments for obese adults with different BMI, WC, and health risks/comorbidities

Country (specialty body/agency)	Lifestyle modification intervention	Behavioural modification intervention	Pharmacotherapy	Surgery
Canada (Obesity Canada) 2006[1,3,94]	First line (dietary therapy, physical activity, CBT) for adults with a BMI ≥ 25 kg/m² or WC ≥ cut-offs (see Table S.3)		Adjunct to lifestyle and behavioural modification for adults with a BMI 27.0 to 29.9 with risk factors, or a BMI ≥ 30 who failed appropriate lifestyle and behavioural modification interventions	Last option for adults with a BMI 35.0–39.9 kg/m² and serious comorbidities, or a BMI ≥ 40, who failed appropriate nonsurgical BT
Canada (CTFPHC) 2006[108]	First line (dietary-lifestyle therapy, physical activity) for adults with a BMI ≥ 25; add behavioural-cognitive therapy and pharmacotherapy, as appropriate, for adults who failed dietary-lifestyle and physical activity			Last option for adults with a BMI ≥ 40 kg/m², who failed appropriate nonsurgical BT
US (ACP) 2005[7]	First line (diet, exercise, behavioural interventions) for adults with a BMI ≥ 30 kg/m²		Adjunct to lifestyle and behavioural modification for adults who failed diet/exercise	Last option for adults with a BMI ≥ 40 kg/m², who failed appropriate nonsurgical BT
UK (NICE) 2006[13]	First line (diet, physical activity, behavioural techniques) for adults with a BMI ≥ 25 kg/m² or WC ≥ cut-offs (see Table S.3)		Adjunct to lifestyle and behavioural modification for adults with a BMI ≥ 25 kg/m² with comorbidities, or a BMI ≥ 35 kg/m² who failed appropriate lifestyle and behavioural modification intervention	Last option for adults with a BMI ≥ 35 kg/m² and comorbidities (that could be improved by weight loss), or a BMI ≥ 40 kg/m² who failed appropriate nonsurgical BT First line option for individuals with a BMI ≥ 50 kg/m²

UK (NHS) 2006[27]	First line (diet, physical activity, behavioural advice) for adults with a BMI ≥ 30 kg/m², or a BMI ≥ 2 kg/m² 8 with co-morbidities; add pharmacotherapy in adults aged 18 to 75, if indicated, according to CPG by NICE		Last option for adults with a BMI ≥ 35 kg/m² and comorbidities, or a BMI ≥ 40 kg/m² who failed appropriate nonsurgical BT
UK (SIGN) 2010[2,18]	First line (dietary interventions, physical activity, behavioural interventions) for adults with a BMI ≥ 25 kg/m² or WC ≥ cut-offs (see Table S.3)	Adjunct to lifestyle and behavioural modification for adults with a BMI ≥ 28 kg/m² and co-morbidities, or a BMI ≥ 30 kg/m² who failed appropriate lifestyle and behavioural modification intervention	Last option for adults with a BMI ≥ 35 kg/m² and severe comorbidities (expected to improve significantly with weight reduction) who completed structured WM program and failed appropriate nonsurgical BT
Europe (EASO OMTF) 2008[6]	First line (dietary interventions, physical activity, cognitive behavioural interventions) for adults with a BMI ≥ 25 kg/m² or WC ≥ cut-offs (see Table S.3)	Adjunct to lifestyle and behavioural modification for adults with a BMI ≥ 27 kg/m² and co-morbidities, or a BMI ≥ 30 kg/m² who failed appropriate lifestyle and behavioural modification intervention	Last option for adults (aged 18 to 60) with a BMI 35.0–39.9 kg/m² and comorbidities (expected to be improved by weight loss), or a BMI ≥ 40 kg/m² who failed appropriate nonsurgical BT

Abbreviations: ACP = American College of Physicians; BMI = body mass index (kg/m²); BT = bariatric treatment(s); CBT = cognitive-bahaviour therapy; CPG = Clinical Practice Guidelines; CTFPHC = The Canadian Task Force on Preventive Health Care; EASO OMTF = Obesity Management Task Force of the European Association for the Study of Obesity; NICE = National Institute for Health and Clinical Excellence; NHS = National Health Service; SIGN = Scottish Intercollegiate Guidelines Network; UK = United Kingdom; US = United States of America; WC = waist circumference; WM = weight management

According to the reviewed CPGs:[1,2,6,7,13,27,108]

- Lifestyle and behavioural modification should be considered as the first line of treatment for all adults with obesity to achieve clinically important weight loss and reduce obesity-related health risks, suggesting that all structured weight management programs should include dietary change, physical activity, and behavioural components.
    - The goal of a dietary intervention is to create a deficit of 500 to 1000 kcal per day to achieve a gradual weight loss of one to two pounds per week, over a 3- to 6-month period. Further weight loss should be considered after a period of weight maintenance. When choosing from various dietary strategies, individualization (based on age, preference and taste, obesity level and health risk category, and the presence of other comorbid disease) is recommended to increase compliance and the chances of success.
    - Individuals consulting about weight management should be encouraged to reduce sedentary behaviour (such as television viewing and computer use) and to gradually incorporate 30 to 60 minutes of moderate physical activity per day on most days of the week. As with dietary interventions, physical activity and exercise should be individually tailored to obesity level, age, and the presence of health risks and comorbidities.
    - Individuals willing to participate in weight management programs should be provided with education and with cognitive and behavioural techniques as adjuncts to dietary therapy and physical activity.

- The addition of a selected pharmacologic agent should be considered in adults with a BMI ≥ 27 kg/m^2 and comorbidities or with a BMI ≥ 30 kg/m^2 who are not attaining or are unable to maintain clinically significant weight loss with lifestyle and behavioural modification interventions. Most guidelines recommend the use of orlistat or sibutramine as an adjunct therapy, which should be considered on an individual case-by-case basis following assessment of risk and benefit.
- Bariatric surgery should be considered on an individual case basis, following assessment of risk/benefit in adults with clinically severe obesity (BMI ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 and severe comorbid disease), after appropriate non-surgical bariatric treatments have been tried and have failed to induce clinically significant weight loss. Identification of obesity-related comorbidities that may improve after surgery should be considered.[2,6,13] According to NICE, in adults with a BMI > 50 kg/m^2 surgery can be offered as the first line option, without a trial of nonsurgical bariatric treatments.[13]
- Multi-disciplinary care is recommended to support surgical interventions. Patients should only be referred to units that are:
    - able to assess patients prior to surgery;
    - able to offer a comprehensive approach to assessment, diagnosis, and treatment;
    - able and willing to provide care before, during, and after surgery;
    - able to provide long-term follow-up.

These recommendations are based on data gathered from younger adult populations and there is limited evidence about their practical application in the elderly (those 65 years and older).[14,15,56,61,63,64-66,78,84-87] For weight management in the elderly, it is recommended that the focus be shifted from weight loss to maintenance of weight. The main goals are to improve physical function and QoL and to reduce dependency. The primary approach is lifestyle modification by using individualized and prudent dietary interventions and physical activity that minimizes muscle and bone loss and accommodates concomitant chronic disease, sensory deficits, functional limitations, and living environments, as well as strategies for overcoming the barriers to dietary change and physical activity.[61,63-65,85,86,143]

Pharmacotherapy for weight management is not usually indicated for the elderly with obesity because of the potential adverse effects and lack of experience in the use of bariatric medication in this population.[61,63-65,84,87] The use of bariatric surgery for weight management in the elderly remains controversial due to concerns about their greater risk for perioperative morbidity and mortality.[14,15,56,61,63-65,78,120] However, bariatric surgery may be considered for obese elderly persons (those 60 years and older) who have functional impairments and/or metabolic complications that are expected to benefit from weight loss and to improve QoL.[46,56,78,120]

All reviewed CPGs recommend an individualized, client-centred, comprehensive weight management program to achieve realistic weight loss and weight maintenance goals.[1,2,6,7,13,27,108] They all acknowledge that bariatric treatments require significant lifestyle and behavioural changes and emphasize the role of working together during bariatric therapy to create a nonjudgmental atmosphere and the need for supportive communication in medical encounters. They also emphasize that the decision to attempt bariatric treatment should take into account the obese individual's readiness to make the necessary changes.

Weight management programs

The literature search conducted for this review did not reveal any published research on the ideal components of a successful weight management program for adult obesity, or on requirements for implementing effective programs.

According to the reviewed literature, the most effective weight management programs appear to be those adopting a disease management/chronic care model and including the following elements:[1,19,31,46,50,90,144-146]

- prevention (education and public awareness campaigns);
- multidisciplinary care involving healthcare providers appropriately trained and experienced in diagnosing and treating adult obesity;
- specialized technical and equipment capacity;
- local administration;
- clinical pathways and standardized protocols based on evidence-based best practice;
- screening for medical and psychological risk, assessing readiness to change, and targeting individuals with obesity-related health risks and complications;
- lifestyle and behavioural modification interventions, bariatric medication, and bariatric surgery;
- a full complement of consultative services (including patient education and counseling on improving dietary and physical activity patterns, and behavioural counseling);
- brief primary care intervention and referral for specialized support;
- effective patient-healthcare provider communication and partnership;
- the infrastructure to provide education, long-term support, and monitoring and ongoing follow-up;
- outcome tracking and reporting.

However, there are many patient-, provider-, and system-level barriers to providing effective weight management.[1,5,8,14,18,31,48,60,67,79,90,145,147-152] A number of patient-related barriers might make it difficult for healthcare providers to initiate and provide obesity-related counseling and bariatric treatment. Individuals may be reluctant to seek medical attention. Although individuals with obesity are generally prepared to go through the initial stage of weight loss, they are often unprepared to accept lifelong lifestyle changes and, in some cases, medication and/or surgery. Socioeconomic status can pose a significant obstacle to bariatric treatment. Lack of time is one of the most frequently encountered patient-level barriers. Various factors within the affected individual's social environment can sabotage and undermine weight loss attempts and weight loss maintenance. Existing comorbidities and/or their treatment can promote weight gain or obstruct weight loss and weight loss maintenance. People with obesity may have psychosocial barriers to seeking, initiating, or continuing treatment for obesity. People with obesity, especially those with binge-eating disorder, may lack self-efficacy (which involves confidence in one's ability to resist food in high-risk situations and to proceed with physical activity in adverse conditions).

Commonly cited provider-level barriers include:

- lack of formal training in nutrition, exercise, behavioural counseling, and counseling on obesity and related topics;
- perceived inability to change patient behavior;
- lack of known long-term effectiveness of bariatric treatments;
- negative attitudes toward obese patients;
- lack of recognition/acceptance of obesity as a disease;
- the belief that obese individuals are not interested in or ready for weight loss and bariatric treatment and/or the belief that obesity is the responsibility of the affected individual;
- lack of time during patient visits;
- lack of knowledge about available bariatric treatment services.[1,5,8,14,18,31,48,67,79,90,145,147-150,153]

Most commonly cited system-level barriers include:

- the lack of resources to support multidisciplinary weight management programs for adult obesity within the current environment of cost containment;
- the lack of available teaching materials for individuals with obesity;
- the lack of infrastructure support/places to which to refer patients;
- limited insurance coverage (public and private) for weight management interventions.[1,31,48,79,90,145,147,150] In Canada, for example, counseling services offered by dietitians and physical-activity specialists are not considered medically necessary and are not covered as part of provincial health plans.[31]

Considering the growing prevalence of obesity in Canada, it has been suggested that the majority of individuals with obesity should be managed by primary care providers.[8,31] Primary care physicians can play a variety of roles, from treating individuals with obesity directly for weight loss or prevention of weight gain and providing care for obesity-related comorbidities, to referring patients to appropriate weight management programs.[154] However, evidence suggests that obesity tends to be neglected in primary care and that many adults with obesity are not even getting lifestyle modification advice from a healthcare professional.[1,5,8,146-151,153,155] The various causes for this include the time limitations of an office visit, attention paid to other immediate healthcare issues, lack of reimbursement for providing treatment and additional counseling, inadequate skills and training, physicians' skepticism about health promotion, and lack of resources for referral. Moreover, physicians may be unaware of the tools necessary to diagnose obesity.[5,146,150]

Management of adult obesity and ethics

Ethical concerns raised by the increasing prevalence of obesity and the treatment of individuals with obesity include:

- the question of whose responsibility it is and of whether bariatric treatment is accurately described as therapy or as research, given its low percentage of long-term success;
- the need for standardized disclosure of the possibility of harm versus the low probability of benefit;

- the status of voluntary and informed consent as a meaningful model of patient cooperation in treatment;
- the issues raised by the difference in quality of care that is provided for people with obesity;
- the policy issues raised by the absence of uniform standards for and regulatory oversight of weight management programs.[60,107,138,148,156-159]

Some of the ethical questions arise when healthcare providers are confronted by an individual with obesity, and they may harbor a bias against obesity and its effects on the health of affected individuals.[60,107,138,148,156-158] The healthcare providers involved in obesity management have the ethical responsibility to know and understand their motives, beliefs, attitudes, and feelings regarding obesity, overeating, physical activity, and health.[107,157,158] Failure to understand and acknowledge these things increases the risk that they will act unethically by unintentionally imposing personal values. Providers also have the ethical responsibility to identify and respond appropriately to a particular individual's needs and to sincerely/objectively inform the individual about what skills they have to offer and whether or not they have the ability to cater appropriately to the individual's needs.

Ethical problems surrounding obesity and its management have an impact in many societal arenas, including socioeconomic environments, the educational system, science, law, and government.[60,107,138,148,156-159] The variability among individuals with obesity and the complexity of factors that cause an individual to seek obesity management suggest that there can be no standard set of rules for ethical decision-making. A new ethical decision needs to be made with each new request for help and, frequently, these decisions need to be made on the spot, without the opportunity of seeking expert advice. There is a need for a general framework for ethical decision-making, considering four domains (the healthcare provider, the client, the treatment resources available, and the social context) and the interplay of these four domains.

Demand for, access to, and utilization of bariatric treatments

The literature search conducted for this review did not retrieve information on the demand for, access to, coverage for, or utilization of currently available non-surgical bariatric treatments in Canada. Neither did the literature search yield information on who receives bariatric medication for adult obesity in Canada and on how such access varies by individual characteristics. The literature retrieved for this review did not provide information on regional variations in the provision of any of the non-surgical bariatric treatments currently available in Canada.

Cawley and Rizzo[160] reported on the utilization of weight management medications in the US using data from the Medical Expenditure Panel Survey for 1996–2002. Their results pointed to wide sociodemographic disparities in bariatric drug use. Women were almost 20% more likely than men to use bariatric drugs and Hispanics and African-American individuals were only 39% as likely as Whites to use them. The probability of using weight management drugs decreased significantly for persons older than age 65. Prescription drug coverage was strongly correlated with utilization of pharmacotherapy. Those with prescription drug coverage were 46% more likely to use bariatric drugs. Use was also correlated with education. No correlation was found between income and use of bariatric drugs.

Cawley and Rizzo[160] found that the vast majority of obese individuals who met the criteria for bariatric drugs were not taking them, and a significant number of those who did not meet the medical criteria were taking them. Bariatric drug users who did not meet the medical criteria were

slightly more likely to have prescription drug coverage but there were no significant differences in education, income, race, ethnicity, or gender.

The results reported by Encinosa et al.[161] also showed a clear difference between genders in the use of pharmacotherapy for weight management in the US, with fewer men than women taking bariatric drugs; however, a larger proportion of men than women used the most costly drug (orlistat).

Provision of bariatric surgery in North America

Since the early 1990s there has been a significant increase in the utilization of bariatric surgery procedures in the US and Canada.[1,14,15,17,46,67-69,79,120,127,128,144,161-170] Contributing factors include an increased awareness of the benefits of bariatric surgery as a treatment option, patient demand, and the increased availability of laparoscopic bariatric surgery. However, the high upfront cost associated with bariatric surgery care is significantly and negatively related to the demand for bariatric surgery.[17,79,144,166-168,171]

Insurance reimbursements in the US range from no coverage of any bariatric surgery procedure to full coverage of all commonly used options (such as laparoscopic adjustable gastric banding and Roux-en-Y gastric bypass).[70,135,166,167,171] Coverage for the cost of multidisciplinary pre- and post-operative care for bariatric surgery patients is variable and often difficult to accurately track.[70] Coverage for pre- and post-operative nutrition therapy is limited. For post-operative mental health evaluation and care, coverage varies.

However, access to bariatric surgery among eligible adults in North America remains an issue both for those with and those without adequate (private or public) health insurance coverage.[14,15,67,68,70,144,166,171] Although more than 5% of the US adult population and 3% of the Canadian adult population meets the medical criteria for bariatric surgery,[14,68,79] only a small fraction of this group is considered for, has access to, and undergoes surgery (180,000 procedures were performed in 2006 in the US[14] and about 1300 procedures were performed in 2007 in Canada[69,79,172]).

Growing evidence suggests that the cohort that undergoes bariatric surgery in North America is not drawn evenly from the suitable candidates, and the demographic characteristics of some individuals who receive bariatric surgery are not reflective of individuals with severe obesity.[14,15,67-70,166] In the US, most bariatric surgical procedures are performed on White women with higher income levels and private insurance, despite the fact that severe obesity is more likely to affect ethnic minorities and those of lower socio-economic status.[14,166] In Canada, bariatric surgery is disproportionately used by women with no baseline medical conditions.[69,172]

The mismatch between eligibility and receipt of bariatric surgery care is related to multiple factors, including:

- gaps in the knowledge of clinicians and eligible patients;
- difference in patient/provider preferences and attitudes toward bariatric surgery;
- patient's socioeconomic status;
- lack of a triage system for prioritizing access according to clinical need;
- ways in which the healthcare system delivers bariatric surgical care.[14,15,68-70,79,144,166,171]

Significant disparities might exist between various ethnic and socioeconomic groups in the perception of obesity and its management, leading to differences in seeking bariatric surgical care.

The referral patterns of primary care providers might be biased by gender, age, ethnicity, insurance status, income, and other factors, again leading to decreased representation of those groups among those seeking or receiving bariatric surgery.

Provision of bariatric surgery in Canada

The number of bariatric surgeries being performed in Canada cannot meet the demand.[67,69,79] Based on 2004 data, estimated demand for bariatric surgery exceeds access by approximately 600-fold.[67] Christou recently conducted a survey of members of the Canadian Association of Bariatric Physicians and Surgeons and reported that in 2007 a total of 6783 patients were waiting for bariatric surgery and 1313 procedures were performed.[79] The estimated average waiting time for bariatric surgery in Canada was "just over five years" (6783/1313). The survey identified a common theme of lack of resources—mainly operating room time and post-operative beds—as contributing to prolonged waits for patients seeking bariatric surgery.

According to Christou,[79] bariatric surgery is difficult to access in Canada because few resources are made available for treating severe obesity. Some provinces do not accept severe obesity as a chronic disease and thus do not include bariatric surgery as an insured service in their health care plans. Provinces that consider bariatric surgery to be an insured service have difficulty providing timely access for various reasons.

A health service impact analysis conducted recently by the Canadian Agency for Drugs and Technologies in Health (CADTH) estimated that the number of eligible obese Canadians who may seek bariatric surgery is between 6000 and 34,000 (and may be higher), and that 1100 to 1200 procedures are performed annually.[69] These estimates are limited by a lack of information on the number of private bariatric surgeries.

Policies and practices relating to the provision of bariatric surgery in Canada vary across provinces.[69,172] Between 2004–2005 and 2008–2009 bariatric surgery was performed in British Columbia, Alberta, Saskatchewan, Ontario, Québec, Nova Scotia, and New Brunswick,[69,172] and almost half the procedures were provided in Québec hospitals.[172] Procedures that are funded by each jurisdiction vary.[69] Among provinces that do not provide bariatric surgery, some provide partial or full funding for patients to receive procedures in other jurisdictions. In provinces that provide bariatric surgery, there are waiting lists.[69]

Data from all bariatric surgery centres in Québec showed that the average waiting time for bariatric surgery in that province in 2007 was just under 7 years (716 surgeries were performed in 2007 in the province and at end of that year, 4868 patients were awaiting bariatric surgery).[79] Québec has two of the largest bariatric surgery programs in Canada: the McGill University Health Centre (MUHC), which performs about 150 bariatric surgeries per year, and the Université Laval, which performs about 250 bariatric surgeries per year.[79] Data from MUHC suggest that the average waiting time of just over 5 years in Canada can put patients at increased risk of premature death.

In some circumstances, obese Canadians may be referred to other jurisdictions or countries (such as the US and Mexico) for bariatric surgery (this practice is referred to as medical or surgical tourism),[69,172,173] but the effectiveness of and complication rates for this practice are unclear.[69] To meet the demand for bariatric surgery, in 2005 the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) in Québec and the Ontario Health Technology Advisory Committee (OHTAC) recommended an increase to their respective provincial capacities.[17,174] AETMIS and OHTAC recommended that all bariatric surgery programs establish strict patient

selection criteria, have facilities and equipment adapted to the specific profile of the suitable candidates, have an experienced multidisciplinary team capable of supplying the full range of care and services tied to this type of bariatric treatment, provide closely monitored lifelong follow-up, and cover the physical and psychological dimensions of this treatment. AETMIS also recommended that a Québec registry on severe obesity and its management be established.

The policy on bariatric surgery for severe obesity developed by the Québec's Association of General Surgeons (QAGS) also emphasizes the need for multidisciplinary care, designation of referral centres, information and training for surgical residents, and increased bariatric surgery training opportunities.[17] Furthermore, in any bariatric surgery management plan it would be advisable to anticipate the potential need for future reconstructive plastic surgery.

According to the CADTH report, it is unclear to what extent additional capacity and infrastructure would be needed in order to increase access to bariatric surgery.[69] If capacity is to be increased, it may be reasonable to create centres of excellence for bariatric surgery that may serve a larger region. Alternative models may include providing a higher volume outside centres of excellence for less complex cases. Pre- and post-surgical management could be dispersed in centres with adequate healthcare-professional training.

Provision of bariatric surgery in Alberta

Using data from the Discharge Abstract Database of the Canadian Institute for Health Information (CIHI), CADTH estimated that 68,324 Albertans had a BMI of 40 kg/m^2 or more, or a BMI of 35 kg/m^2 or more with comorbidity in 2007.[69] Assuming that between 1% and 5% would undergo bariatric surgery offered, it was anticipated that between 683 and 3416 Albertans would seek surgery. Only 207 procedures were performed in 2007 in Alberta.

An overview of changes in in-patient bariatric surgery delivery in Canada between 2004–2005 and 2008–2009 (using data from CIHI's Hospital Morbidity Database and Discharge Abstract Database) indicates that during this period at least 361 Canadians had bariatric surgery outside of their home province/territory.[172] Twenty-five of them were from Alberta (five received bariatric surgery in Saskatchewan, seven in Ontario, and 13 in British Columbia). The data also indicate that Alberta had the largest inflow of out-of-province patients (N=177) over the 5-year period. Most patients were from Manitoba (N=87) and the Northwest Territories (N=14), where bariatric surgery was not provided. Alberta also provided bariatric surgery for patients from Saskatchewan (N=46) and British Columbia (N=30), where bariatric surgery was available.

An examination of 2006 data from the Alberta Discharge Abstract Database indicates that 34 out-of-province patients received bariatric surgery procedures in Alberta in 2006 (see Table S.5).

Table S.5: Number of bariatric surgical procedures provided to out-of-province patients in 2006

Province/Territory	Number
Manitoba	20
Saskatchewan	3
British Columbia	7
Nunavut and Northwest Territories	2
Yukon	2
Total	**34**

As of January 2008, in the Weight Wise Program—which is a regional population-based medical and surgical weight management program in Alberta—2470 patients were waiting for a clinic appointment for an initial assessment.[67] According to Padwal and Sharma, that represented a waiting time of 4.3 years.

Management of Adult Obesity in Alberta

The literature search did not reveal any published reports about the current practice of managing adult obesity in Alberta and/or about issues related to the provision of appropriate non-surgical and surgical bariatric treatments for this indication in Alberta. None of the retrieved articles identified patient-, provider-, and system-level barriers to the effective management of adult obesity in Alberta or evaluated whether/how they impact care for obese adults in Alberta.

Healthcare providers from weight management programs in Alberta were contacted by email and telephone for a description of their programs and for information about the bariatric treatment options available for adult obesity in the province. They were also asked questions regarding the demand for and usage of non-surgical and surgical bariatric treatments for adult obesity, issues related to access to and barriers to using appropriate bariatric treatments for different obesity classes, training of healthcare providers, and the current number of trained/certified healthcare providers and support staff who provide bariatric services for different obesity classes in Alberta.

The following commentary summarizes the information gathered from the replies received by email and telephone surveys, as well as from the Alberta Health Services website (www.albertahealthservices.ca) and from handouts obtained during a tour of the Weight Wise Adult Weight Management Clinic in Edmonton.

Current options and standard procedure used for adult obesity management

In Alberta, adults with obesity are selected for non-surgical and surgical bariatric care based on BMI classification of obesity.

Non-surgical bariatric treatment options that are available in Alberta include education and counseling for nutrition and physical activity, psychological therapy (including behavioural modification techniques and counseling for mental health), and pharmacotherapy (*it is not clear which of the available weight management medications are more frequently used).*

Bariatric surgery procedures currently performed in Alberta include: laparoscopic adjustable gastric banding, laparoscopic sleeve gastrectomy, open and laparoscopic gastric bypass, and revision surgeries (including Stomphyx).

Demand for, access to, and utilization of bariatric treatments

The demand for bariatric treatments (non-surgical and surgical) to manage adult obesity in Alberta is currently unknown, but all obese adults searching for bariatric care in the province can be considered candidates. Obese adults must be referred by their family physician to be considered by one of the bariatric surgery centres. The waiting times for surgical treatments are measured differently by the different centres, but from referral to completion of surgery, a patient can expect the process to take between 2 and 5 years.

Access to other non-surgical weight management programs that are offered by healthcare professionals varies by the program, but the waiting time for initial consultation can be as short as a couple of days.

Barriers to using appropriate bariatric treatments

Bariatric healthcare providers that were contacted for information provided their opinions on access barriers and compliance issues for bariatric services in Alberta.

The main barriers to accessing bariatric care (non-surgical and surgical) in Alberta include the lack of interest on the part of some family physicians in treating their patients (that is, providing counseling on obesity and obesity management and encouraging obese individuals to seek specialized bariatric care), the lack of specialized training and focus in the medical community, and limited follow up.

Main barriers to accessing bariatric surgery in Alberta include limited capacity (the small number of procedures being performed annually), certain patients' characteristics (such as the presence of major mental health problems, lack of/limited readiness to/limited motivation for change, inability to make the needed lifestyle changes, fear of surgery, or limited social support available), and the need for patients to travel long distances to receive pre- and post-operative bariatric care.

Main reasons for dropping out of bariatric surgery programs include patient non-compliance with the preoperative regimen, and in some cases, patient success in losing weight with lifestyle changes before surgery (so they choose not to go through with it). The main compliance issues associated with using bariatric surgery for adult obesity in Alberta include the presence of mental health problems (particularly depression), and the rigours of pre- and post-operative regimes (patients have difficulty in maintaining healthy lifestyle and behaviour changes).

Healthcare system capacity in Alberta

Currently, four urban healthcare centres provide tertiary bariatric treatment services for adult obesity in Alberta: the Weight Wise Adult Weight Management Clinic (AWMC) at the Royal Alexandra Hospital in Edmonton; the Weight Management Program at the Richmond Road Diagnostic and Treatment Centre in Calgary (which is part of the Diabetes, Hypertension, and Cholesterol Services); and bariatric surgery coordinated by individual surgeons and their staffs in Red Deer and Medicine Hat.

Eight surgeons currently perform bariatric surgery procedures in the above mentioned locations and at least six physicians (who specialize in different specialties in medicine), six registered nurses (RNs), eight mental health practitioners, nine registered dietitians (RDs), one physiotherapist, and one occupational therapist provide specialized bariatric care as part of the centres' multidisciplinary teams. In Edmonton and Calgary, social workers and diabetes educators can also be accessed on a need-to-refer basis. These professionals received on-the-job training to address the issues related to adult obesity and its management. Dietitians may receive certification via the American Dietetic Association Certificate of Training in Adult Weight Management. Surgeons and nurses may receive training and certification through the American Society for Metabolic and Bariatric Surgery (ASMBS). Currently, there is no accreditation for bariatric surgery programs beyond the ACS Center of Excellence recognition.

To access bariatric surgical care in Alberta, adults with obesity must be referred by their family physician. Once referred, patients are placed on a waiting list before they make their initial consult. During the initial consult (usually with an RD or an RN), the patient's health and lifestyle are assessed and the patient is provided with information or a personalized plan to assist in achieving control over their weight problem and in beginning their journey toward surgery (if appropriate). Clinic staff, made up of multidisciplinary teams that may include physicians, surgeons, registered nurses, psychologists/psychiatrists, dietitians, occupational therapists, physiotherapists, social

workers and other professionals, continue to educate, counsel, and assess the patient during multiple clinic sessions before surgery. The number of preoperative sessions varies among programs and is a function of the staff resources available to the programs.

Some individuals with obesity may not be considered suitable candidates for surgery during this time, and other treatment options may be determined to be more appropriate and successful in the long term. Adults who qualify for bariatric surgery are required to demonstrate a change in lifestyle and behaviour before the surgery. Compliance assessment is generally based on weight stabilization, full commitment to attending all pre-operative clinic sessions and follow-up appointments, and full commitment to self-monitoring (by practicing lifestyle journaling). The support of these multidisciplinary teams is offered to the patient throughout pre-operative periods, as well as during and immediately after the surgery, and may continue long-term to help the patient maintain weight loss.

Additional weight management programs exist that provide only nonsurgical bariatric care for adult obesity in Alberta. As well, a number of private clinics and programs, including the Calgary Weight Management Program (www.cwmc.ca), the Lefebre Clinic in Calgary (www.calgaryweightlossclinic.com), and the 12 locations of the Dr. Bernstein clinics (http://ab.drbdiet.com), offer medically supervised weight loss in Alberta. The non-surgical weight management programs vary according to their weight loss philosophies, the components of the programs, and the costs that individuals pay while accessing these services.

Additionally, the database of the College of Physicians and Surgeons of Alberta lists over 60 general practitioners or family doctors that declare obesity, bariatric care, or weight management as one of their primary interests. There are also 15 specialists (not including bariatric surgeons) who consider obesity to be one of their primary interests.

Limitations

The present review has several limitations. The literature review was limited to reports of articles and documents that were written in English and published between January 2005 and June 2010. Proprietary reports were excluded. Only full-text articles were selected because abstracts provide insufficient details to allow an accurate, unbiased assessment and comparison of the study results. The authors of the abstract-only publications were not contacted for full details of their studies.

The present review only summarizes the recommendations from reports of relevant, evidence-based clinical practice guidelines and care pathways, and does not appraise their scientific foundations.

A literature search focused on program evaluation studies was not conducted.

Clear answers could not be provided for some questions due to the absence of relevant data for Alberta.

Summary

The social systems and demographics review summarizes the available evidence from the scientific literature published in Canada and worldwide (mainly in North America) and the information obtained from Canadian databases to address the questions about the burden of adult obesity, the population dynamics of affected individuals, the current patterns of care and issues related to the implementation and provision of bariatric treatments within weight management/bariatric programs. The following sections highlight the key findings.

Overview of adult obesity

Over the past 30 years, obesity has become one of the most prevalent conditions in countries with developed market economies. It is now recognized as a major public health problem and has been identified as an epidemic by the World Health Organization and medical organizations around the globe.

Adult obesity has emerged as a chronic medical condition characterized by an accumulation of excess body fat caused by a long-term energy imbalance that mainly results from a complex interaction of biological, environmental, and behavioural factors.

In practice, adult obesity is defined according to body mass index (BMI), with a BMI of 30–34.9 kg/m^2, 35–39.9 kg/m^2, and 40 kg/m^2 or greater corresponding to mild (class I) obesity, moderate (class II) obesity, and severe/extreme/morbid (class III) obesity, respectively. Because BMI is an indirect measure of body composition, a measure of central adiposity (that is, waist circumference) is also recommended as a screening and diagnostic test for adult obesity, to assess more accurately the level of cardiometabolic risk.

Obesity is regarded as a health problem because it is associated with multiple organ-specific and psychosocial consequences that may result in reduced quality of life, increased morbidity, and premature mortality. The most serious adverse health risks and consequences are associated with severe (class III) obesity.

Epidemiology of adult obesity

In Canada, as in other countries with developed market economies, the prevalence of obesity has increased steadily within all demographic groups over the past few decades and continues to rise. Class II and class III obesity subgroups are experiencing the most rapid increase. The determinants of this rapid rise in obesity prevalence are many and their complex interactions are still poorly defined. Obesity prevalence among children and adolescents is increasing at a more rapid pace than is adult obesity, causing concern.

- Self-reported data from surveys of nationally representative samples of Canadian adults showed a steady increase in the prevalence of adult obesity, from 6.1% in 1985 to 15.7% in 2003 and 17% in 2007. The proportion of adults with class II obesity increased from 0.8% in 1985 to 3% in 2003, and in class III the proportion increased from 0.4% to 1.3%.
- Directly measured data, which are considered more accurate than self-reported data, suggest that the prevalence of adult obesity has almost doubled during the past several decades, increasing from 13.8% in 1978–1979 to 23.1% in 2004. The prevalence of class II obesity increased from 2.3% in 1978–1979 to 5.1% in 2004, while class III obesity rates increased from 0.9% to 2.7%.

According to the most recently released prevalence rates for adult obesity in Alberta, among Alberta's 2007 population of 2,619,032 adults (aged 18 years and over), 17.7% were classified as obese (12.5% in class I, 3.7% in class II, and 1.5% in class III obesity), based on self-reported data from the 2007 CCHS.

- Women were less likely than men to be classified as obese (15.9% and 19.5%, respectively).

- Obesity rates increased with age, from 8.1% among adults aged 18 to 24 years to the peak at 23.5% among individuals aged 55 to 64 years. The proportion of obesity drops among the elderly (those over 65 years of age).
- Albertans who are high school graduates are less likely than those who did not graduate from high school to be classified as obese (17.2% and 22.5%, respectively).
- Obesity prevalence rates were higher for married and widowed adults (over 19%) than for single persons (12.4%)
- The relationship between obesity rates and household annual income did not vary in a linear fashion. Obesity rates were lower (approximately 16%) for those in income categories of less than $20,000 or between $40,000 and $59,000, and higher for those with incomes between $20,000 and $39,000 (17.7%) or between $60,000 and $70,000 (19.2%). The highest obesity rate (21.6%) was observed in individuals with incomes of more than $80,000.
- Obesity rates were lower in the Edmonton and Calgary zones (17.7% and 14.2%, respectively) than in other health zones in the province, where the rates ranged from 20% to 25%.

The latest directly measured adult obesity prevalence rates for Alberta were obtained from 2004 CCHS data. In 2004, the adult obesity rate for Alberta was 25.2%, with the rates for classes I, II, and III obesity being 15.4%, 6.7%, and 3.2%, respectively.

Patterns of care

Given that long-term maintenance of weight loss is difficult to achieve once an individual becomes obese, both prevention strategies (to keep more individuals from becoming obese) and bariatric treatment strategies (to assist those diagnosed with obesity in losing excess weight and keeping it off permanently) should be considered when addressing obesity. A comprehensive and multisectoral approach to obesity prevention is recommended, and effective action requires addressing the commercial, environmental, and social policy drivers of obesity. Healthy behaviours need to be supported by public health measures, such as supportive environments and effective policy changes that promote healthy weight and prevent obesity and its related health risks and consequences.

Bariatric treatment for adults with obesity

Evidence-based recommendations suggest that bariatric care for adults with obesity should address both the medical and the psychological burdens of obesity, and include prevention of further weight gain. A weight management program based on lifestyle and behavioural modification that includes dietary changes, increased physical activity, and behavioural therapy remains the cornerstone of effective bariatric care for adult obesity. Realistic weight loss goals must be clearly defined with the affected individual, and the treatment plan should be individually tailored based on age, gender, degree of obesity, individual health risks, cardiometabolic and psychobehavioural characteristics, and outcome of previous weight loss attempts. Pharmacotherapy may be added if lifestyle and behavioural modification alone are insufficient to achieve clinically significant weight loss. Bariatric surgery combined with long-term lifestyle modification may be an appropriate option for adults with severe and moderate obesity (when BMI reaches 40 kg/m^2 and even 35 kg/m^2 if it is associated with comorbidities) who do not respond to appropriate nonsurgical approaches.

The therapeutic approach to adult obesity is multifaceted and complex, particularly for severe obesity, and is based on intensive patient education and counseling about improving dietary patterns,

the need for regular physical activity, and how to better regulate the lifestyle habits that need to be modified. According to best practice recommendations, an effective weight management program requires a specially adapted treatment structure offering:

- a range of bariatric treatments targeted at the various subgroups of the population;
- the availability of a multidisciplinary team;
- a specialized technical and equipment capacity.

Long-term, if not lifelong, follow-up and continued supervision and support are necessary to prevent weight regain, monitor disease risks, and treat co-morbidities. Implementation of effective weight management programs should also include a continuous improvement approach integrating ongoing audit and evaluation.

To improve adherence to bariatric treatments and to enhance the success of long-term weight management, patient-, provider-, and system-level barriers to effective weight control should be identified and addressed. Patients' readiness and motivation to make the necessary lifestyle changes are critical. Professional support and involvement are also necessary for sustained lifestyle and behavioural changes to take place. An environment free of bias toward obesity is an important requirement in providing quality of care for individuals with obesity. The quality of bariatric care also depends on healthcare professionals receiving appropriate training and accreditation and having an awareness of available local resources. Although long-term multidisciplinary care and follow-up underlies the best practice, it may present certain barriers to the implementation of evidence-based weight management programs because of the lack of resources to support such programs within the current environment of cost containment, and the lack of widespread insurance coverage for weight management.

The disease management and chronic care models may provide helpful templates for redesigning clinical practice in adult obesity management and for helping to overcome some of the barriers to effective weight management. According to the reviewed literature, the most effective weight management programs adopted a comprehensive disease management/chronic care approach that combines health promotion at the population level with clinical interventions and support. The development of a multi-level obesity management network of mutually collaborating facilities involving primary care physicians, specialists in bariatric care, other specialists, and support groups is encouraged as a sensible response to the current demand for action.

Appendix S.A: Search Strategy for Social Systems and Demographics (S) Approach to Analysis

Liz Dennett, MLIS

The IHE Research Librarian conducted the literature search for publications published between 2005 and 1 May 2010. The search was further limited to human studies and to publication types. The search was developed and carried out prior to the study selection process. In addition to the strategy outlined below (which was conducted between April 14 and June 4, 2010), reference lists of retrieved articles were reviewed for potentially relevant articles.

Medical Subject Headings (MeSH) terms relevant to this topic are shown in Table S.A.1.

Table S.A.1: Search strategy

Database	Edition or date searched	Search Terms ‡‡
MEDLINE (includes in-process and non-medline citations) OVID Licensed Resource	1 May 2005 – 1 May 2010	1. *obesity/ 2. *obesity, morbid/ 3. (obes* or superobes* or weight or bariatric*).ti. 4. 1 or 2 or 3 5. limit 4 to english language 6. limit 5 to yr="2005 - 2010" 7. limit 6 to "all child (0 to 18 years)" 8. limit 7 to "all adult (19 plus years)" 9. 6 not (7 not 8) 10. limit 9 to animals 11. 9 not 10 12. (unplanned weight or unintended weight or involuntary weight or antipsychotic or schizophreni* or bipolar or Parkinson* or Alzheimer* or smoking or dementia or bulimi* or anorexi* or urinary incontinence or ui or pelvic floor or asthma or adhd or attention-deficit or apn?ea or cancer or colorectal or gastroesophageal or fatty liver of osteoarthriti* or arthriti* or urologic* or mood disorders or birth weight or diarrhea or kidney or gallstone*).ti. 13. 11 not 12 14. Bariatric surgery/ 15. gastric bypass/ 16. gastroplasty/ 17. lipectomy/ 18. roux-en-y.ti. 19. (bariatric surgery or LAGB or laprascopic adjustable gastric band* or lap band* or gastric balloon or intragastric balloon).ti. 20. Bariatrics/ 21. Weight Loss/ 22. Anti-Obesity Agents/ 23. Appetite Depressants/ 24. diethylpropion/ or phenmetrazine/ or phentermine/ or

		phenylpropanolamine/ 25. Sibutramine.tw. 26. (reductil or meridia or sibutrex).tw. 27. Orlistat.tw. 28. (xenical or alli or tetrahydrolipstatin).tw. 29. diet therapy/ or diet, carbohydrate-restricted/ or diet fads/ or diet, fat-restricted/ or diet, reducing/ 30. diet.ti. 31. Exercise/ 32. Exercise Therapy/ 33. exercise.ti. 34. Physical Fitness/ 35. lifestyle.ti. 36. life style.ti. 37. physical activity.ti. 38. walking.ti. 39. Behavior Therapy/ 40. Cognitive Therapy/ 41. Psychotherapy/ 42. Psychotherapy, Group/ 43. Counseling/ 44. counseling.ti. 45. behavio?ral.ti. 46. weight management.ti. 47. Patient Education as Topic/ 48. Health Education/ 49. modification.ti. 50. (obes* adj3 intervention*).ti. 51. or/14-50 52. exp Canada/ 53. (Canad* or BC or British Columbi* or Ontario or Alberta* or Saskatchewan or Manitoba* or Quebec* or Newfoundland or Yukon or NWT or Nunavut or Prince Edward Island or Nova Scotia* or New Brunswick or Toronto or Ottawa or Montreal or Halifax or Edmonton or Calgary or Vancouver).tw. 54. (Canad* or BC or British Columbi* or Ontario or Alberta* or Saskatchewan or Manitoba* or Quebec* or Newfoundland or Yukon or NWT or Nunavut or Prince Edward Island or Nova Scotia* or New Brunswick or Toronto or Ottawa or Montreal or Halifax or Edmonton or Calgary or Vancouver).in. 55. or/52-54 56. (obes* or superobes*).ti. 57. 1 or 2 or 56

	EPI	58. *Obesity, Morbid/ep [Epidemiology] 59. *"Obesity"/ep [Epidemiology] 60. 58 or 59 61. (incidence or prevalence or epidemiolog* or burden).ti. 62. incidence/ or prevalence/ 63. demography/ or age distribution/ or sex distribution/ 64. population groups/ or exp american native continental ancestry group/ or exp ethnic groups/ 65. Minority Groups/ 66. population surveillance/ or sentinel surveillance/ 67. epidemiologic methods/ 68. income/ 69. poverty/ 70. social class/ 71. social conditions/ 72. exp social environment/ 73. (sociodemographic* or social demographic*).tw. 74. or/61-73 75. 57 and 74 76. 60 or 75 77. limit 76 to yr="2005 - 2010" 78. ((child* or adolescent or youth or pediatric or school*) not adult*).ti. 79. 77 not 78 80. limit 79 to english language 81. 80 and 55
	Guidelines and management	82. limit 57 to english language 83. limit 82 to yr="2005 - 2010" 84. limit 83 to "all child (0 to 18 years)" 85. limit 84 to "all adult (19 plus years)" 86. 83 not (84 not 85) 87. limit 86 to animals 88. 86 not 87 89. management.ti. 90. standard of care.ti. 91. practice guideline/ 92. 89 or 90 or 91 93. 55 and 88 and 92
	Quality of Life	94. "Quality of Life"/ 95. Quality-Adjusted Life Years/ 96. (quality of life or well-being or wellbeing or qol or hrqol or hrql or quality adjusted life year* or QALY or self-rated health).mp. 97. 94 or 95 or 96

	Compliance and Adherence	98. 13 and 51 and 97 99. exp *"Patient Acceptance of Health Care"/ 100. (adherence or compliance or acceptability or dropout* or drop out* or noncompliance or (acceptable or satisfaction or attrition or participation or nonrespondents or motivation or attendance or preference* or enrol?ment or incentive*).ti. 101. 99 or 100 102. 13 and 51 and 101
	Demand and utilization	103. *"Health Services Needs and Demand"/ 104. *waiting lists/ 105. demand.ti. 106. ut.fs. 107. or/103-106 108. 13 and 51 and 107
	Barriers and Key Components	109. ((key or important) adj1 concepts).tw. 110. ((essential or key or recommended) adj3 component*).tw. 111. ((cultural or ethnic or psychological or linguistic or economic or socioeconomic or psychosocial or social or policy or financial or lifestyle or emotional or psychological or key or important) adj2 (factor* or consideration* or implication* or concern* or issue*)).ti. 112. ((cultural or ethnic or psychological or linguistic or economic or socioeconomic or psychosocial or social or policy or financial or lifestyle or emotional or psychological or key or important) adj2 (barrier* or disparities or consideration* or implication* or concern* or issue*)).ab. 113. (barrier* or disparities).ti. 114. best practice*.tw. 115. (quality not (quality of life or diet* quality)).ti. 116. (barrier* adj3 (implement* or treat* or therapy*)).tw. 117. health services accessibility/ 118. (access not access-port).ti. 119. or/109-118 120. 13 and 51 and 119
	Patient/ healthcare workers awareness beliefs knowledge attitudes	121. attitude to health/ 122. attitude of health personnel/ 123. health knowledge, attitudes, practice/ 124. (perception* or perceived or knowledge or belief* or attitude* or perspective* or awareness or views).ti. 125. or/121-124 126. 13 and 55 and 125 127. or/122-124 128. 13 and 51 and 127 129. 126 or 128

CRD Databases (DARE, HTA, & NHS EED) http://nhscrd.york.ac.uk	1 May 2005 – 1 May 2010	#1 (obes* OR bariatric*) #2 (ethic* OR bioethic*) #3 MeSH Ethics EXPLODE 1 2 3 4 #4 (#1 AND (#2 OR #3) **6 results**
Clinical Practice Guidelines		
AMA Clinical Practice Guidelines www.topalbertadoctors.org/informed_practice/clinical_practice_guidelines.html	18 May 2010	No obesity guidelines
CMA Infobase http://mdm.ca/cpgsnew/cpgs/index.asp	18 May 2010	Obesity, bariatric
National Guideline Clearinghouse www.ngc.gov	18 May 2010	Keyword: obesity or bariatric Age Range: Adult (19 to 44 years), Middle Age (45 to 64 years) Publication Date(s): 2010, 2009, 2008, 2007, 2006, 2005 (16 relevant results)
NICE Guidance http://guidance.nice.org.uk/	18 May 2010	Obesity, bariatric (an enormous guideline)
Health Regulatory Sites		
Alberta Health and Wellness www.health.gov. ab.ca	4 June 2010	Browsed list of publications Searched bariatrics, obesity (found past IHE economic analysis)
Health Canada (www.hc-sc.gc.ca) Medical Devices Active License Listing (MDALL) http://webprod.hc-sc.gc.ca/mdll-limh/index-eng.jsp Drug Product Database www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php	18 May 2010	 Gastric band (11 results) Lap band (nine results) Gastric balloon (four results) Bariatric (none relevant) Sibutramine (active ingredient) (four results) Orlistat (active ingredient) (one result)
CDC – Centers for Disease Control and Prevention www.cdc.gov/obesity/index.html	4 June 2010	Reviewed their Overweight and Obesity page

Aetna Clinical Policy Bulletins www.aetna.com/about/cov_det_policies.htm	4 June 2010	Obesity; bariatrics
MHRA www.mhra.gov.uk/index.htm	4 June 2010	Obesity; bariatrics (1 sibutramine safety warning)
American Society of Bariatric Physicians www.asbp.org/	4 June 2010	About ASBP> Bariatric Practice Guidelines (found 1 document)
HTA Agencies		
AETMIS www.aetmis.gouv.qc.ca	4 June 2010	Browsed list of publications, 2000–2010 (0 results)
CADTH www.cadth.ca	4 June 2010	Obesity; bariatric; weight loss
Institute for Clinical and Evaluative Sciences (ICES) www.ices.on.ca/	4 June 2010	Bariatric; bariatrics; obesity; LAGB
Health Technology Assessment Unit at McGill www.mcgill.ca/tau/	4 June 2010	Browsed list of publications (2002–2009)
Medical Advisory Secretariat www.health.gov.on.ca/english/providers/program/mas/mas_mn.html	4 June 2010	Browsed publication list (2001–2010) (also checked rapid review list) (1 publication on LAGB safety; 1 publication on bariatric surgery (has economic analysis))
BlueCross BlueShield Technology Evaluation Center	4 June 2010	Browsed publication list (LAGB publication)
AMA Clinical Practice Guidelines www.topalbertadoctors.org/informed_practice/clinical_practice_guidelines.html	18 May 2010	No obesity guidelines
CMA Infobase http://mdm.ca/cpgsnew/cpgs/index.asp	18 May 2010	Obesity, bariatric
National Guideline Clearinghouse www.ngc.gov	18 May 2010	Keyword: obesity or bariatric Age Range: Adult (19 to 44 years), Middle Age (45 to 64 years) Publication Date(s): 2010, 2009, 2008, 2007, 2006, 2005 (16 relevant results)
NICE Guidance http://guidance.nice.org.uk/	18 May 2010	Obesity, bariatric (an enormous guideline)

Note: ††

"*", "#", and "?" are truncation characters that retrieve all possible suffix variations of the root word, e.g., surg* retrieves surgery, surgical, surgeon, etc.

APPENDIX S.B: PREVALENCE OF ADULT OBESITY IN ALBERTA IN 2007

By sex

BMI	Male	Female	Total (%)**
Missing data	39,016	99,885	138,902 (5.30)
Underweight	9,994	47,802	57,796 (2.21)
Normal weight	495,807	620,423	1,116,229 (42.62)
Overweight	521,074	321,809	842,883 (32.18)
Obese class I	194,740	132,602	327,342 (12.50)
Obese class II	47,999	49,190	97,190 (3.71)
Obese class III	14,708	23,983	38,691 (1.48)
Total	1,323,338	1,295,694	2,619,033
%*	19.45%	15.88%	17.69%

By age (years)

BMI	18 to 24	25 to 34	35 to 44	45 to 54	55 to 64	65+	Total
Missing data	17,781	35,188	22,154	20,956	9,491	33,333	138,902
Underweight	14,257	12,717	11,257	7,659	5,986	5,919	57,796
Normal weight	218,045	242,277	217,726	200,066	119,506	118,609	1,116,229
Overweight	80,047	161,858	165,716	195,269	120,632	119,360	842,883
Obese class I	19,780	63,166	64,752	75,562	56,317	47,765	327,342
Obese class II	7,564	18,948	17,925	26,045	15,605	11,102	97,190
Obese class III	1,863	7,426	8,128	9,684	6,567	5,023	38,691
Total	359,337	541,580	507,658	535,241	334,104	341,111	2,619,033
%	8.13%	16.53%	17.89%	20.79%	23.49%	18.73%	17.69%

By education

BMI	Less than	High school	Missing	Total
Missing data	25,415	102,966	10,520	138,902
Underweight	5,822	49,235	2,739	57,796
Normal weight	117,450	975,855	22,924	1,116,229
Overweight	105,629	721,656	15,598	842,883
Obese class I	47,465	274,312	5,566	327,342
Obese class II	21,763	74,302	1,124	97,190
Obese class III	4,498	34,193	0	38,691
Total	328,042	2,232,519	58,471	2,619,033
%	22.47%	17.15%	11.44%	17.69%

By income ($ thousands)

BMI	<20	20-39	40-59	60-79	>80	Missing	Total
Missing data	43,255	30,988	16,315	6,752	5,544	36,049	138,902
Underweight	14,704	10,633	10,701	4,888	3,543	13,327	57,796
Normal weight	250,270	228,250	198,063	114,633	131,414	193,600	1,116,229

Overweight	123,821	172,971	157,623	103,326	155,090	130,052	842,883
Obese class I	56,969	66,667	51,956	37,656	63,233	50,862	327,342
Obese class II	18,763	21,762	17,649	11,111	14,442	13,461	97,190
Obese class III	9,218	7,030	7,582	5,878	3,912	5,071	38,691
Total	517,000	538,301	459,889	284,244	377,178	442,422	2,619,033
%	16.43%	17.73%	16.78%	19.22%	21.63%	15.69%	17.69%

By marriage

BMI	Married or common law	Widowed	Single	Missing	Total
Missing data	94,746	16,055	27,495	606	138,902
Underweight	31,548	5,697	20,278	272	57,796
Normal weight	666,071	117,145	330,127	2,886	1,116,229
Overweight	591,330	88,224	159,677	3,652	842,883
Obese class I	241,128	39,060	46,987	167	327,342
Obese class II	67,197	10,259	19,376	358	97,190
Obese class III	24,687	4,620	9,383	0	38,691
Total	1,716,707	281,060	613,323	7,941	2,619,033
%	19.40%	19.20%	12.40%	6.60%	17.70%

Comorbidities

Cancer

BMI	No	Yes	Total
Missing data	135,674	2,890	138,564
Underweight	55,897	1,899	57,796
Normal weight	1,098,598	16,436	1,115,034
Overweight	829,190	12,929	842,120
Obese class I	321,470	5,704	327,173
Obese class II	95,207	1,226	96,432
Obese class III	36,620	2,071	38,691
Total	2,572,656	43,155	2,615,810
%	17.62%	20.86%	17.67%

Diabetes

BMI	No	Yes	Total
Missing data	125,418	13,275	138,694
Underweight	56,954	842	57,796
Normal weight	1,091,785	24,020	1,115,805
Overweight	806,890	35,784	842,674
Obese class I	290,695	36,647	327,342
Obese class II	83,742	12,346	96,089
Obese class III	29,762	8,928	38,691
Total	2,485,246	131,842	2,617,091
%	16.26%	43.93%	17.66%

High blood pressure

BMI	No	Yes	Total
Missing data	112,341	25,742	138,082
Underweight	53,676	3,988	57,664
Normal weight	1,008,399	102,977	1,111,376
Overweight	693,921	147,609	841,530
Obese class I	236,279	89,361	325,640
Obese class II	66,235	30,113	96,349
Obese class III	22,911	15,669	38,581
Total	2,193,762	415,459	2,609,222
%	14.83%	32.53%	17.65%

Heart disease

BMI	No	Yes	Total
Missing data	132,039	5,369	137,408
Underweight	56,061	1,458	57,520
Normal weight	1,091,358	23,449	1,114,807
Overweight	806,570	34,488	841,058
Obese class I	310,123	16,793	326,917
Obese class II	90,425	5,299	95,725
Obese class III	36,092	2,562	38,653
Total	2,522,669	89,418	2,612,088
%	17.31%	27.57%	17.66%

By health region

BMI	South zone	Calgary zone	Central zone	Edmonton zone	North zone	Total
Missing data	14,100	51,500	17,023	42,430	13,848	138,902
Underweight	6,287	20,717	6,632	21,193	2,967	57,796
Normal weight	75,163	457,974	122,154	362,993	97,945	1,116,229
Overweight	64,160	316,738	110,391	253,193	98,401	842,883
Obese class I	27,609	92,827	47,796	106,809	52,301	327,342
Obese class II	7,943	33,353	13,560	28,335	13,999	97,190
Obese class III	4,577	14,479	3,887	11,094	4,654	38,691
Total	199,839	987,588	321,443	826,047	284,115	2,619,033
%	20.08%	14.24%	20.30%	17.70%	24.97%	17.69%

Notes:

1. **Source:** Canadian Community Health Survey, 2007.
2. The data presented are for Albertans aged 18 years and older.
3. Missing data indicate those not responding to the survey questions.

* % was calculated by dividing the sum of obese classes I, II, and III by total population in each category.

** Numbers in brackets are the percentages of a total adult population of 2,619,032 in Alberta in 2007.

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SECTION TWO: TECHNOLOGY EFFECTS AND EFFECTIVENESS

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SAFETY AND EFFICACY/EFFECTIVENESS OF BARIATRIC TREATMENT STRATEGIES (T)

Introduction

Purpose of assessment

The purpose of this section was to determine the potential role of various bariatric treatment strategies in Alberta in the management of obesity.

For the purposes of this report, a bariatric treatment strategy refers to one or more surgical and/or non-surgical interventions within a program of bariatric services, including different combinations and sequences of administration of individual interventions. These interventions are grouped into the following five broad categories:

(1) dietary therapy;

(2) physical exercise;

(3) behavioural therapy;

(4) pharmacotherapy;

(5) surgery.

Objectives

The objective of this section is to perform a systematic review and critical appraisal of the available evidence on the safety and efficacy or effectiveness of various bariatric treatment strategies for people with obesity and to determine:

- the comparative safety of various bariatric treatment strategies for adults with obesity;
- the comparative efficacy/effectiveness of various bariatric treatment strategies for adults with obesity;
- the sub-populations of adults with obesity that are most appropriately treated with the various bariatric treatment strategies;
- the program-based aspects that should be considered within the bariatric treatment strategies.

Research questions

The **T**echnology (**T**) section of the report attempts to address the following overall questions:

- How do various bariatric treatment strategies compare with respect to safety and efficacy or effectiveness in the treatment of obesity across relevant patient sub-groups?
- What are the indications for the various bariatric treatment strategies?

This section will address a set of more detailed questions from Alberta Health and Wellness in terms of condition, pattern of care, effects and effectiveness, and program context.

Condition

- What is the aetiology of the condition that the bariatric treatment strategies are meant to address?
- What are clinical indicators for the various bariatric treatment strategies for obesity?
- What is the best practice for treating obesity?
- Which technologies have received Health Canada approvals for the treatment of obesity, and for which condition(s) they have been approved?

Pattern of care

- What is the history behind the development of the various bariatric treatment strategies?
- What are the current options and what is the standard/gold standard procedure?
- What are the current situations and trends of use of bariatric treatment strategies for obesity?
- Does the potential exist for one bariatric treatment strategy to replace another in the treatment of obesity?

Effects and Effectiveness

- What are the actions or effects of the bariatric treatment strategies?
- What are the differences between the strategies across sub-populations (defined according to BMI)?
- What are the expected benefits of various strategies across sub-populations (defined according to BMI)?
- What are the risks, side effects, and safety issues for patients and providers for various strategies across sub-populations (defined according to BMI)?
- What are the measurements and indicators of outcomes (benefits, risks, side effects)?
- What is the available evidence of benefit or effectiveness with respect to key outcomes?
- Are the outcomes dependent on the following factors?
    - patient characteristics (such as age, gender, comorbidity, co-medication, etc.)
    - specific training or experience of the providers (learning curve)
    - equipment used
    - other factors

Program Context

- Are any other interventions/technologies required for appropriate use of bariatric treatment strategies?
- Can any of the bariatric treatment strategies use equipment already being used for publicly funded procedures?

- Are any follow-up or related procedures required?

Project scope

The scope of the **T** section of the report was defined as follows:

Population: adult patients (≥ 18 years) who are overweight (defined as BMI between 25 and 29.9 kg/m^2) or obese (defined as BMI ≥ 30 kg/m^2).

Intervention: any kind of bariatric treatment strategies (dietary therapy, physical exercise, behavioural therapy, pharmacotherapy, and surgeries) or any combination of different treatment strategies.

Comparator: comparisons between and within treatment strategies.

Outcome measures: safety outcomes include adverse events/complications associated with treatment strategies; efficacy/effectiveness outcomes include any of the following: weight change, health-related quality of life, prevention/improvement in risk factors and comorbidities, psychological measurement, and mortality.

Description of Technology

Overview of bariatric treatment strategies

The prevalence of obesity continues to increase worldwide. The cause of obesity is complex and multi-factorial.[1] Major genetic, environmental, and socio-cultural (or behavioural) factors have played important roles in the development of obesity. In particular, alterations of an individual's energy balance caused by inappropriate food intake and/or reduction in physical activity levels have contributed significantly to the current worldwide epidemic of obesity.[2]

Population approaches to dealing with the obesity problem have focused on reducing fat intake in association with increased physical activity. Diet and lifestyle changes have been the cornerstones for obesity treatment over the years.

People lose weight when energy expenditure exceeds energy intake for a defined period of time.[3] Successful maintenance of weight loss occurs when expenditure and intake are matched at the reduced body weight for a continued period of time.[3]

Currently available strategies for treating overweight and obesity include:[1,4]

- dietary therapy
- physical exercise
- behavioural therapy
- pharmacotherapy
- surgery

Dietary therapy

Definition

Reduction of body weight requires a deficit in caloric intake. A key element of weight management is a moderate reduction in caloric intake to achieve a slow but progressive weight loss.[5] The goal of

dietary therapy is to reduce total energy intake from food by either reducing calories or by changing the intake of carbohydrate, fat, or protein.[6]

Types

Dietary strategies for the treatment of obesity can be broadly divided into five categories (see Table T.1):[6-8]

- low-fat diet
- low-calorie diet
- very-low-calorie diet
- low-carbohydrate diet
- low glycemic index diet

Table T.1: Types of dietary therapy

Type	Description
Low-fat diet	Restricts fat intake to less than 25% to 35% of daily energy intake.
Low-calorie diet	Reduces the amounts of all macronutrients, including fat, to achieve a daily caloric intake of 800 to 1200 kcal.
Very-low-calorie diet	Provides a daily caloric intake of < 800 kcal and invariably restricts fat and carbohydrate while maintaining a near-normal protein intake.
Low-carbohydrate diet	Provides either a modest restriction of carbohydrate intake and an increase in protein intake or a severe restriction of carbohydrate intake and an increase in protein and fat intake.
Low glycemic index diet	Maintains carbohydrate intake, but the type of carbohydrate consumed is changed to deliver a lower glycemic load.

Sources: [4,6-8]

Low-fat diet

High carbohydrate, low-fat diets became popular about 20 years ago, when it was thought that calories from carbohydrates were less fattening than the same number of calories from fat.[9]

Low-fat diets are probably one of the most commonly recommended diets because fat is energy-dense, poorly satiating, and easy to over-consume. Fat consumption is high in developed countries where obesity rates are high.[7]

Low-calorie diet

Several mechanisms have been suggested for the possible added value of low-calorie diets in promoting weight loss including:

(1) higher amounts of protein, which promote satiety more than carbohydrates

(2) ongoing gluconeogenesis, which is an energy-consuming process, to compensate for the body's carbohydrate needs

(3) increased diuresis

(4) loss of glycogen stores and their associated water

(5) high levels of circulating ketones, which suppress appetite

(6) limited food choices[8]

Very-low-calorie diet

Very-low-calorie diets have waned in popularity since the 1980s.[10] A very-low-calorie diet is not recommended without medical supervision because of the higher risks associated with greater deficits, such as nutritional deficiencies, vitamin deficiencies, and gallstones.[11] The contraindications to the use of the very-low-calorie diet include kidney or liver diseases, systemic infection, myocardial infarction or cerebrovascular attack, type 1 diabetes, pregnancy, or a BMI under 25 kg/m^2.[5]

Low-carbohydrate diet

Low-carbohydrate diets, that is, diets providing less than 60g of carbohydrate daily, have received increased attention in recent years.[12] There are two popular forms of carbohydrate-restricted weight loss diets. One replaces a moderate amount of carbohydrate with protein and is low in fat. The other replaces the majority of the carbohydrate with both protein and fat.[7] Normal protein intake is in the range of 12% to 18% of the daily energy intake. Protein intake from a carbohydrate-restricted diet might be in the range of 25% to 35% of daily intake.[7]

Low glycemic index diet

The glycemic index is a rating system for foods based on the extent to which they raise blood glucose levels two hours after their consumption.[12] Substitution of fat with high glycemic index foods can cause increased hunger, anabolism of adipose tissue, and weight gain.[8] The rapid absorption of sugar from a high glycemic index food results in a large increase in insulin secretion, which then exerts its anabolic effects. In addition, the high insulin levels decrease blood glucose levels, causing greater hunger a few hours after consumption of a meal that has a high glycemic index.[8]

In an insulin-resistant person, the high demand on the β cell might potentially result in β-cell secretion defects and apoptosis, leading to type 2 diabetes. With a low glycemic index diet, the ambient insulin secretion is lower and without large swings, and these unwanted effects can be minimized.[8]

Physical exercise

Definition

Physical activity is a key component of any weight management program because it increases the expenditure of energy, may inhibit food intake, and may improve quality of life by enhancing self-esteem and relieving depression.[5,13] In addition to weight loss, sustained physical activity has the benefit of reducing the overall risk of coronary heart disease.[5]

Types

Two kinds of exercise, endurance and strength training, have been used to treat obesity. Endurance exercise—such as walking briskly, jogging, running, or bicycling—is useful for increasing cardiovascular fitness, whereas strength exercises such as weight lifting strengthen individual muscle groups.[6]

Additional benefits of exercise over dietary therapy

A negative energy balance can be attained through either eating less, or exercising more or both.[8] A deficiency of 500 kcal per day is recommended to achieve a weight loss rate of approximately 0.5 kilograms per week.[8] The same energy deficit obtained through either increased exercise or through dietary restriction may yield similar changes in body weight, but the composition of the lost tissue differs. On average, the composition of weight loss is approximately 70% fat and 30% lean body mass, whereas loss of the latter causes a decrease in the resting metabolic rate.[8] Exercise aids in minimizing the loss of lean body mass, thereby reducing the decrease in metabolic rate (for increased efficiency) that accompanies any loss in body weight.

To obtain the desired energy deficit for weight loss under normal circumstances, caloric intake must be reduced; it is much easier to reduce caloric intake by 500 kcal per day, for example, than to increase expenditure by that magnitude. Examples of activities that use approximately 500 kcal of energy, for a person weighting approximately 80 kilograms, are an hour of jogging at 5 kilometers per hour, or 35 minutes of jumping rope.[8]

In addition to increasing energy expenditure and promoting fat loss, physical exercise has additional benefits including:

- reducing abdominal fat and increasing lean mass;
- reducing blood pressure and improving glucose tolerance, insulin sensitivity and the lipid profile;
- improving physical fitness;
- improving compliance to the dietary regimen;
- improving feelings of well-being and self esteem;
- reducing anxiety and depression.[11]

Behavioural therapy

Definition

Behavioural therapy, an important component of weight management, refers to the principles and techniques used to change a patient's behaviour and habits.[5] The goal of behavioural therapy is to alter learned eating and activity habits in overweight and obese individuals.[11]

Although behavioural modification recognizes the role of genetics and cultural influences on weight, it focuses on current behaviour, with a particular focus on increasing energy expenditure and reducing energy intake to achieve weight loss.[14] Behavioural therapy provides the individual with coping skills to handle various cues to overeat and to manage lapses in diet and physical activity when they occur.[15] Behavioural therapy also provides the motivation essential to maintaining adherence to a healthier lifestyle over a long period of time.[15]

Types

Key features of typical behavioural therapy include self-monitoring, goal setting, nutrition, exercise, stimulus control, problem solving, social support, cognitive restructuring, and relapse prevention (see Table T.2).[5,13,14]

Brief history and development

Since the evolvement of behavioural principles for obesity treatment during the late 1960s and early 1970s, behavioural treatment strategies have developed significantly in terms of improved cognitive procedures for relapse prevention training and correction of negative thinking.[5] The addition of such cognitive procedures has led to the renaming of behavioural treatment as "cognitive-behavioural therapy." Currently, typical behavioural therapies in the treatment of obesity include cognitive behavioural therapy strategies.[5]

Behavioural therapy works primarily by enhancing dietary restraint through provision of adaptive dietary strategies and discouragement of maladaptive dietary practices, and by increasing motivation to be more physically active.[15] Cognitive behavioural therapy aims at identifying and modifying aversive thinking patterns and mood states in order to facilitate weight loss.[15]

Table T.2: Behavioural modification strategies

Self-monitoring
Keeping an extended food and exercise diary to give insights into personal behaviours and to bring unrecognized behaviours to light
Stress management
Developing coping strategies and meditation and relaxation techniques
Stimulus control
Learning to shop carefully for healthy foods, keeping high-calorie foods out of the house, limiting the times and places of eating, and consciously avoiding situations in which overeating occurs
Problem solving
Identifying problems → choosing solutions → planning and implementing → evaluating the outcome
Contingency management
Rewarding changes in behavior
Cognitive restructuring
Modifying negative thoughts, unrealistic goals, and inaccurate beliefs about weight loss, and preparing in advance for relapses
Social support
Developing a network of family members, friends, or colleagues who can assist in maintaining motivation and providing positive reinforcement
Relapse prevention training
Developing the skills to overcome setbacks and to cope with problems

Source: Lang & Froelicher 2006[5]

Pharmacotherapy

Definition

Antiobesity medications can reduce energy intake by decreasing the appetite or increasing satiety; reduce the absorption of nutrients; or increase energy expenditure.[16] Current available medications work through two mechanisms: (1) monoamines in the central nervous system, or (2) blockade of lipase digestion in the intestine[17] Pharmacotherapy for obesity should be regarded as an adjunct to dietary restriction, physical exercise, and behavioural therapy.[18,19]

Type

Approved antiobesity medications can be divided into three broad categories:

- medications that inhibit intestinal fat absorption—the drug orlistat inhibits pancreatic and other lipase; it is the only agent currently available in this class.[20]
- medications that suppress appetite, increase satiety, or increase thermogenesis—drugs in this class modify the central nervous system neurotransmission of norepinephrine, dopamine, and serotonin. Sibutramine, a serotonin-norepinephrine reuptake inhibitor, belongs to this class.[12]
- medications that inhibit the endocannabinoid system—rimonabant is the first drug of this class and acts by both central and peripheral mechanisms to reduce food intake and body weight.[20]

History and trend

An assessment of US national trends revealed that the use of antiobesity medications drastically rose with the increased popularity of fenfluramine-phentermine.[6] Fenfluramine was withdrawn from the market worldwide in 1997 because of reports of aortic valvular regurgitation associated with its use.[6] Since then the use of antiobesity medications has declined, but use still remains higher than 1990 levels.[14] A brief history of the use of antiobesity medications is summarized in Table T.3.

Table T.3: History and mechanisms of antiobesity medications

Medication	Year of introduction	Mechanism of action			Status
		Thermo-genesis	Appetite suppression	Decreased fat absorption	
Thyroid hormone	1893	√			Widely used until 1980s
Dinitrophenol	1933	√			Withdrawn
Amphetamines: *Dexamfetamine* *Methamphetamine*	1936	√	√		Banned, restricted, or discouraged
Amphetamine-like analogues:					
Phentermine	1959 US	√			Withdrawn (2000, UK)
Amfepramone (diethylpropion)	1959 US		√		for short-term use (≤ 12 weeks)
Phenylpropanolamine	1939 US		√		Withdrawn (2004)
Aminorex	1965		√		Withdrawn (1968)
Ephedrine/caffeine	1970s Denmark	√	√		Banned (2004)
Mazindol	1970s		√		Discontinued
Fenfluramine	1963 Europe 1973 US		√		Withdrawn (1997)
Dexfenfluramine	1985 Europe 1996 US		√		Withdrawn (1997)
Orlistat	1998 Europe 1999 US			√	Available in several countries

Sibutramine	1997 US 1999 Europe	√	√		Available in US, Canada; Suspended in Europe (2010)
Rimonabant	2006 Europe		√		Suspended (2008)

Sources: Ioannides-Demos et al. 2005,[16] Padwal, 2007,[21] European Medicines Agency, 2010,[22] US FDA 2010[23]

Orlistat is a synthetic gastrointestinal lipase inhibitor which decreases fat absorption by binding to pancreatic lipase and increasing fecal fat excretion.[6,16] Orlistat is the most extensively studied medication currently available for obesity treatment.[24] Since its introduction in the early 1990s, more than 150 clinical trials have been published on the use of orlistat alone or in combination with other antiobesity medications, antidiabetic, antilipidemic, and other related medications for management of different aspects of the dysmetabolic syndrome.[24]

Sibutramine, a serotonin and norepinephrine reuptake inhibitor, was originally developed as an antidepressant but was subsequently shown to suppress appetite and possibly increase thermogenesis.[14,25,26]

Rimonabant is a selective cannabinoid receptor-1 antagonist with resultant central and metabolic peripheral effects; it decreases food intake by blocking the 'munchie receptor' that stimulates hunger.[16]

Criteria for the efficacy of drug therapy

The US FDA recommend a 5% placebo-subtracted weight loss as the criterion for efficacy.[27] The European Medicines Evaluation Agency suggests a weight loss of greater than 10% from baseline (or of at least 5% placebo-subtracted) as a valid primary efficacy criterion.[28] The National Heart, Lung, and Blood Institute and the North American Association for the Study of Obesity recommend continuing therapy for responders who have lost 4.4 pounds (or 2 kilograms) in the first 4 weeks after initiating therapy, and discontinuing in non-responders.[19] The London Royal College of Physicians recommend stopping drug treatment if a 5% weight loss is not achieved after 12 weeks.[29]

Indications/contraindications

Because all medications inherently have more associated risks than do dietary therapy and physical exercise, antiobesity medications should only be used when the benefit justifies the risk[30] and in combination with lifestyle education and careful monitoring.[13]

Patients with a BMI of 30 kg/m^2 or greater or a BMI of 27 kg/m^2 or greater with a major obesity-related comorbidity (for example, hypertension, diabetes, obstructive sleep apnea) are currently eligible for antiobesity drug treatment.[1,19]

Orlistat might be useful in patients at high risk for developing type 2 diabetes, with high LDL cholesterol concentrations, or with pre-existing cardiovascular disease.[21] Orlistat should be avoided for patients with chronic diarrhea, chronic mal-absorption syndrome and cholestasis.[4,21]

Because of its satiety-enhancing effects, sibutramine might be beneficial for those patients in whom a lack of satiety or frequent snacking is a major barrier to weight reduction. Sibutramine should be avoided for patients with inadequately controlled hypertension, pre-existing cardiovascular disease, or psychiatric illness.[4]

Rimonabant may be considered for patients with dyslipidemia associated with metabolic syndrome (low HDL cholesterol and high triglyceride concentrations) and in patients who are concurrently attempting to stop smoking. The drug should be avoided for patients with pre-existing major depressive illness or with liver or kidney function impairment.[4]

For patients who fail to respond to the antiobesity medications—that is, who fail to lose 2 kilograms after four weeks or 4 to 5 kilograms after 3 months—drug therapy should be discontinued because long-term success is unlikely.[30] In contrast, if the drug is effective it should be continued because withdrawal of an effective antiobesity drug can lead to rapid weight regain and worsening of cardio-metabolic risk factors.[30]

Surgery

Definition

Bariatric surgery promotes weight loss primarily through gastric restriction and intestinal diversion.[31] Some procedures contain both restriction and diversion elements. In addition to structural alteration of the gastrointestinal tract, bariatric surgery may also influence the levels of the gut hormones that are involved in energy regulation.[32]

Brief history

Since the introduction of bariatric surgery in the 1950s, various surgical procedures have been developed and have undergone continuing modification and refinement.[33] Minimally invasive laparoscopic surgery became the technique of choice in the 1990s.[33]

Types

Bariatric surgeries can be divided into three categories:

(1) restrictive—producing weight loss by limiting the amount of food ingested

(2) mal-absorptive—producing weight loss by limiting the amount of nutrient absorbed

(3) mixed—producing weight loss through both mechanisms[34,35]

Several commonly performed surgical procedures are listed in Table T.4. Bariatric surgeries can be performed by either open or laparoscopic approaches; currently, most bariatric procedures are being performed laparoscopically.[36] Gastric bypass and laparoscopic adjustable gastric banding (LAGB) are the most commonly performed procedures internationally. Sleeve gastrectomy is a new treatment that is gaining popularity,[37] whereas vertical banded gastroplasty, jejunoileal bypass, and minigastric loop bypass have been abandoned.[38,39]

Table T.4: Bariatric surgery

Procedure	Mechanism of action
adjustable gastric banding	restrictive
vertical banded gastroplasty	restrictive
sleeve gastrectomy	restrictive
Roux-en-Y gastric bypass	restrictive and mal-absorptive (mixed)
biliopancreatic diversion with duodenal switch	restrictive and mal-absorptive (mixed)
biliopancreatic diversion	mal-absorptive

Source: Fried et al, 2007[33,34,40]

Adjustable gastric banding

Adjustable gastric banding is the least invasive of the purely restrictive bariatric surgery procedures. It limits food intake by placing a constricting ring completely around the top end of the stomach. The currently used bands incorporate an inflatable balloon within their lining to allow adjustment of the size of the stoma to regulate food intake.[41]

Adjustment is undertaken without the need for surgery by altering the amount of saline through a subcutaneous access port.[34] As a restrictive procedure, gastric banding avoids the problems associated with mal-absorptive techniques. Gastric banding is technically a reversible procedure.[41]

Roux-en-Y gastric bypass

Roux-en-Y gastric bypass (RYGB) combines restriction and mal-absorption techniques by creating both a small gastric pouch and a bypass that prevents absorption of ingested food. The RYGB procedure, most commonly performed in the United States, entails partition of the upper part of the stomach, using surgical staples, to create a small (10- to 30-millilitre) pouch with an small outlet (gastroenterostomy stoma) to the intestine that is attached to the pouch.[36,39,41]

Adaptations of the procedure have been used to increase malabsorption and increase weight loss. Often a prosthetic band is used to stabilize the gastroenterostomy, preventing late stretching of the opening and improving long-term weight control. It is technically possible to reverse a gastric bypass.[41]

Sleeve gastrectomy

Sleeve gastrectomy, a restrictive procedure, is usually used as a staged procedure for super-obese pateints or patients having a high operative risk because of excessive comorbidity.[42] The sleeve gastrectomy divides the stomach vertically to reduce its size to about 25%.[41] It leaves the pyloric valve at the bottom of the stomach intact so that stomach function and digestion are unaltered. A more definitive procedure (such as RYGB) can be performed 6 to 12 months after sleeve gastrectomy that allow significant weight reduction and improvement in risk factors/comorbidities.[41,42] The sleeve gastrectomy is currently also performed as a stand-alone procedure.[34] In contrast to AGB or RYGB, sleeve gastrectomy is not reversible.[41]

Safety concerns

Complications of bariatric surgery can be divided into:

(1) perioperative or immediate complications

(2) short term complications, occurring in the first year

(3) long term complications[43]

The immediate complications are specific to the type of surgery. Procedures that include division or anastomosis of the gastrointestinal tract carry the risk of leakage and bleeding, which can be life threatening and can increase the risk of peri-operative death. Venous thrombolic disease, cardiorespiratory events, and wound infections are uncommon after laparoscopic bariatric surgery as compared to open approaches.

Short-term complications—such as nausea and vomiting, anastamotic ulcers, pouch outlet stenosis, and bowel obstructions—can be procedure-related, or they can be weight loss related, such as gallstone formation.[43]

Long-term complications are specific to the type of surgery performed and may include nutritional and metabolic problems. Mal-absorptive procedures increase the risk of long-term vitamin and nutrient deficiencies; gastric banding leads to the risk of slippage, erosion, and port-site complications.[38]

Non-surgical complications of bariatric surgery include nutritional deficits, increased incidence of psychosocial issues, increased reports of accidental death and suicide, and complications arising from excess, redundant tissue after significant weight loss.[38]

Special considerations for bariatric treatment strategies

Weight loss versus weight maintenance

In general, when weight loss treatment strategies are followed, weight loss is quick at first, reaches its greatest levels at 6 months, and then slowly returns to original levels.[44] Maintaining the lost weight remains a significant challenge of any weight loss strategy. Any study with a follow-up period of 6 months or longer can be considered a weight maintenance study.[7]

Strategies to promote weight loss maintenance include ongoing therapist contact, training in relapse prevention, problem-solving therapy, use of prepackaged foods, incorporation of support from peers, and participation in multifaceted programs after weight loss treatment.[44] However, the issue of poor maintenance of lost weight remains, despite the use of multiple behavioural change strategies, raising the question of whether maintenance programs are helpful or only postpone weight regain at an added cost.[44]

A suggested definition for "success" is the maintenance of an intentional weight loss of at least 10% of initial body weight over 1 year.[45] This amount of weight loss was suggested because of the associated reduction in risk factors for developing type 2 diabetes and cardiovascular disease.

Psychological factors related to bariatric surgery

Factors that motivate a person to seek weight loss treatment include:

- a willingness to lose weight for actual health reasons
- the discomfort of the excess weight
- medical problems
- the fear of increased health risks

Following successful weight loss, the person enters a weight maintenance stage. During this stage, some people may suffer emotional pain which can be triggered by various factors, including:a sense of denial, psychological reasons, the perception that being thin is problematic, parental messages, physiological factors, and the fear of weight regain.[46]

Patients and their family members may not realize that the social system that worked prior to surgery may not work after surgery. Furthermore, while patients are usually encouraged by initial support from significant others, they may be discouraged by their significant others' eventual resistance to change. This resistance, along with the general struggles associated with weight loss, becomes a major obstacle to successfully achieving the long-term objective of weight loss and overall improved physical and emotional health.[46]

Because extreme obesity can potentially affect all organ systems and psychological health, optimal surgical treatment of weight loss requires communication and collaboration among a multidisciplinary team of caregivers.[47]

Regulatory status

Medications

Health Canada

Orlistat (Xenical®, manufactured by Hoffmann-La Roche Ltd, Ontario, Canada) and sibutramine (manufactured as Apo-Sibutramine® by Apotex Incorporated, Ontario, Canada, and as Meridia® by Abbott Laboratories, Ltd, Québec, Canada) are two drugs currently approved by Health Canada for the treatment of obesity.[48-50]

In October 2010 Health Canada announced that Abbott Laboratories had voluntarily withdrawn the prescription weight loss drug sibutramine (Meridia®) from the Canadian market. The decision was made based on the data from the Sibutramine Cardiovascular OUTcomes (SCORT) trial, a large trial that suggested an increased risk of serious cardiovascular events associated with sibutramine use in patients with heart problems.[51]

Other

In January 2010 the European Medicines Agency recommended suspension across the European Union of marketing authorizations for sibutramine-containing medicines, including Reductil, Reduxade, Zelium, and other trade names.[22] The decision was made based on the European Medicines Agency's most recent safety review, which had found an increased risk of cardiovascular events associated with the use of sibutramine-containing medicines.

At the same time, at the request of the US FDA, the manufacturer of sibutramine agreed to add a new contraindication to the sibutramine drug label.[23] The contraindication will state that sibutramine is not to be used in patients with a history of cardiovascular disease, including a history of:

- coronary artery disease (for example: heart attack, angina)
- stroke or transient ischemic attack
- heart arrhythmias
- congestive heart failure
- peripheral arterial disease
- uncontrolled hypertension (that is, > 145/90 mmHg)

Rimonabant (Acomplia® and Zimulti®) was granted a community marketing authorization by the European Commission on 19 June 2006.[52] The European Medicines Agency has recommended the suspension of marketing authorization for this drug as of 23 October 2008 because of the risk of psychiatric side-effects.[53]

Devices used for bariatric surgery

Health Canada has issued licenses to several manufacturers for the marketing of bariatric devices, including bariatric laparoscopes and adjustable gastric bands (manufactured by Smith & Nephew, Inc, MA, United States), Swedish adjustable gastric bands (manufactured by Obtech Medical Sarl, Le Locle, Switzerland), and the lap-band adjustable gastric banding (LAGB) system (manufactured by Allergan, Inc, CA, United States).[54]

Local context

In Alberta, four urban centres (Edmonton, Calgary, Red Deer, and Medicine Hat) currently provide bariatric treatment services to adults.

The Weight Wise Adult Weight Management Clinic at the Royal Alexandra Hospital, Edmonton, provides various medical, psychological, and surgical interventions, including:

- behaviour modification
- counseling for nutrition, physical activity, and mental health
- drug treatment
- bariatric surgery

Patients 17 years or older with a BMI equal to or greater than 35 kg/m^2 or Edmonton Obesity Staging System (55) stage 2, 3, 4 are eligible for this program (Source: www.albertahealthservices.ca/services.asp?pid=service&rid=1008784, accessed 18 February 2010).

The Weight Management Program at Richmond Road Diagnostic and Treatment Centre, Calgary, offers a wide range of services and treatment options. Services include:

- classes
- individualized dietary and lifestyle counseling
- supervised exercise
- psychological counseling
- medications
- laparoscopic gastric banding surgery

Patients who are 18 years or older with a BMI between 35 kg/m^2 and 39.9 kg/m^2, with one or more obesity-related comorbidity, or BMI greater than 40 kg/m^2, with no necessary obesity-related comorbidities, are eligible for this program. (Source: www.albertahealthservices.ca/services.asp?pid=service&rid=1008786, accessed 18 February 2010).

Three surgical procedures, including adjustable gastric banding, gastric bypass, and sleeve gastrectomy, are currently performed in Alberta. All these procedures are performed laparoscopically. Gastric bypass is also performed using an open approach (Dr. Daniel Birch, personal communication, August 2010).

Methodology

Literature search

A comprehensive literature search was conducted to identify the most recent systematic reviews/HTAs of randomized controlled trials (RCTs) that compared various bariatric treatment strategies. A detailed description of the literature search strategy, including sources (databases, websites, grey literature), dates searched, and search terms used, is provided in Appendix T.A: Methodology/Search strategy.

Selection of literature

Eligibility of key studies (that is, systematic reviews/HTAs of RCTs) was determined according to the pre-specified inclusion/exclusion criteria outlined in Appendix T.A: Methodology/Study selection.

Quality assessment

Two independent reviewers appraised the methodological quality of the included studies using an IHE quality appraisal tool for systematic reviews. The quality assessment tool and the quality assessment results are presented in Appendix T.C.

Data extraction

Information on the safety and efficacy/effectiveness of various bariatric treatment strategies was extracted from each included systematic review/HTA according to a pre-developed data extraction form (see Appendix T.A: Methodology/Data extraction). Data extracted from each of the systematic reviews/HTAs are summarized in Appendix T.D.

Data analysis and synthesis

Data extracted from the included systematic reviews/HTAs were described and integrated using a narrative approach.

For anti-obesity medications, this report will focus on orlistat and sibutramine because these are the only two drugs approved by Health Canada for long-term use. Detailed information is also presented about rimonabant, because it is a newly developed drug.

For bariatric surgery, this report will focus on three procedures that are currently performed in Alberta: AGB, RYGB, and sleeve gastrectomy. Because dietary therapy and physical exercise are often used together, rather than presenting outcomes in five categories, as previously mentioned in the section "Description of Technology," this report will present outcomes in four intervention categories:

- dietary therapy/physical exercise (combined)
- behavioural therapy
- pharmacotherapy
- surgery

Description of the Included Systematic Reviews/HTAs

Characteristics of the included studies

Using the search strategy described in Appendix T.A, the literature search identified 1298 citations. For articles that appeared to be relevant, the full text was retrieved and reviewed. Sixteen systematic reviews/HTAs[2,15,20,38,56-67] met the inclusion criteria. Excluded systematic reviews/HTAs and the reasons for their exclusion are listed in Appendix T.B. Two reviews[61,63] were further excluded because of their poor methodological quality rating (see Appendix T.C). Fourteen systematic reviews/HTAs are included for analysis and synthesis (see Table T.5).

Table T.5: Overview of the included systematic reviews/HTAs

Treatment strategy (Number of SRs/HTAs)	SRs/HTAs	Number of included RCTs (Interventions)
Dietary therapy/ physical exercise (3)	Galani & Schneider, 2007[56]	30 (lifestyle intervention)
	Shaw et al., 2006[57]	41 (E, D)
	Curioni & Lourenco, 2005[58]	6 (D, E)
Behavioural therapy (1)	Shaw et al., 2005[15]	36 (BT, BT+D/E, CBT)
Pharmacotherapy (3)	Johansson et al., 2009[59]	28 (orlistat, sibutramine, rimonabant)
	Padwal et al., 2006[20]	30 (orlistat, sibutramine, rimonabant)
	Li et al., 2005[60]	29 (orlistat)
Surgery (2)	Klarenbach et al., 2010[38]	64 (various surgical procedures)
	Colquitt et al., 2009[62]	23 (various surgical procedures)
Multiple treatment strategies (5)	Tsai, 2009[64]	10 (D, E, P)
	Maciejewski et al., 2005[65]	34 (BT, P, S)
	Avenell et al., 2004[2]	84 (D, E, BT, P, S)
	McTigue et al., 2003[66]	33 (BT, P, S)
	Poobalan et al., 2007[67]	8 (lifestyle intervention, S)

Abbreviations: BT = behavioural therapy; CBT = cognitive behavioural therapy; D = diet; E = exercise; FU = follow-up; HTA = helath technology assessment; P = pharmacotherapy; RCTs = randomized controlled trials; S = surgery; SR = systematic reviews

Of the 14 systematic reviews/HTAs, three reviews focused on dietary therapy/physical exercise,[56-58] one review[15] on behavioural therapy, three reviews[20,59,60] on weight loss medications, two reviews[38,62] on bariatric surgery, and the other five reviews[2,64-67] assessed the safety and efficacy of multiple treatment strategies.

As shown in Table T.5, for each intervention category (except behavioural therapy) a varying number of RCTs was included in different systematic reviews/HTAs. However, a careful checking of the reference lists revealed a great deal of overlap among the RCTs included in these reviews. For reviews that focused on dietary therapy/physical exercise,[56-58] pharmacotherapy,[20,59,60] and surgery,[38,62] the number of overlapping RCTs were 5, 37, and 18, respectively.

For the primary studies assessed in the included systematic reviews/HTAs:

- details regarding the objectives, search strategies, and selection criteria are presented in Appendix T.D (Table T.D.1)

- information regarding patient characteristics and interventions is presented in Appendix T.D (Table T.D.2)

Methodological quality of the included systematic reviews

Quality assessment results for the 16 systematic reviews/HTAs are presented in Appendix T.C (Table T.C.1). Methodological quality was rated as "good" for six systematic reviews,[15,20,57-60] "average" for eight systematic reviews,[38,55-62] and "poor" for two reviews.[61,63]

Most reviews searched databases beyond that of MEDLINE. Nine reviews used and reported a standardized method for data extraction; however, data extraction was conducted by two independent reviewers in only seven reviews. In more than half of the reviews, the methodological quality of the included studies was assessed by two independent reviewers. Conclusions from all of these reviews were supported by the results presented.

Two reviews[61,63] were excluded from analysis and synthesis because of their poor quality rating related to the robustness of the methodology used.

Evidence on Safety

Data about safety profile of each bariatric treatment strategy are presented in Appendix T.E (Table T.E.1).

Dietary treatment/physical exercise

Two systematic reviews[56,58] did not report any adverse events associated with dietary therapy or physical exercise. The other review[57] reported that no data were identified on adverse events.

Behavioural therapy

The only systematic review[15] in this category did not report any adverse events associated with behavioural therapy.

Pharmacotherapy

As shown in Table T.E.1, one systematic review[59] specifically examined the rates of discontinuation of antiobesity medications due to their side effects. This review assessed 28 RCTs that included a total of 13,457 patients having a mean BMI ranging from 33 to 38 kg/m^2. Another systematic review[20] also provided detailed information regarding adverse events (AEs) associated with the use of orlistat, sibutramine, or rimonabant.

AEs for orlistat

Gastrointestinal (GI) adverse events are predominant in patients treated with orlistat. Fatty/oily stool, fecal urgency, and oily spotting are most common. Over 80% of patients experienced at least one GI event.[20]

Most studies reported that GI side effects were mild and transient, and decreased as patients adjusted to a low fat diet. However, high study attrition rates may reflect a differential dropout of patients who were unable to tolerate the medication, and may partly explain the improved tolerance of patients who remained in the study.

AEs for sibutramine

As compared to a placebo, sibutramine increased both systolic and diastolic blood pressure and heart rate (the proportion of patients who experienced these AEs were not reported).[20] These side effects of sibutramine are of particular concern because even mild increases in blood pressure can be expected to result in an increase in cardiovascular events in a population already at risk. Patients with pre-existing cardiovascular disease were excluded from these trials.

Other adverse effects associated with sibutramine, occurring in 7% to 20% of patients, included insomnia, nausea, dry mouth, and constipation.[20]

AEs for rimonabant

Psychiatric disorders—including depression, anxiety, irritability, and aggression—occurred in 6% of patients treated with rimonabant.[20]

Dropout rates of drug therapy

The overall dropout rates were high and were comparable in groups taking the antiobesity medication and in placebo groups, with overall dropout rates of 30% for orlistat, 34% for sibutramine, and 39% for rimonabant.[59] Median dropout rates due to drug side effects were highest for rimonabant at 15.0% (ranging from 12.8% to 17.5%), intermediate for sibutramine at 9.3% (ranging from 0.0% to 12.2%), and lowest for orlistat at 7.1% (ranging from 0.0% to 12.8%).

Risk ratios for discontinuation due to adverse events were significantly increased for rimonabant and orlistat, but not for sibutramine.[59] Compared to placebo, the risk difference was the largest for rimonabant, followed by orlistat, while no significant difference was observed for sibutramine.[59]

The most common adverse events leading to drug discontinuation were gastrointestinal side effects for orlistat (40%) and psychiatric side effects for rimonabant (47%).[59]

In summary, the major safety concerns are gastrointestinal adverse events for orlistat, increases in blood pressure and heart rate for sibutramine, and psychiatric disorders for rimonabant. Because there is a lack of direct head-to-head comparisons of the three drugs, the comparative safety of the three drugs remains to be determined.

Bariatric surgery

Both the CADTH review[38] and the Cochrane review[62] provided detailed information regarding early and late adverse events associated with bariatric surgeries (see Appendix E: Table T.E.1). Since the 2010 CADTH review included more RCTs and the majority of RCTs assessed in the Cochrane review[62] were also included in the CADTH review,[38] the section below will focus on the information obtained from the CADTH review. Only information about RYGB, AGB, and sleeve gastrectomy is summarized in this report.

Hospitalization

Two trials with 248 patients showed that patients who received AGB had significantly shorter hospital stays than patients who received RYGB.

Results from seven trials with 507 patients indicated that patients who underwent laparoscopic surgeries had significantly shorter hospital stays than did patients who had undergone open surgeries.

Results from two trials with 100 patients did not reveal any significant difference in incidence of post-operative readmission between RYGB and AGB groups.

Reoperations and revisions

Two trials with 248 patients found that, when compared with the RYGB group, the AGB group had more late failed surgeries (conversions and reversals); however, no significant differences were revealed in rates of early/late reoperation and reversals between the RYGB and the AGB group.

Comparing open to laparoscopic RYGB and VBG, four trials with 286 patients found no significant difference in incidence of early reoperation and three trials with 233 patients found no significant difference in incidence of late reoperation.

One trial with 69 patients did not find any significant difference in incidence of late reversal between open and laparoscopic AGB.

Gastrointestinal disturbances

Sixteen trials reported incidences of dumping syndrome, dyspepsia, dysphagia, gastritis, reflux, ulcer, or vomiting. There were significantly fewer late ulcers in the AGB group than in the RYGB group. No direct comparisons for other AEs were available for AGB, RYGB, or sleeve gastrectomy.

Five clinical trials involving 556 patients reported the incidence of reflux, ulcer, or vomiting. The patients with open surgeries experienced significantly less vomiting. No other results were significantly different in comparing laparoscopic and open surgeries.

Surgical complications

Compared to RYGB groups, AGB groups had a significantly lower risk of early wound infection, late stenosis, and late hernia, but a significantly higher risk of late slippage or dilatation. No trials reported the comparative incidence of myocardial infarction.

Eight trials involving 694 patients reported the incidence of anastomotic leak, bowel obstruction, hernia, respiratory failure, staple-line breakdown, luminal stenosis, wound infection, or venous thromboembolic disease. Compared to open surgeries, laparoscopic surgeries were associated with significantly fewer incidents of early wound infection and late hernias, but significantly higher incidents of late luminal stenosis.

In summary, compared to RYGB patients, AGB patients had significantly shorter hospital stays and a lower risk of early wound infection, late ulcers, late stenosis, and late hernia, but had a higher risk of late slippage or dilatation and late failed surgeries (conversions and reversals).

Compared to open surgery patients, those who received laparoscopic surgery had significantly shorter hospital stays and fewer incidents of early wound infection and late hernias, but had significantly higher incidents of late luminal stenosis and experienced more vomiting. No differences were observed in reoperation and revision rates between laparoscopic and open surgeries.

No trials reported the comparative incidence of myocardial infarction following bariatric surgeries.

Neither the incidence rates of the above-noted AEs nor the timeframe for their occurrence were reported in this review.

Evidence on Efficacy/Effectiveness

Weight loss

Weight loss is the primary outcome of interest in almost all included systematic reviews/HTAs. Weight loss outcome was measured by changes in weight, BMI, waist circumference or % excessive weight loss.

Dietary therapy/physical exercise

Description of the included studies

All three reviews[56-58] in this category reported weight loss/weight change outcome. Seventy-two RCTs were included in these reviews.

Methodological quality and limitations

The Cochrane review[57] reported that all 41 RCTs had some methodological weakness. Few studies reported the method for randomization and for the remaining studies it was not clear whether allocation to treatment groups were concealed. Blinded outcome assessment was performed in only three studies. Some studies suffered from potential selection bias. The sample size in many trials was small, and an intention-to-treat analysis was conducted in only two studies.

Effects

One review[56] that included 30 RCTs found that, as compared to standard care, lifestyle interventions significantly reduced body weight (−5.1 kg), body mass index (−1.8 kg/m^2), and waist circumference in overweight and obese adults. The average follow-up time of intervention was 3 years. Sensitivity analysis of high quality studies confirmed the results of the main analysis.

Table T.6 summarizes weight loss data in overweight and obese adults for the different comparisons assessed in the Cochrane review.[57]

Table T.6: Effects of dietary therapy/exercise on weight reduction[57]

Intervention/Comparator (Number of RCTs)	Weight (kg)	BMI (kg/m^2)
E versus no treatment (12)	E: −0.5 to −4.0 versus no treatment: −0.1 to +0.7	E: −0.3 to −0.7 versus no treatment: +0.3 to +0.4
E versus D (10)	E: 0.5 to 4.0 versus D: −2.8 to −13.6	E: −0.3 to 0.8 versus D: −0.3 to −3.3
E+D versus D (17)	E+D: −3.4 to −17.7 versus D: −2.3 to −16.7	E+D: −0.6 to −4.0 versus D: −0.3 to −4.0
High versus low-intensity E (8)	High-intensity E: −1.3 to −8.9 versus Low-intensity E: −6.3 to +0.1	Insufficient data available for analysis
High versus low-intensity E+D (7)	Increasing the intensity did not increase the weight loss if patients were on a diet.	Insufficient data available for analysis

Abbreviations: BMI = body mass index; D = dietary therapy; E = exercise; kg = kilogram; WL = weight loss

As shown in Table T.6, compared to no treatment, exercise resulted in a greater loss of weight or BMI. Compared to exercise, dietary therapy resulted in greater reduction in weight and BMI. Compared to dietary therapy alone, the combination of dietary therapy and exercise resulted in

greater reduction of weight and BMI. Increasing the intensity of exercise resulted in increased weight loss if participants were not on a dietary therapy; high-intensity exercisers lost 1.5 kilograms more than did low-intensity exercisers. However, if exercisers were also on a dietary therapy, high exercise intensity did not increase weight loss compared to low exercise intensity.

A subgroup analysis by gender did not show any relevant changes in pooled estimates. Analysis by age demonstrated that, as compared to the dietary-therapy-alone group, the pooled effect for weight reduction in the exercise and diet group was 1.6 kilograms more for participants with a mean age of 45 years or less, and 1.0 kilograms more for participants with a mean age greater than 45 years. No subgroup analysis was conducted based on BMI cutoffs.

The other review[58] of adults with a BMI greater than 25 kg/m^2 showed that the combination of dietary therapy and physical exercise resulted in a mean weight loss approximately 20% greater than that experienced by the dietary-therapy-alone group, both immediately after the intervention period and after 1 year follow-up; these difference were not statistically significant. In both groups, the magnitude of weight reduction immediately after intervention and after 1 year of follow-up is compatible with clinically significant benefits; that is, with a reduction in obesity-related risk factors.

However, adults in both groups regained 50% of their lost weight after 1 year. Adding exercise to diet did not produce better long-term maintenance of the weight losses.

Behavioural therapy

Description of the included studies

The only systematic review[15] in this category assessed 36 RCTs for the effects of various psychological interventions on weight loss in 3495 overweight and obese adults (Table T.F.1-2). The included studies were heterogeneous in terms of participants, interventions, outcome measures, and settings. Most studies had a follow-up period of less than 12 months. Studies with an attrition rate higher than 15% were excluded in this review.

Methodological quality and limitations

All 36 RCTs suffered from some methodological weakness. Only two studies reported the method of randomization. Blinding of investigators to outcomes was not clear or not done in all but one study. Sample sizes in many studies are small. Intention-to-treat analysis was performed in only three studies. Only one study met all the quality criteria.

Effects

Main findings from this systematic review are summarized in Table T.7.

Table T.7: Effects of behavioural therapy on weight reduction[15]

Intervention/Comparator (No. of RCTs)	Weight reduction
BT versus no treatment (10)	**Qualitative synthesis of four trials:** BT: −0.6 to −5.5 versus no treatment: −2.8 to +1.8 kg* **MA of the remaining six trials:** Study duration <12 months (5 trials): 2.5 kg WL more in BT than in no treatment (ss) Study duration >12 months (2 trials): 2.0 kg more WL in BT than in no treatment (ss)
High versus low-intensity BT (17)	**Qualitative synthesis of six trials:** Both groups lost weight overall High-intensity BT: −1.4 to −8.4 kg versus low-intensity BT: −0.9 to −10.5 kg * Greater WL in high-intensity BT than in low-intensity BT in four trials, while greater WL in low-intensity BT than in high-intensity BT in two trials **MA of the remaining 11 trials:** Study duration <12 months (10 trials): eight trials favoured high-intensity BT while two trials favoured low-intensity BT; 2.3 kg more WL in high-intensity BT than in low-intensity BT (ss) Study duration >12 months (one trial, follow-up 36 months): nss
BT + D/E versus D/E alone (8)	**Qualitative synthesis of two trials:** BT + D/E: −10 kg versus D/E alone: +0.5 kg* **MA of the remaining six trials:** Five trials favoured the BT + D/E group while 1 trial favoured the D/E alone group
Cognitive therapy versus BT (3)	In all three trials, BT groups lost more weight than cognitive therapy groups
Cognitive therapy versus placebo (1)	At 6 months: cognitive therapy: +1.35 kg versus placebo: +0.6 kg*
CBT + D/E versus D/E alone (2)	**MA of two trials:** Both groups lost weight overall; 4.9 kg more WL in CBT + D/E than in D/E alone (ss)
CBT versus no treatment (1)	At 6 months: CBT −0.6 kg versus no treatment +4.1 kg*
CBT versus BT (1)	At 6 months: CBT: −7 kg versus BT: −4.5 kg (ss) At 12 months: CBT: −10 kg versus BT −4.3 kg (ss)
CBT + D/E versus CBT alone (1)	At 3 months: CBT + D/E: −1.9 versus CBT alone: +0.5 kg*

* Statistical significance not reported.

Abbreviations: BT = behavioural therapy; CBT = cognitive behavioural therapy; D = diet; E = exercise; kg = kilogram; MA = meta-analysis; nss = not statistically significant; ss = statistically significant; WL = weight loss

As shown in Table T.7, behavioural therapy in combination with dietary therapy/physical exercise appeared to be more effective in reducing weight than dietary therapy/physical exercise alone. Adding a cognitive component to behavioural therapy appeared to be more effective in producing weight reduction than did behavioural therapy alone. Findings from the comparison between high-intensity and low-intensity behavioural therapy were inconsistent, but the majority of studies demonstrated greater weight loss with high-intensity behavioural therapy than with low-intensity behavioural therapy. At 6 and 12 months of follow-up, cognitive behavioural therapy seemed to be more effective than behavioural therapy.

Pharmacotherapy

Description of the included studies

One Cochrane systematic review and meta-analysis[20] assessed 30 double-blind, placebo-controlled trials (16 trials on orlistat, 10 on sibutramine, and four on rimonabant). Twenty-seven RCTs (16 on orlistat, seven on sibutramine, and four on rimonabant) were weight loss trials, in which antiobesity medications were used in conjunction with a weight loss diet for 1 to 4 years. Four orlistat weight loss trials and one rimonabant weight loss trial also contained a secondary weight maintenance year. The remaining three sibutramine trials were weight maintenance studies with follow-up periods of 1 and 1.5 years from the point of randomization. Because another review[59] focused on discontinuation rates of antiobesity drugs and the other review[60] only included 29 RCTs on orlistat, the following section will present information mainly from the Cochrane review.[20]

Methodological quality and limitations

Eligibility criteria were reported in all 30 studies. In all studies, co-interventions appeared to be equally applied to intervention and control arms. No details about double-blinding were provided in any study. Blinding of outcome assessors was not specified in any study.

The major methodological limitation was high attrition rates. The average attrition rate of the 16 studies on orlistat was about 30%, with rates ranging from 0% to 66%. In XENDOS (Xenical in the Prevention of Diabetes in Obese Subjects), the largest and longest orlistat trial, approximately 66% of patients dropped out over the 4-year follow-up period. The average attrition rate for studies on sibutramine was about 40%, with rates ranging from 11% to 51%. The average of attrition rate for studies on rimonabant was also about 40%, with rates ranging from 32% to 49%.

High attrition rates in both treatment and control groups compromised the internal validity of pharmacotherapy studies. Investigators attempted to address this limitation by using a last-observation-carried-forward analysis, which can bias results in either direction depending on the differential dropout rates in the treatment and control arms and the reasons for withdrawal. It is difficult to compensate for such high attrition rates by using any form of analysis.

Effects

Meta-analysis of RCTs that used orlistat, sibutramine, or rimonabant demonstrated that each drug resulted in average placebo-subtracted weight reductions of approximately 5 kilograms or less. Weight maintenance studies for each drug reported similar amounts of weight regain in both the medication treatment and the placebo study arms; therefore, the original difference in weight loss between groups was maintained.

Studies that enrolled patients with diabetes reported slightly smaller losses of weight with orlistat or rimonabant therapy, but this finding was not observed with sibutramine therapy.

Since no head-to-head comparison studies of the three drugs were assessed in the included systematic reviews/HTAs, the comparative effectiveness of the three drugs (and particularly of orlistat and sibutramine) remains to be determined.

Surgery

Description of the included studies

Two recent reviews, the CADTH review[38] published in 2010 and the Cochrane review[62] published in 2009, specifically examined the effects of bariatric surgery in obese patients.

The CADTH review[38] included 64 RCTs that enrolled severely obese adults (16 years or older) who had a BMI of 40 kg/m^2 or more, or a BMI of 35 kg/m^2 or more with at least one obesity-related comorbidity. Comparisons were made within the following five categories:

- surgery compared to another surgery or standard care (diet/exercise) (31 RCTs);
- laparoscopic surgery compared to open surgery (eight RCTs);
- band-related elements (eight RCTs);
- limb-related elements (five RCTs);
- different types of operative technical manoeuvers (12 RCTs).

For the purposes of this report, information is presented only from the first two of the above-noted categories, that is, studies that compared one surgery with another type of surgery or standard care (diet and exercise), or studies that compared laparoscopic surery with open approaches (see Appendix F, Tables T.F.1-3). Comparisons between different technical aspects were beyond the scope of this report.

The Cochrane review[62] included 23 RCTs; five of these overlap with RCTs assessed in the CADTH review.[38] Twenty RCTs compared different surgical procedures. Three RCTs compared surgery with non-surgical treatments; two of these compared surgery with conventional or medical treatment in patients with lower BMIs (30 to 35 kg/m^2 and 30 to 40 kg/m^2, respectively); these two RCTs were not included in the CADTH review.

This review also assessed three prospective cohort studies, including the Swedish Obesity Subject (SOS) study, which reported on long-term outcomes. To compensate for the paucity of RCTs with long-term outcomes, the results from the SOS study will be summarized separately in a later section.

Methodological quality and limitations

As reported in the CADTH review,[38] of the 31 RCTs that compared surgery to another surgery or standard care (defined as diet/exercise), 39% of trials reported adequate concealment of treatment assignments. Of the 32% of trials that described the method of randomization, 20% described a suboptimal method of randomization (for example, use of hospital numbers or date of admission). Although the surgical trials are difficult to blind, 10% of trials attempted to blind patients or outcome assessors to treatment assignment. Twenty-three per cent of trials reported sample size calculations and 13% of trials performed intention-to-treat analysis. About one-third of trials adequately reported rates of and reasons for lost to follow-up cases; in 20% of these trials, 10% or more of patients were lost to follow-up. The majority of studies did not report a source of funding.

Of the eight RCTs that compared laparoscopic surgeries to open surgeries, six trials reported adequate concealment of intervention assignments. Two trials described an adequate method of randomization. Two trials blinded participants and outcome assessors to treatment assignments. Three trails reported sample size calculations and four trials conducted an intention-to-treat analysis. Six trials adequately described lost to follow-up (frequencies and reasons by intervention group); in

one of these trials, more than 10% of patients were lost to follow-up. None of the eight trials reported a source of funding.

The Cochrane review[62] reported that fewer than half of the 23 RCTs described adequate sequence generation and only five had adequate concealment of allocation. The risk of bias in many trials was uncertain.

Effects

The CADTH review[38] reported weight loss results at 1-, 2- and 3-to-5-year follow-up periods, as shown in Table T.F.1-4 (see Appendix T.F).

When comparing a surgical procedure with standard care (diet and exercise) or another surgical procedure at 1-year follow-up, a network analysis of 15 RCTs showed the following ranking in effects for reducing BMI, from most to least efficacious: jejunoileal bypass (JB), loop gastric bypass, mini-gastric bypass, biliopancreatic diversion (BPD), sleeve gastrectomy, Roux-en-Y gastric bypass (RYGB), horizontal gastroplasty (HG), vertical banded gastroplasty (VBG), adjustable gastric banding (AGB), and standard care.

Network analysis indicated that RYGB produced significantly greater decreases in BMI from baseline than did AGB and standard care; direct evidence supported the findings of network analysis for RYGB versus AGB, although statistical heterogeneity was large.

At two-year follow-up, a network analysis of 10 RCTs indicated that RYGB produces significantly greater decreases in BMI than do VBG and AGB. Direct evidence was available and supportive for RYGB versus VBG, and for RYGB versus AGB. No data on BMI were available at 2 years for loop gastric bypass, sleeve gastrectomy, or standard care.

At 3- to 5-year follow-up, a network analysis of seven RCTs showed similar ranking of the effectiveness to the ranking at 1 and 2 years: JB, RYGB, VBG, and AGB. RYGB produced significantly greater decreases in BMI from baseline than did AGB. Direct evidence was available and supportive for RYGB versus AGB. No other result from network analysis was significant. No data were available for this period with regard to AGB with omentectomy or sleeve gastrectomy.

For comparison between open and laparoscopic approaches, at one-year follow-up, results from five RCTs indicated a small but significantly greater decrease in BMI in the laparoscopic surgery group than in the open surgery group.

At 3- to 5-year follow-up, analysis of RCTs did not reveal any statistically significant difference in BMI reduction between open surgery and laparoscopic surgery.

The two additional RCTs included in the Cochrane review[62] compared laparoscopic adjustable gastric banding with conventional treatment (lifestyle change) or medical treatment, and demonstrated significantly greater weight reduction at two to three years after surgery than at 2 to 3 years after non-surgical treatment.

Risk factors/comorbidities

Dietary therapy/physical exercise

A review[56] of 30 RCTs found that, as compared to standard care, lifestyle interventions significantly reduced blood pressure, blood lipids, and blood glucose in overweight and obese adults. The average

follow-up time was 3 years. Results from the sensitivity analysis of high quality studies confirmed the results of the main analysis.

A subgroup analysis in overweight and obese adults with impaired glucose tolerance showed that as compared to standard care (not defined), lifestyle interventions significantly reduced body weight and cardiovascular risk factors with the exception of low-density lipoprotein (LDL) and HbA1c levels.

The results from another review[57] suggested that physical exercise was associated with an improvement in cardiovascular disease risk factors (see Appendix T. F, Table T.F.3-1). However, the effect of physical exercise on disease endpoints—such as myocardial infarction, cerebrovascular accident, and type 2 diabetes—could not be demonstrated.

Behavioural therapy

The review[15] for behavioural therapy noticed that the effects of psychological intervention on secondary outcomes (for example, biological markers) were examined in only a small number of studies. Reductions in blood pressure, fasting plasma glucose, and serum cholesterol and triglycerides were found to be associated with weight loss. Quality of life and well-being outcomes were not reported.

Pharmacotherapy

One review[20] examined the effect of pharmacotherapy on risk factors and comorbidities. Compared to placebo, orlistat significantly reduced total cholesterol, LDL-cholesterol, blood pressure, and diabetes incidence, and improved glycemic control, but slightly lowered high-density lipoprotein (HDL) levels. Compared to placebo, sibutramine significantly improved HDL-cholesterol and triglyceride levels. Compared to placebo, rimonabant significantly improved HDL-cholesterol, triglyceride, and blood pressure levels, and improved glycemic control in patients with diabetes.

Both orlistat and rimonabant improved glycemic parameters in patients with diabetes, while sibutramine did not. The underlying reasons for and the clinical significance of these findings are unclear.

Surgery

In comparison of one surgical procedure with another or with standard care (diet and exercise), six RCTs reported resolution of or improvements in comorbidities. It should be noted that patients without pre-existing comorbidities at baseline were excluded in the analysis. All risk differences were not statistically significant. No RCTs reported the incidence of knee or hip replacement.

One small study with 13 patients reported a significantly greater resolution of diabetes with open surgery as compared to laparoscopic surgery. Another small study with 22 patients demonstrated a significantly greater resolution of dyslipidemia in the laparoscopic group compared resolution in the open surgery group.

Health-related quality of life (HrQoL)

One systematic review[65] specifically examined the effect of weight loss interventions—including behavioural therapy, pharmacotherapy, and surgical therapy—on HrQoL. Within the 34 RCTs (22 on behavioural therapy, seven on pharmacotherapy, four on surgical therapy, and one on acupuncture), various HrQoL measures were used (see Table T.8).

Table T.8: HrQoL measures used in the 34 RCTs[65]

Generic HrQoL measures	Obesity-specific measures	Non-obesity-specific measures
SF-36	Binge Eating Scale	Beck Depression Inventory
Visual Analog Scale	Eating Disorder Inventory	State-Trait Anxiety Inventory
General Well-being Scale	Three Factor Eating Questionnaire	Rosenberg Self-Esteem Scale
General Health Rating Index	Impact of Weight on QoL	Perceived Stress Scale
Sickness Impact Profile	Scale of Obesity Problems	Profile of Mood States

Abbreviations: HrQoL = health-related quality of life; QoL = quality of life; RCTs = randomized controlled trials; SF = short form

This review assessed methodological quality of the included RCTs. Concealment of randomization was explicitly stated in only four RCTs. Twenty RCTs did not indicate whether or not the investigation team was blinded to the treatment arm. Twenty-two RCTs reported lost to follow-up, with the most common reason for loss to follow-up being patient dropout. Overall, an average of 21% of the original sample was lost to follow-up and a higher percentage was lost in the control group (23%, with a range from 0% to 65%) than in the intervention group (19%, with a range from 0% to 41%).

Thirty-three RCTs conducted intention-to-treat analyses. In 13 RCTs, multivariate analyses of HrQoL outcomes were conducted, but only three RCTs reported results, both controlled and uncontrolled, for weight change in the analysis of HrQoL.

Another methodological issue is that many of the RCTs lack statistical adjustments for multiple comparisons. Although HrQoL was only one of several outcomes measured in these trials, only eight RCTs controlled for multiple comparisons in the HrQoL analyses.

The studies showed that weight-loss treatments appeared to affect HrQoL among different dimensions, and that these effects varied over time. Treatment effects on HrQoL, as measured by generic measures, were positive for at least one domain in every time period, but the domain varied across studies. HrQoL assessed by generic measures was not consistently improved; only 9 of 34 RCTs showed QoL improvements in one or more domains. For the two types of condition-specific measures, results were inconsistent for all measures except for the obesity-specific scale of obesity problems. Of the 11 RCTs that included obesity-specific measures, six RCTs showed positive treatment effects; however, only two of the 15 RCTs that used non-obesity-specific measures showed positive treatment effects. A meta-analysis of eight RCTs that used the Beck Depression Inventory did not find significant improvement in depressive symptoms in the intervention group as compared to the control group.

The CADTH report[38] also examined the effect of bariatric surgeries on HrQoL. One trial of 197 patients used a generic instrument—the Medical Outcomes Study 36-Item Short Form (SF-36), to measure HrQoL. At one-year follow-up, no significant differences across all eight domains were found between AGB and RYGB. Another trial used SF-36 to measure HrQoL in patients treated with laparoscopic surgery or open surgery. Compared to open surgery, laparoscopic surgery received significantly better scores in three of the eight domains (that is, in physical functioning, social functioning, and mental health).

Two trials with 160 patients measured HrQoL using an obesity-specific measure—the Gastrointestinal Quality-of-Life Index. One trial found a significantly better QoL in the RYGB

group as compared to the VBG group. The other trial did not find any significant difference between mini-gastric bypass patients and RYGB patients. Two trials used another obesity-specific measure—the Moorehead-Ardelt instrument—but none of the five domains showed significant results.

Of the three reviews on dietary therapy/physical exercise, while two reviews[56,58] did not look at HrQoL outcome, the third review[57] did not identify any data on HrQoL among included trials. The review[15] on behavioural therapy did not find any data on HrQoL. The three reviews[20,59,60] of antiobesity medications did not examine the effects of drugs on HrQoL.

Mortality

No data were available on the effect of anti-obesity drugs on mortality or cardiovascular morbidity.

The CADTH report[38] assessed overall mortality following bariatric surgeries. In the comparison of one surgery with another surgery or standard care (diet and exercise), an analysis of 23 RCTs with follow-up of less than five years found no significant difference in mortality risk (30-day mortality, or mortality during follow-up) between any pair of interventions.

An analysis of seven RCTs with 574 patients showed that the risk difference of death between laparoscopic and open surgeries was not significant.

Long-term outcomes

One systematic review[67] specifically examined the effect of bariatric treatment strategies on long-term overall mortality. Eight prospective studies with a follow-up period of 5 years or longer were included in this review (see Table T. F.4). This review assessed the effects of both intentional and unintentional weight loss, but did not clearly and consistently describe bariatric interventions used in the eight primary studies.

Results for women only

Two studies reported the mortality risk with weight loss for white women in the United States. One study showed significantly increased mortality for all overweight or obese women with weight loss. However, because the reference group was those of normal weight with small weight loss, the two groups were not comparable. The other study involved women who were at least overweight (BMI > 25 kg/m^2). Information about weight loss intention and obesity-related diseases was obtained from each person. The study showed that, for those with obesity-related diseases and the intention to lose weight, the mortality risk significantly improved in women who lost 20 pounds or more within 1 year, compared to those without weight change. However, for those who lost less than 20 pounds and who took more time (1 year or longer) to lose the weight, no significant difference in mortality risk was found between the weight loss group and the group having no weight change.

Results for men only

Three studies examined the long-term effect of weight loss in men. One study included men who were at least overweight (BMI > 25 kg/m^2). The intention of weight loss and the presence of comorbidities were considered separately. Compared to the weight-stable group, intentional weight loss of 20 pounds or more for longer than 1 year was detrimental for all men. Unintentional weight loss was also marginally detrimental. However, intentional weight loss of less than 20 pounds in men with comorbidities did not show any detrimental effects.

Another study also reported that, when compared to the weight-stable group, weight loss was detrimental for non-cancer mortality. However, the intentionality of weight loss was not reported. The third study conducted an analysis on overweight men and adjusted for several variables to control for demographic variations and the probably of underlying diseases. This study showed that mortality risk improved in the intentional weight loss group as compared to the weight-stable subgroup; however there was no difference for those with comorbidities or who lost weight unintentionally.

Overall, the impact of weight loss on mortality in men is not clear. A meta-analysis of all the studies using a random effect model demonstrated that, as compared to the reference group of overweight but weight-stable men, the overall effective weight loss was shown to be slightly detrimental. When studies with the outcome of intentional weight loss were combined using a fixed effect model, the hazard ratio became non-significant.

Results for women and men combined

Three studies—one conducted in the United States, one in Canada, and one in Finland—examined the impact of weight loss on mortality risk in overweight or obese men and women. All three studies reported mortality for a similar time period, from the mid 1980s to the beginning of the new millennium. The participants in the US study were about a decade older than those in the other studies, hence the average age varied slightly between the studies.

The US study adjusted their analysis for more than 13 variables and also attempted to account for known underlying diseases. For those who claimed to be trying to lose weight, the effects were marginally beneficial if they remained weight-stable or lost small amounts of weight. In contrast, the Finnish study found that for those with intentional weight loss, the effect of weight loss was detrimental. A meta-analysis of these two studies indicated no significant difference between the groups.

The Canadian study examined the impact of bariatric surgery on mortality in morbidly obese patients. Of the 1035 patients who received surgery, seven patients (0.7%) died as compared to those under standard treatment, where 354 of 5746 patients (6.2%) died. Usually surgery is only considered for those to whom obesity is life-threatening. Consequently, the surgical group does have a substantially reduced mortality risk as compared to a comparable control group who did not undergo surgery. Similarly, the effects of the surgery are difficult to disentangle from any weight loss benefits for this subgroup.

Factors that may have an impact on the outcomes

Gender differences, the presence of comorbidities, and the notion of intentionality of weight loss have been identified as important factors that may have impacted outcomes. With respect to gender, for studies with men only and with men and women combined, the effects of weight loss on mortality were inconsistent regardless of intentionality. On the other hand, one study demonstrated benefits from weight loss in overweight or obese women with pre-existing comorbidities. However, patients with diabetes, regardless of gender, benefited from intentional weight loss.

Methodological limitations

Benefits of weight loss on all-cause mortality for overweight or obese patients are meager. The most important explanations are intentionality, self-reporting of weight loss, and the time lapse between the last recorded weight loss measurement and the mortality outcome.

The authors identified many methodological limitations in the primary studies that related to either study design or statistical issues. These, in turn, had an impact on their findings and on the conclusions drawn in their review.

Summary of the SOS study

The SOS study, a large prospective multicentre cohort study with matched concurrent controls, investigates the long-term effects of bariatric surgery on comorbidities and mortality rates. The overall aim of the SOS study was to address the apparent discrepancy between the effects of weight loss on risk factors and the hard end points reported in previous studies.[68]

The Cochrane review on bariatric surgery[62] presented findings extracted from more than 20 publications of the SOS study published between 1997 and 2008. These findings, supplemented by information from two other recent publications,[69,70] are presented in Appendix G (see Table T.G.1-4) and summarized below.

Study participants and interventions

Four thousand forty-seven patients, aged 37 to 60 years, and having a BMI ≥ 34 kg/m^2 for men and ≥ 38 kg/m^2 for women (a cut-off that was chosen before the consensus on BMI cut-off in 1991), were recruited between September 1987 and January 2001. Patients were allocated to either the bariatric surgery group (n = 2010) or a contemporaneously matched, conventionally treated obese control group (n = 2037). Surgical procedures included VBG, adjustable or non-adjustable gastric banding, or gastric bypass. Conventional treatment was not standardized, and ranged from sophisticated lifestyle intervention and behavioural modification to no treatment.

The SOS study is not an RCT. Patients were matched according to sequential treatment assignment. The following 18 variables were matched between the groups: gender, age, weight, height, waist and hip circumferences, systolic blood pressure, serum cholesterol and triglyceride levels, smoking status, diabetes, menopausal status, four psychosocial variables with documented association with the risk of death, and two personality traits related to treatment preferences. The investigators had no influences on the computerized matching process.

The SOS study involved an interval of about nine months between matching of controls and the start of surgical treatment that led to significant differences in weight and other possible risk factors. Compared to controls, patients in the surgical group were younger, had a higher prevalence of hypertension, higher BMI, blood pressure, and energy intake at the time of surgery.

Mean baseline energy intake was higher among the surgically treated patients (2882 kcal/day) than among the controls (2526 kcal/day). The baseline adjusted energy intake was significantly lower in the surgery group than in the control group over the 10-year period. Similarly, the fraction of patients who were physically active during their leisure time was higher in the surgery group over the 10-year period, and the fraction of those who were physically active during work time was higher in the surgery group for the first six years after the intervention.

On 1 November 2005, the vital status was known for all but three of the initial study participants; the follow-up rate with respect to vital status on the date of analysis was 99.9%. At 2-, 10-, and 15-year follow-up, participation rates in the surgery group were 94%, 84%, and 66%, respectively, and the corresponding participation rates in the control group were 83%, 75%, and 87%, respectively. As of February 2008 the follow-up ranged from 6 to 20 years.

Weight reduction

The mean weight change of the control group was less than ±2% over 15 years of weight recording. Maximum weight losses in the surgical group were observed after 1 to 2 years. After 10 years, the weight reduction from baseline was stabilized at 25% with gastric bypass, 16% with VBG, and 14% with gastric banding.

HrQoL

The SOS study assessed HrQoL using several measures, including:

- current health perceptions from the General Health Rating Index
- social interaction from the Sickness Impact Profile
- overall mood from the Mood Adjective Check List
- the obesity-related problems scale and the Hospital Anxiety and Depression Scale

At baseline, the patients in the surgery group had generally worse HrQoL than those in the conventional treatment group. These differences may reflect the significant differences in BMI and prevalence of hypertension that developed between the matching of controls and the start of treatment, or may indicate bias in the selection of patients for surgery.

At 2-year follow-up of 974 patients, those receiving gastric surgery had significant improvements in all HrQoL measures as compared to patients receiving conventional treatment. These changes were significantly related to the magnitude of the weight lost and may have been expected, given that the patients in the surgical group, as compare to the controls, had significantly higher BMIs at the time of treatment.

A more recent report of 1276 patients found that improvements in HrQoL, which peaked 1 year after surgery, were followed by a gradual decline or improvement between 1 and 6 years, and then relatively stable improvement between 6 and 10 years follow-up. All HrQoL measures were improved at 10 years compared with baseline for the surgery group, but for the conventional group some had improved while others had worsened.

Risk factors/comorbidities

At 2- and 10-year follow-up, rates of recovery from diabetes, hypertriglycemia, low level of HDL cholesterol, hypertension, and hyperuricemia were more favourable for the surgery group than for the control group. No difference was observed in hypercholesterolemia levels between the two groups.

Results from the SOS study indicate that the long-term effects (that is, at 10 years) of maintained weight loss on risk factors cannot always be estimated from short-term (up to 2 years) observations.

Cancer

Bariatric surgery was associated with reduced cancer rates in obese women but not in obese men.[70]

Long-term mortality

At 10-year follow-up, bariatric surgery, as compared to conventional treatment, was associated with a greater reduction in overall mortality.

The investigators pointed out that the effects of weight loss on mortality rate cannot be evaluated separately within the two study groups, given the limits of the study's statistical power. Therefore, it cannot be determined whether the favourable survival effect of bariatric surgery is explained by weight loss or by other beneficial effects of the surgical procedures.

Findings from other SRs that assessed multiple treatment strategies

One comprehensive systematic review/HTA,[2] published in 2004, assessed the evidence on the safety and efficacy/effectiveness of various bariatric treatment strategies—including dietary therapy, exercise, behavioural therapy, pharmacotherapy, and surgery—in patients with a BMI of 28 kg/m^2 or greater. A number of articles have been published on different outcomes from this review; these are listed in the exclusion table in Appendix T.B. The results from the original review that assessed 84 RCTs are briefly summarized below.

Weight loss, risk factors/comorbidities

Dietary therapy

Low-fat diets (which included 600 kcal/day deficit diets) were associated with the prevention of type 2 diabetes and improved control of hypertension. These diets were associated with a weight loss of approximately 5 kilograms after 12 months and an improvement in risk factors, with weight loss continuing for 3 years. Insufficient evidence was available to assess the putative benefits of low-calorie or very-low-calorie diets.

Adding physical exercise to dietary therapy

The addition of an exercise program to dietary therapy was associated with improved weight loss and risk factors for at least 1 year. Studies that combined low-fat diets and exercise, with or without behavioural therapy, suggested improved control of hypertension and type 2 diabetes.

Adding behavioural therapy to dietary therapy

The addition of a behavioural therapy program to dietary therapy was also associated with improved weight loss for at least one year.

Adding exercise and behavioural therapy to dietary therapy

It was unclear whether both exercise and behavioural therapy together further enhanced the effect of dietary therapy.

Adding medications to dietary therapy

Use of orlistat was associated with a weight loss of approximately 3 kilograms after 2 years, and with beneficial changes in risk factors. Sibutramine was associated with a weight loss of 3 kilograms after 18 months for people on a maintenance diet and with beneficial changes in risk factors except for diastolic blood pressure.

In addition to the RCTs on short-term outcomes, this review also included 37 observational studies for long-term outcomes.

Mortality

For women with obesity-related comorbidities, intentional weight loss, irrespective of the amount of weight lost, was associated with risk reduction of death, death from cardiovascular disease, cancer,

and diabetes related deaths. Weight loss appeared to be more beneficial if it was achieved within 1 year.

For men with general illnesses, intentional weight loss appeared to be associated with a reduced risk of diabetes-related death, but did not demonstrate any effect on mortality caused by cardiovascular disease; cancer mortality appeared to be increased.

Diabetes

Long-term weight loss was associated with a risk reduction for the development of type 2 diabetes and an improved glucose tolerance in men and women, especially after bariatric surgery.

Hypertension

A weight loss of 10 kilograms was associated with a fall in total cholesterol of 0.25 mmol/L and a decrease in diastolic blood pressure of 4 mmHg. A weight loss of 10% was associated with a decrease in systolic blood pressure of 6 mmHg.

Psychological well-being

Two studies showed that weight loss improved the psychological status of people who suffer from obesity.

Sleep apnea

Results from three studies indicated that weight loss was associated with an improvement in sleep apnea and related syndromes. However, the number of people who were available at follow-up was small in two of the three studies.

Summary

In summary, this review found that olistat, sibutramine, and metformin appeared to be beneficial for the treatment of adults with obesity. Physical exercise and/or behavioural therapy appear to improve weight loss when added to dietary therapy. Low-fat diets with physical exercise, with or without behavioural therapy, are associated with the prevention of type 2 diabetes and hypertension. Furthermore, long-term weight loss was also associated with a reduced risk of developing diabetes and a potential protection against cardiovascular diseases.

Another systematic review[64] particularly examined studies that were conducted in primary healthcare settings in the United States. Interventions were classified into three categories: (1) primary care provider counseling alone, (2) primary care provider counseling plus pharmacotherapy; and (3) collaborative obesity care (treatment delivered by a non-physician provider).

Of the 10 included primary studies, eight studies provided low- to moderate-intensity (defined by monthly contact) counseling, as defined by the US Preventive Services Task Force. Only two studies used high-intensity intervention (that is, at least two visits per month for the first three months). Weight loss in the active treatment arms of the three categories ranged from 0.1 to 2.3 kilograms, 1.7 to 7.5 kilograms, and 0.4 to 7.7 kilograms, respectively.

Another systematic review[66] also examined the evidence on pharmacotherapy and bariatric surgeries. Among people with a BMI of 30 kg/m^2 or greater, intensive counseling and behavioural therapy for obesity is effective in reducing mean weight by approximately 3 to 5 kilograms after 1 year. Pharmacotherapy with sibutramine or orlistat is also effective in reducing mean weight by

approximately 3 to 5 kilograms. For people with a BMI of 35 kg/m^2 or greater, surgical therapy leads to substantial reductions in weight of 20 kilograms or more.

Both counseling-based and drug-based maintenance interventions were helpful in retaining weight loss. Reduction of 5% to 7% of body weight is associated with lower incidences of diabetes, reduced blood pressure, and improved dyslipidemia. Greater weight loss has been linked with greater improvements in glycemic control and lipids in limited surgical outcomes data.

In terms of adverse events, potential harms of counseling-based interventions were not reported. Sibutramine is sometimes associated with increased blood pressure (mean increase of 0 to 3.5 mmHg) and orlistat causes gastrointestinal distress in 15% to 37% of patients taking the drug. Surgical procedures lead to peri-operative mortality in less than 1% of patients, and over a 5-year period up to 25% of patients require a reoperation.

Clinical Practice Guidelines/Position Statements

Several clinical practice guidelines addressed the potential role of various bariatric treatment strategies for patients with obesity. Clinical decision on selecting appropriate treatment strategies is based on BMI and/or waist circumference, risk factors and comorbidities (see Table S.4 in S-section). The majority of the documents used the WHO BMI obesity classification. No document was found that used the Edmonton Obesity Staging System.[55]

Table T.9 presents an algorithm of treatment interventions based on patients' gender, BMI, waist circumference, and comorbidities.

Table T.9: European clinical practice guidelines, 2008[4]

BMI (kg/m^2)	Waist circumference (cm)		Comorbidities
	Men < 94 Women < 80	Men ≥ 94 Women ≥ 80	
25 to 29.9	L	L	L ± D
30.0 to 34.9	L	L ± D	L ± D
35 to 39.9	L ± D	L ± D	L ± D ± S
≥ 40	L ± D ± S	L ± D ± S	L ± D ± S

Abbreviations: L = life style interventions (dietary therapy and physical exercise); D = drugs; S = surgery

Discussion

Assessment limitations

The T-section of this report suffers from several methodological limitations.

First, this report only included systematic reviews/HTAs of RCTs as the primary source of evidence for the safety and efficacy of bariatric treatment strategies. RCTs published after the search dates (2005 for dietary therapy/exercise, 2003 for behavioural therapy, 2008 for pharmacotherapy, and 2009 for surgery) of the most recent reviews were not searched due to time constraints. However, most of the included systematic reviews/HTAs were published within the last 5 years. For example, the CADTH review on bariatric surgeries was conducted in 2010, which limited the possibility that more recent studies on newer surgical procedures (for example, sleeve gastrectomy) were missed.

Second, qualitative research evidence was not sought to address the question as to why various treatment strategies may not be effective or why their effects were smaller than expected.

Third, although this report only included systematic reviews/HTAs of RCTs, results from a pivotal non-RCT study (the Swedish Obesity Subject study) described in one systematic review[62] were also presented to compensate for the lack of evidence in RCTs on long-term outcomes. However, no attempt was made to include long-term outcomes from other non-randomized controlled trials.

Finally, although findings from program evaluation studies may be helpful in addressing some of the questions from Alberta Health and Wellness, a literature search was not done specifically to locate program evaluation studies. Furthermore, due to time constraints, a search was not conducted for specific clinical practice guidelines (for example, for dietary therapy, exercise therapy, pharmacotherapy, or surgery).

Methodological issues of the primary studies

In general, RCTs assessed in the included systematic reviews/HTAs were of poor quality. Few described the randomizing process or provided sufficient information about the blinding of participants, providers, and outcome assessors. Intention-to-treat analysis was conducted very rarely, probably due to the high dropout rates.

In pharmacotherapy studies, the available evidence was limited in two major ways: internal validity was limited by high attrition rates and external validity was limited by the enrolment of highly selected patient populations.[20]

A recent study using administrative data from British Columbia, Canada, found poor adherence rates with orlistat and sibutramine treatment in a 'real word' setting. Among approximately 3500 users of sibutramine and 17,000 users of orlistat, persistence rates were less than 10% at 1 year and less than 2% at 2 years. Overall, data from within and outside of the clinical trial setting suggest that a lack of adherence to therapy is a major limiting factor to the efficacy and effectiveness of antiobesity drug therapy.[20]

Another important issue associated with pharmacotherapy studies is the use of two different types of study designs—'weight loss' studies and 'weight maintenance' studies. Weight maintenance studies examine the impact of the drug on weight after a weight loss induction phase that uses a low-calorie or very-low-calorie diet. However, weight maintenance studies consistently tend to include the weight losses achieved during the induction phase in the overall weight changes reported for each study arm. In addition, many weight loss trials included a short-term 'run-in' phase during which patients were treated with placebo and diet. Patients unable to achieve a predefined amount of weight loss were excluded from the studies. As a consequence, this method blurs the distinction between weight loss and weight maintenance.

Another limitation is that many weight loss studies reported only the mean group weight changes, but not the frequency of expected responses to the intervention; therefore, they provided no information on how many people actually attained a clinically significant weight loss.

Impacts of patient characteristics on outcomes

Age/gender

In a review[57] of dietary therapy/physical exercise interventions, a subgroup analysis by gender did not show relevant changes in pooled estimates. Analysis by age demonstrated that the pooled effect

for studies with a mean age of participants of less than 45 years was a reduction in weight of 1.6 kilograms in the exercise and diet group as compared to the diet alone group. The pooled effect for studies with a mean age of participants of greater than 45 years was a reduction in weight of 1.0 kilograms in the exercise and diet group as compared to the diet alone group. However, no subgroup analysis was conducted based on the BMI cut-offs.

BMI

In general, patients with a BMI less than 30 kg/m^2 were selected for lifestyle interventions, behavioural therapy, and pharmacotherapy, while patients with a BMI greater than 35 kg/m^2 (severe obesity) were considered for bariatric surgery. Some reviews included both overweight and obese patients, but no sub-group analysis was conducted for different BMI cut-offs.

Presence of comorbidity

In a review[56] of lifestyle interventions, a subgroup analysis was conducted in overweight and obese patients with impaired glucose tolerance in the prevention of diabetes. Compared with standard care (not defined), lifestyle interventions significantly reduced body weight and cardiovascular risk factors but had limited impact or no impact on low-density lipoprotein and HbA1c levels.

Motivation/compliance

High drop-out rates are a major problem with obesity studies and may contribute to a substantial variation in outcomes such as weight loss among participants.[7]

Patients participating in obesity clinical trials usually achieve better results than non-trial participants, as they are more motivated and receive greater supervision and encouragement. Thus, results in clinical practice will inevitably be less favourable and more variable than those in a trial setting.[7]

A number of factors, listed in Table T.10, have been identified that may impact clinical outcomes. Strategies that address these factors may help achiving longer-term weight loss and weight maintenance.[71]

Table T.10: Factors underlying weight regain after weight loss

Pre-treatment	Post-treatment
Older age	Weight reduction greater than 15% to 30%
High number of previous diets	Early weight regain
High maximum or baseline body weight	Not responding to early weight regain
Frequent binge eating	High levels of perceived hunger
"All or nothing" thinking	Dissatisfaction with weight loss
Lack of dietary restraint	Lack of dietary restraint
Low level of exercise and diet self-efficacy	Frequent emotional eating
Low motivation	Frequent binge eating
	Diet high in calories, fats, and sugars
	Decreased frequency and level of exercise
	Television viewing more than two to four hours/day

Source: Ulen et al., 2008[71]

In the present report, none of the included systematic reviews/HTAs specifically reported on patient motivation and compliance with treatments. In the pharmacotherapy studies, patients eventually selected for randomization were those who complied with the treatment and lost the required weight during the run-in phase.

Gaps in evidence and future research

A number of research gaps and suggestions for future research were identified from the included systematic reviews/HTAs.

General

- Determining the optimal duration of treatment.
- Identifying program patterns that are more effective in the long-term.
- Verifying the reasons for dropouts.
- Including outcomes such as frequency of pre-established responses to interventions.
- Describing the randomization and blinding processes and including intention-to-treat analyses.
- Analyzing the effect of treatment assignment on health-related quality of life, with and without adjustment for weight change, to determine the true relationships among obesity treatment, weight loss, and health-related quality of life.
- Conducting subgroup analyses by age, gender, and initial weight to explore effect size differences.
- Investigating issues of intentionality, type of weight loss, and objective measurements of weight changes in well-designed prospective studies, to assess the real impact of weight loss on all-cause mortality in the long-term, for overweight/obese populations.

Dietary therapy/physical exercise

- Adapting lifestyle interventions based on the need of each patient population, taking into consideration different dietary and physical activity backgrounds.
- Examining additional outcomes to evaluate possible associations—behavioural and physiological factors, among others—as well as to explore differences between individuals that regained weight and those who maintained weight loss.

Pharmacotherapy

- Conducting longer and more scientifically rigorous studies of antiobesity drugs that are powered to examine endpoints such as mortality and cardiovascular morbidity.
- Determining the long-term effect of antiobesity drugs on health outcomes.
- Conducting head-to-head comparisons to determine the relative efficacy of different drugs.
- Examining whether combinations of drugs promote greater weight loss than use of individual drugs.

- Examining whether use of any of the antiobesity drugs combined with more aggressive behavioural interventions and dietary therapies would be more effective than the results seen in the RCTs to date, in which many of the dietary interventions were modest.

Surgery

- Consulting good-quality, long-term RCTs, which compare different operative techniques for obesity that include an assessment of patient quality of life.
- Reporting RCT data comprehensively—ideally including more than one widely used outcome measure such as weight, per cent excess weight loss or BMI, and details of the standard deviation about the mean for each outcome reported—to enable future meta-analysis.
- Consulting good-quality RCTs to provide clinical effectiveness and quality of life evidence for adults with Class I or Class II obesity.
- Consulting reports on the resolution/development of comorbidities so that the potential benefits of early intervention can be assessed.
- Identifying a core set of important adverse outcomes so that a standardized approach to describing adverse outcomes can be developed.
- Consulting good-quality, long term cohort studies to:
    - identify re-operation for late complications following all bariatric procedures and conversion to gastric bypass for patients initially managed with gastric banding;
    - identify the duration of remission, following surgical or non-surgical management, of comorbidities associated with obesity to determine whether this is primarily associated with durability of weight loss or with other prognostic factors;
    - identify providers at different stages of the learning curve and to document the impact of experience on the safety, effectiveness, and efficiency of surgery.

Implementation consideration

When implementing a weight management program, some factors identified from the included systematic reviews/HTAs should be taken into consideration.

Dietary therapy/physical exercise

A central issue in the effectiveness of a lifestyle intervention program is adherence; poor adherence to a given lifestyle change protocol might explain why RCTs often fail to demonstrate an association between lifestyle interventions and weight maintenance.

Programs to treat overweight or obese individuals should explore the best strategies for promoting prolonged changes in lifestyle leading to caloric adequacy and an increase in physical activity. Findings from qualitative research may help to address this issue.

Behavioural therapy

Because increased intensity of behavioural therapy appears to improve the effects of the intervention, weight management programs containing behavioural therapy components should offer more behavioural strategies and more frequent clinical contacts for a longer duration.

Pharmacotherapy

Pharmacotherapy can be offered to overweight or obese patients who have failed to achieve or maintain their weight-loss goals through dietary therapy and physical exercise. The decision to prescribe antiobesity drugs requires a careful assessment of the risks and benefits. The average amount of weight lost is modest, and most patients will remain significantly obese or overweight even with drug therapy. Furthermore, currently-available antiobesity drugs are costly, each drug has associated adverse effects, and the ultimate effect on cardiovascular morbidity and mortality remain unknown.

Since near-maximal weight loss was usually achieved by three to six months in most trials, drug therapy should be discontinued at this point if significant weight loss has not occurred.

There appear to be no definitive data demonstrating that one particular drug is clearly more efficacious than another, therefore, initial drug selection can be guided by factors such as (1) patient preference, (2) local cost, availability, and drug plan coverage, and/or (3) patient comorbidities and the adverse effect profiles.

Bariatric surgery

Of the three surgical procedures provided in Alberta, RYGB appears to be more effective than AGB in reducing weight, but is associated with a higher risk of adverse events. Clinical research evidence was limited for sleeve gastrectomy. Preferences of the patient and experiences of the surgeon may influence the choice of surgery.

Conclusion

Evidence from randomized controlled trials assessed in the 14 recently published systematic reviews/HTAs suggests that all dietary therapy, physical exercise, behavioural therapy, pharmacological therapy, and bariatric surgery are effective, to varying degrees, in reducing weight in overweight or obese adults over the short term.

Information is lacking on the adverse events associated with the use of dietary therapy, physical exercise, and behavioural therapy. Of the two antiobesity drugs approved by Health Canada for long-term use, gastrointestinal tract side effects are common, with orlistat and sibutramine increasing heart rate and blood pressure. Of the three surgical procedures currently performed in Alberta, evidence for sleeve gastrectomy was limited. Compared to RYGB, AGB is associated with shorter hospitalization, and a lower risk of early wound infection, late hernia, and stenosis, but a higher risk of late slippage or dilatation and late reoperation.

Compared with standard care, dietary therapy significantly reduced body weight, body mass index, waist circumference, blood pressure, blood lipids, and blood glucose levels in overweight or obese people. There appeared to be no differences between the different types of diets.

Physical exercise is effective in reducing weight, particularly when combined with dietary interventions. Exercise is also an effective intervention for improving various risk factors even when weight loss does not occur.

Available evidence suggests that overweight or obese adults benefit from behavioural and cognitive-behavioural therapies that enhance weight reduction. Behavioural therapy is particularly useful when combined with dietary and exercise strategies, which resulted in weight loss as well as reductions of blood pressure, fasting plasma glucose, serum cholesterol, and triglycerides.

Evidence from placebo-controlled clinical trials suggests that three anti-obesity drugs—orlistat, sibutramine, and rimonabant—are modestly effective in reducing weight and have different effects on cardiovascular risk. The SRs/HTAs assessed in this report did not include primary studies on head-to-head comparisons of the three drugs; it is not clear at this time whether one particular drug is more efficacious than another.

Although data from large, adequately powered, long-term RCTs are lacking, bariatric surgery appears to be more effective than dietary therapy, with or without physical exercise, for the treatment of severe obesity in adults. Evidence from a small RCT also suggests that, compared to intensive medical treatment, surgery results in significantly greater weight reduction in obese people (BMI 30 to 40 kg/m^2) diagnosed with type 2 diabetes.

Procedures that are mainly diversionary (for example, BPD) result in the greatest amounts of weight loss, hybrid procedures (for example, RYGB) are of intermediate effectiveness, and restrictive procedures (for example, AGB) result in the least amounts of weight loss. The choice between RYGB and AGB depends on trade-offs between the risk of adverse events and the need for procedure conversion or reversals. The evidence base for sleeve gastrectomy was limited.

Various patients' characteristics and comorbidities play an important role, but these variables have not been fully explored. The evidence base is biased and of poor quality due to short-term follow-up and high attrition rates. In addition, there is a lack of information as to how outcomes are measured and analyzed.

As obesity is a chronic disease and its etiology is complex, a comprehensive provincial weight management program equipped with a multidisciplinary team, consisting of dieticians, physical therapists, psychologist, medical doctors/nurses, and bariatric surgeons, is necessary. Dietary therapy and physical exercise should be the cornerstone of such a program, upon which pharmacotherapy and bariatric surgery can be provided for appropriate individuals who are overweight or obese.

APPENDIX T.A: METHODOLOGY

Search strategy

The IHE Research Librarian conducted the literature search for publications published between 2000 and April 8, 2010. The search was further limited to adult, human studies and to systematic reviews and Health Technology Assessment (HTAs). The search was developed and carried out prior to the study selection process.

Search for systematic reviews/HTAs of RCTs

A literature search was conducted using key health information resources including MEDLINE, EMBASE, the Cochrane Library, and the Centre for Reviews and Dissemination (CRD) databases, to identify systematic reviews/HTAs of RCTs published between 2000 and 8 April 2010. The search was limited to the last 10 years because of the ongoing evolvement of bariatric treatment strategies.

Search for grey literature

Grey literature searches were conducted between 18 May 2010 and 4 June 2010 for information about local context and regulatory status (Health Canada). A thorough review of HTA agency websites was conducted, as were searches for clinical practice guidelines and ongoing clinical trials.

Reference lists from the included studies were also checked for other relevant studies.

Table T.A.1: Search strategy

Database	Edition or date searched	Search Terms ††
The Cochrane Database of Systematic Reviews www.thecochranelibrary.com	2000 – 2010	#1 (obes* OR superobes*):ti,ab,kw, from 2000 to 2010 #2 (diet OR lifestyle OR "life style" OR exercise OR walking OR behavioural OR behavioural OR cognitive OR psychological OR modification):ti #3 "weight loss" OR "weight reduction" OR "weight management" OR "physical activity":ti,ab,kw #4 (sibutramine OR orlistat OR "appetite suppressants" OR "antiobesity agents" OR counseling OR "cognitive therapy" OR "behavioural therapy" OR psychotherapy OR counseling OR "patient education"):ti,ab,kw #5 (#1 AND (#2 OR #3 OR #4)) #6 (child not adult):ti #7 #5 not #6 **35 reviews**
MEDLINE (includes in process and other non-indexed citation) OVID Licensed Resource	2000 – 8 April 2010	1. *obesity/ 2. *obesity, morbid/ 3. or/1-2 4. (superobes* or obes* or bariatric* or weight).ti. 5. 3 or 4 6. (unplanned weight or unintended weight or involuntary weight or antipsychotic or schizophreni* or bipolar or Parkinson* or Alzheimer* or smoking or dementia or bulimi* or anorexi* or urinary incontinence or ui or pelvic floor or asthma or adhd or attention-deficit or apnea or cancer or

		colorectal or gastroesophageal or fatty liver of osteoarthritis or arthritis or urologic* or mood disorders or birth weight or diarrhea or kidney or gallstone*).m_titl. 7. 5 not 6 8. Bariatrics/ 9. Weight Loss/ 10. Anti-Obesity Agents/ 11. Appetite Depressants/ 12. diethylpropion/ or phenmetrazine/ or phentermine/ or phenylpropanolamine/ 13. Sibutramine.tw. 14. (reductil or meridia or sibutrex).tw. 15. Orlistat.tw. 16. (xenical or alli or tetrahydrolipstatin).tw. 17. diet therapy/ or diet, carbohydrate-restricted/ or diet fads/ or diet, fat-restricted/ or diet, reducing/ 18. diet.ti. 19. Exercise/ 20. Exercise Therapy/ 21. exercise.ti. 22. Physical Fitness/ 23. lifestyle.ti. 24. life style.ti. 25. physical activity.ti. 26. walking.ti. 27. Behaviour Therapy/ 28. Cognitive Therapy/ 29. Psychotherapy/ 30. Psychotherapy, Group/ 31. Counseling/ 32. counseling.ti. 33. behavio?ral.ti. 34. weight management.ti. 35. psychological.ti. 36. Patient Education as Topic/ 37. Health Education/ 38. modification.ti. 39. or/8-38 40. limit 39 to "all child (0 to 18 years)" 41. limit 40 to "all adult (19 plus years)" 42. 39 not (40 not 41) 43. limit 42 to animals 44. 42 not 43 45. limit 44 to yr="2000 - 2010" 46. 7 and 45 47. meta-analy*.mp,pt. 48. ((systematic* adj2 review*) or Medline or pubmed or psychinfo or psycinfo or search*).tw. 49. 47 or 48

		50. (hta or heatlh technology assessment).tw. 51. Technology Assessment, Biomedical/ 52. 50 or 51 53. 46 and (49 or 52) **366 SRs and HTAs**
CRD Databases (DARE, HTA & NHS EED) http://nhscrd.york.ac.uk	2000 – 8 April 2010	# 1 obes* OR superobes* RESTRICT YR 2000 2010 # 2 diet:ti OR lifestyle:ti OR exercise:ti OR walking:ti OR behavioural:ti OR behavioural:ti OR cognitive:ti OR psychological:ti OR modification:ti # 3 "weight loss" OR "weight reduction" OR "weight management" OR "physical activity" # 4 sibutramine OR orlistat OR "appetite suppressants" OR "antiobesity agents" OR counseling OR "cognitive therapy" OR "behavioural therapy" OR psychotherapy OR counseling OR "patient education" # 5 child*:ti NOT adult:ti # 6 #2 OR #3 OR #4 # 7 #1 AND #6 # 8 #7 NOT #5 **136 DARE** **44 HTAs**
EMBASE Licensed Resource (Ovid Platform)	2000 – 8 April 2010 (2010 Week 13)	1. *obesity/ 2. *morbid obesity/ 3. *diabetic obesity/ 4. *abdominal obesity/ 5. or/1-4 6. (superobes* or obes* or bariatric* or weight).ti. 7. (unplanned weight or unintended weight or involuntary weight or antipsychotic* or schizophreni* or bipolar or Parkinson* or Alzheimer* or smoking or dementia or bulimi* or anorexi* or urinary incontinence or ui or pelvic floor or asthma or adhd or attention-deficit or apnea or cancer or colorectal or gastroesophageal or fatty liver or osteoarthritis or arthritis or contaceptive* or erectile or urologic* or mood disorders or birth weight or diarrhea or kidney or gallstone*).ti. 8. (5 or 6) not 7 9. bariatrics/ 10. weight reduction/ 11. antiobesity agent/ 12. exp anorexigenic agent/ 13. sibutramine/ 14. sibutramine.tw. 15. (reductil or meridia or sibutrex).tw. 16. orlistat.tw. 17. (xenical or alli or tetrahydrolipstatin).tw. 18. diet therapy/ 19. diet restriction/ or caloric restriction/ 20. diet therapy/ or diabetic diet/ or low calory diet/ or low fat diet/ 21. diet.ti. 22. exercise/ or aerobic exercise/ or anaerobic exercise/ or aquatic exercise/ 23. fitness/ 24. exercise.ti.

		25. exp physical activity/ 26. physical activity.ti. 27. yoga/ or pilates/ 28. lifestyle.ti. 29. life style.ti. 30. walking.ti. 31. behaviour therapy/ 32. cognitive therapy/ 33. psychotherapy/ 34. behaviour modification/ 35. group therapy/ 36. counseling/ or nutritional counseling/ 37. counseling.ti. 38. behavi?ral.ti. 39. weight management.ti. 40. psychological.ti. 41. patient education/ or health education/ 42. modification.ti. 43. or/9-42 44. limit 43 to (child or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>) 45. limit 44 to adult <18 to 64 years> 46. 43 not ((44 not 45) or school.mp.) 47. (exp vertebrate/ or animal/ or exp experimental animal/ or nonhuman/ or animal.hw.) not (exp human/ or human experiment/) 48. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ti,ab,sh. not (exp human/ or human experiment/) 49. 47 or 48 50. 46 not 49 51. limit 50 to yr="2000 - 2010" 52. 8 and 51 53. meta analysis/ 54. "systematic review"/ 55. (search* or meta-analysis or medline or pubmed or psychinfo or psycinfo or (systematic* adj3 review*)).tw. 56. technology assessment.mp. or HTA.tw. 57. 53 or 54 or 55 or 56 58. 52 and 57
Web of Science ISI Interface Licensed Resource	2000 – 8 April 2010	#1 TS=(obes* OR superobes*) Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=2000-2010 #2 TI=("weight loss" OR "weight reduction" OR "weight management" OR diet OR lifestyle OR "life style" OR exercise OR walking OR physical activity OR behavioural OR behavioural OR cognitive OR psychological OR modification) OR TS=(sibutramine OR orlistat OR "appetite suppressants" OR "antiobesity agents" OR counseling OR "cognitive therapy" OR "behavioural therapy" OR psychotherapy OR counseling OR "patient education") #3 #1 AND #2

		#4 TI=(antipsychotic* OR schizophreni* OR smoking OR "fatty liver" OR bipolar OR "mood disorders" OR athritis OR osteoarthritis OR anorexi* OR bulimi* OR adhd OR asthma OR colorectal OR cancer OR "pelvic floor" OR apnea OR gastroesophageal OR kidney OR diarrhea OR gallstone* OR urologic OR dementia OR alzheimer* OR Parkinson*) #5 #3 NOT #4 #6 TI=((child* OR adolescent OR pediatric OR child OR juvenile OR youth OR school*) NOT adult) #7 #5 NOT #6 #8 TI=(dog OR dogs OR sheep* OR lamb OR lambs OR rat OR rats OR cats OR mice OR mouse OR murine OR rabbit* OR animal* OR pig OR pigs OR piglet* OR porcine) #9 #7 NOT #8 #10 TS=(meta-analysis OR metaanalysis OR search OR pubmed OR medline OR cinahl OR HTA OR "technology assessment" OR (systematic* SAME review*)) #11 #9 AND #10 **(420 results)**
CINAHL (EBSCO licensed resource)	2000 – 8 April 2010	S1 (MH "Obesity") S2 (MH "Obesity, Morbid") S3 TI (superobes* or obes* or bariatric* or weight) S4 TI "unplanned weight" or "unintended weight" or "involuntary weight" or "birth weight" S5 TI antipsychotic* or schizophreni* or bipolar or dementia or alzheimer* or Parkinson* or mood disorders or bulimi* or anorexi* S6 TI smoking or urinary or ui or pelvic floor or asthma or adhd or attention-deficit or apnea or cancer or colorectal or gastroesophageal or fatty liver or osteoarthritis or arthritis or urologic* or diarrhea or kidney or gallstone* S7 (S1 OR S2 OR S3) not (S4 OR S5 OR S6) S8 (MH "Weight Loss") S9 (MH "Weight Reduction Programs") S10 (MH "Antiobesity Agents+") S11 (MH "Sibutramine") S12 TX reductil or meridia or sibutrex or sibutramine or orlistat or xenical or alli or tetrahydrolipstatin S13 (MH "Diet, High Protein") or (MH "Diet, Ketogenic") or (MH "Diet, Low Carbohydrate") or (MH "Diet Fads") S14 (MH "Diet Therapy") S15 (MH "Physical Activity") S16 TI diet or exercise or lifestyle or life style or physical activity or fitness or walking S17 (MH "Behaviour Therapy+") or (MH "Behaviour Modification") or (MH "Counseling") or (MH "Nutritional Counseling") or (MH "Psychotherapy") or (MH "Psychotherapy, Group")

		S18 TI counseling or behavioural or behavioural or psychological or weight management or modification S19 (MH "Health Education") or (MH "Patient Education") S20 S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 S21 S7 AND S20 S22 S7 AND S20 Limiters - Publication Year from: 2000-2010 S23 S22 Limiters – Publication type: Systematic Review S24 meta-analysis OR metaanalysis OR pubmed OR medline OR cinahl OR search* OR (systematic* AND review*) S25 (S25 and S27) OR S26 S26 S25 Limiters - Age Groups: All Child S27 S25 not S26 **247 results**
Grey Literature		
Clinical Practice Guidelines		
AMA Clinical Practice Guidelines www.topalbertadoctors.org/informed_practice/clinical_practice_guidelines.html	18 May 2010	No obesity guidelines
CMA Infobase http://mdm.ca/cpgsnew/cpgs/index.asp	18 May 2010	Obesity, bariatric
National Guideline Clearinghouse www.ngc.gov	18 May 2010	**Keyword:** *obesity or bariatric* **Age Range:** *Adult (19 to 44 years), Middle Age (45 to 64 years)* **Publication Date(s):** 2010, 2009, 2008, 2007, 2006, 2005 (16 relevant results)
NICE Guidance http://guidance.nice.org.uk/	18 May 2010	Obesity, bariatric (an enormous guideline)
Health Regulatory Sites		
Alberta Health and Wellness www.health.gov.ab.ca	4 June 2010	Browsed list of publications Searched bariatrics, obesity (found past IHE economic analysis)
Health Canada (www.hc-sc.gc.ca) Medical Devices active license listing (MDALL) http://webprod.hc-sc.gc.ca/mdll-limh/index-eng.jsp Drug Product Database www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php	18 May 2010	 Gastric band (11 results) Lap band (9 results) Gastric balloon (4 results) Bariatric (none relevant) Sibutramine (active ingredient) (4 results) Orlistat (active ingredient)(1 results)

CDC – Centers for Disease Control and Prevention www.cdc.gov/obesity/index.html	4 June 2010	Reviewed their Overweight and Obesity page (1 effectiveness result) (1 economic result)
Aetna Clinical Policy Bulletins www.aetna.com/about/cov_det_policies.htm	4 June 2010	Obesity; bariatrics
MHRA www.mhra.gov.uk/index.htm	4 June 2010	Obesity; bariatrics (1 sibutramiine safety warning)
American Society of Bariatric Physicians www.asbp.org/	4 June 2010	About ASBP> Bariatric Practice Guidelines (found 1 document)
HTA agencies		
AETMIS www.aetmis.gouv.qc.ca	4 June 2010	Browsed list of publications, 2000–2010 (0 results)
CADTH www.cadth.ca	4 June 2010	Obesity; bariatric; weight loss (1 useful result, LAGB clinical and economic 2007)
Institute for Clinical and Evaluative Sciences (ICES) www.ices.on.ca/	4 June 2010	Bariatric; bariatrics; obesity; lagb (1 result on cost of obesity worldwide)
Health Technology Assessment Unit At McGill www.mcgill.ca/tau/	4 June 2010	Browsed list of publications (2002-2009) (1 publication on gastric banding (with economic info)
Medical Advisory Secretariat www.health.gov.on.ca/english/providers/program/mas/mas_mn.html	4 June 2010	Browsed publication list (2001-2010) (Also checked rapid review list) (1 publication on LAGB safety; 1 publication on bariatric surgery (has economic analysis))
BlueCross BlueShield Technology Evaluation Center	4 June 2010	Browsed publication list (LAGB publication)

Note: ††

"*", "#", and "?" are truncation characters that retrieve all possible suffix variations of the root word, e.g. surg* retrieves surgery, surgical, surgeon, etc.

Study selection

One reviewer (BG) determined the eligibility of studies according to the following predefined inclusion/exclusion criteria.

Inclusion criteria

Studies were included if they met all of the following criteria.

Study design: systematic reviews/HTAs of RCTs

Note: An article was deemed to be a systematic review if it met all of the following criteria as defined by Cook et al., 1997:[72]

- focused clinical question
- explicit search strategy
- use of explicit, reproducible, and uniformly applied criteria for article selection

- critical appraisal of the included studies
- qualitative or quantitative data synthesis

Systematic reviews of observational studies will also be included for long-term (defined as ≥ 5 years) clinical outcomes if they are not available in RCTs.

Population: adults (18 years or older) who are overweight (BMI between 25 and 29.9 kg/m^2) or obese (BMI ≥ 30 kg/m^2).

Intervention: dietary treatment, physical exercise, behavioural therapy, pharmacotherapy, and bariatric surgery, alone or in combination.

Comparator: comparisons of multiple (≥ 3) treatment options within the same intervention strategy (for example, different medications); comparisons of different intervention strategies (for example, dietary treatment versus exercise); and comparisons of combination of intervention strategies to one of the intervention strategies within the combination (for example, exercise and diet versus diet alone).

Outcome of interest: included at least one of the following outcome measures:[1]

- **anthropometric outcomes**: body weight, BMI, waist circumference
- **biomedical or physical outcomes:** fasting glucose, total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides, ratio of total cholesterol to HDL cholesterol, and systolic and diastolic blood pressure
- **clinical outcomes:** comorbidities, mortality, and quality of life
- **Psychosocial outcomes:** depression, mood disorders and eating disorders, suicidal behaviour, and suicide.

Publication: Full text articles published in English.

Exclusion criteria

Studies are excluded if they meet any of the following criteria.

Study design: Systematic reviews/HTAs of a single treatment, or comparison between two treatment options within the same treatment strategy or primary studies.

Population: Systematic reviews/HTAs that targeted a specific population such pediatric patients (<18 years), pregnant women, elderly patients, patient groups with specific comorbidities such as diabetes, hypertension, or cardiovascular disease; systematic reviews/HTAs that targeted people other than overweight or obese patients (for example, healthcare providers).

Intervention: Systematic reviews/HTAs of commercial weight loss programs or complimentary and alternative medicine treatments such as acupuncture.

Selection of other studies

Review articles: for current options and standard treatments; advantage/disadvantages of various bariatric treatment strategies.

Regulatory documents from federal regulation agencies: for regulatory status of medications and devices used for obesity.

Clinical practice guidelines/care pathways: for clinical indications/contraindications for the various treatment strategies.

Data extraction

One reviewer (BG) extracted data from the included systematic reviews/HTAs according to a predetermined data extraction form.

- **search strategy** (databases searched and search dates)
- **study selection criteria** (inclusion and exclusion criteria)
- **characteristics of the included studies** (patients characteristics: number, age, gender, ethnic origin, baseline weight, BMI, and comorbidity; intervention characteristics: type, dose, duration, drop-out rate, follow-up)
- **methodological quality of the included studies**
- **results**

  evidence of safety

  - Any adverse events associated with the treatment strategies

  evidence of efficacy

  - **anthropometric outcomes**: body weight, BMI, waist circumference
  - **biomedical/physical outcomes:** fasting glucose, total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides, ratio of total cholesterol to HDL cholesterol, and systolic and diastolic blood pressure
  - **clinical outcomes:** comorbidities, mortality, and quality of life
  - **psychosocial outcomes:** depression, mood disorders and eating disorders, suicidal behaviour, and suicide

Methodological quality assessment

Two reviewers (BG and MO) independently assessed methodological quality of the included studies using an IHE quality assessment tool for systematic reviews. The quality rating results from the two reviewers were compared and discrepancies between the reviewers' results were resolved by discussion.

Data analysis and synthesis

Data extracted from the included systematic reviews/HTAs were described and integrated using a narrative approach.

External review

Members of the provincial expert advisory committee assembled for this project reviewed this draft report.

APPENDIX T.B: EXCLUDED STUDIES

Table T.B.1: Excluded studies and reasons for exclusion

Excluded reviews	Main reasons for exclusion
Allgood P. Surgical interventions for morbid obesity. Report, 2001.	Not an SR
Anderson JW, et al. Long-term weight-loss maintenance: a meta-analysis of US studies. *American Journal of Clinical Nutrition* 2001;74(5):579-84.	Did not meet Cook's criteria for SR
Aucott L, et al. Effects of weight loss in overweight/obese individuals and long-term hypertension outcomes: a systematic review. *Hypertension* 2005;45(6):1035-41.	Multiple publication of Avenell et al.[2]
Aucott L, et al. Weight loss in obese diabetic and non-diabetic individuals and long-term diabetes outcomes—a systematic review. *Diabetes Obesity & Metabolism* 2004;6(2):85-94.	Multiple publication of Avenell et al.[2]
Aucott L, et al. Long-term weight loss from lifestyle intervention benefits blood pressure? A systematic review. *Hypertension* 2009;54(4):756-62.	Did not meet Cook's criteria for SR
Avenell A, et al. What are the long-term benefits of weight reducing diets in adults? A systematic review of randomized controlled trials. *Journal of Human Nutrition and Dietetics* 2004;17(4):317-35.	Multiple publication of Avenell et al.[2]
Avenell A, et al. What interventions should we add to weight reducing diets in adults with obesity? A systematic review of randomized controlled trials of adding drug therapy, exercise, behaviour therapy or combinations of these interventions. *Journal of Human Nutrition and Dietetics* 2004;17(4):293-316.	Multiple publication of Avenell et al.[2]
Blue Cross Blue Shield Association. *Special report: the relationship between weight loss and changes in morbidity following bariatric surgery for morbid obesity*. Systematic review, 2003.	Did not meet Cook's criteria for SR; not a review of RCTs
Buchwald H, et al. Bariatric surgery: a systematic review and meta-analysis. *JAMA* 2004;292(14):1724-37.	Did not meet Cook's criteria for SR
Buchwald H, et al. Bariatric surgery reduces obesity-related disease. *Evidence-Based Healthcare and Public Health* 2005;9(3):255-6	Abstract
Buchwald H. Weight and Type 2 Diabetes after bariatric burgery: systematic review and meta-analysis. *American Journal of Medicine* 2009;122(3):248-56.	Most included studies are case series studies
Chaston TB, et al. Changes in fat-free mass during significant weight loss: a systematic review. *International Journal of Obesity* 2007;31(5):743-50.	Did not meet Cook's criteria for SR
Chaston TB, Dixon JB. Factors associated with percentage of change in visceral versus subcutaneous abdominal fat during weight loss: findings from a systematic review. *International Journal of Obesity* 2008;32(4):619-28.	Did not meet Cook's criteria for SR; not a review of RCTs
Chavez-Tapia NC, et al. Bariatric surgery for non-alcoholic steatohepatitis in obese patients. *Cochrane Database of Systematic Reviews*: R 2010;(1).	No RCTs were included
Clegg A, et al. Clinical and cost-effectiveness of surgery for morbid obesity: a systematic review and economic evaluation. International Journal of Obesity & Related Metabolic Disorders: *Journal of the International Association for the Study of Obesity* 2003;27(10):1167-77.	An older review of 18 studies; all of them are included in a newer review[38]
Colquitt J, et al. Surgery for morbid obesity. [Update in Cochrane Database Syst Rev. 2009;(2):CD003641; PMID: 19370590]. *Cochrane Database of Systematic Reviews* 2003;(4):003641.	An older review of 18 studies; 16 were included in a newer review[38] and the remaining two are abstracts

Christensen R, et al. Efficacy and safety of the weight-loss drug rimonabant: a meta-analysis of randomised trials. *Lancet* 2007;370(9600):1706-13.	Focused on a single drug
DeLaet D, Schauer D. Obesity in adults. *Clinical Evidence* 2010;02:1-26.	Did not meet Cook's criteria for SR
Douketis JD, et al. Systematic review of long-term weight loss studies in obese adults: clinical significance and applicability to clinical practice. *International Journal of Obesity* 2005;29(10):1153-67.	Did not meet Cook's criteria for SR
Ferchak CV. Obesity, bariatric surgery and type 2 diabetes—A systematic review. *Diabetes/Metabolism Research and Reviews* 2004;20(6):438-45.	Did not meet Cook's criteria for SR
Flodgren G, et al. Interventions to change the behaviour of health professionals and the organisation of care to promote weight reduction in overweight and obese people. *Cochrane Dtabase of Systematic Reviews* 2010;(3).	Did not target patients with obesity
Franz MJ, et al. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. *Journal of the American Dietetic Association* 2007;107(10):1755-67.	Did not meet Cook's criteria for SR
Harrington M, et al. A review and meta-analysis of the effect of weight loss on all-cause mortality risk. *Nutrition Research Reviews* 2009;22(1):93-108.	Did not meet Cook's criteria for SR; not a review of RCTs
Kay SJ, Fiatarone Singh MA. The influence of physical activity on abdominal fat: a systematic review of the literature. *Obesity Reviews* 2006;7(2):183-200.	Did not meet Cook's criteria for SR
Kelley GA, et al. Aerobic exercise, lipids and lipoproteins in overweight and obese adults: a meta-analysis of randomized controlled trials. *International Journal of Obesity* 2005;29(8):881-93.	Did not meet Cook's criteria for SR
Laederach-Hofmann K. Long-term effects of non-surgical therapy for obesity on cardiovascular risk management: A weighted empirical review. *Journal of Public Health* 2008;16(1):21-9.	Did not meet Cook's criteria for SR
Maggard MA, et al. Meta-analysis: surgical treatment of obesity. *Annals of Internal Medicine* 2005;142(7):547-59.	Did not meet Cook's criteria for SR; most included studies are case series studies
Manterola C, et al. Surgery for morbid obesity: selection of operation based on evidence from literature review. *Obesity Surgery* 2005;15(1):106-13.	Outcomes from RCTs were not reported separately
McTigue KM, et al. Screening and interventions for obesity in adults: summary of the evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine* 2003;139(11):933-949.	Duplicate publication of McTigue et al.[52]
Medical Advisory Secretariat. *Bariatric surgery: an evidence-based analysis*. Systematic review, 2005.	Did not meet Cook's criteria for SR; most included studies are non-RCTs
Medical Advisory Secretariat. *Safety of laparoscopic adjustable gastric banding. Rapid review*. Toronto ON: Medical Advisory Secretariat, 2009.	Not a systematic review (a rapid review)
Monteforte MJ. Bariatric surgery for morbid obesity. *Obesity Surgery* 2000;10(5):391-401.	Did not meet Cook's criteria for SR
Neovius M, et al. Head-to-head studies evaluating efficacy of pharmaco-therapy for obesity: a systematic review and meta-analysis. *Obesity Reviews* 2008;9(5):420-7.	Did not meet Cook's criteria for SR
O'Brien PE, et al. Systematic review of medium-term weight loss after bariatric operations. *Obesity Surgery* 2006;16(8):1032-40.	Did not meet Cook's criteria for SR
Ohkawara K, et al. A dose-response relation between aerobic exercise and visceral fat reduction: systematic review of clinical trials. *International Journal of Obesity* 2007;31(12):1786-97.	Did not meet Cook's criteria for SR

Padwal R, Li SK, Lau DC. Long-term pharmacotherapy for overweight and obesity: a systematic review and meta-analysis of randomized controlled trials. *International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity 3002;27(12):1437-46*.	Earlier publication of Padwal et al.[20]
Pichon RA, et al. *Usefulness of surgical treatments for obesity*. Ciudad de Buenos Aires: Institute for Clinical Effectiveness and Health Policy (IECS), 2004.	Non-English publication
Picot J. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. *Health Technology Assessment* 2009;13(41):ix-214	Duplicate publication of Colquitt et al.[62]
Poobalan A, et al. Effects of weight loss in overweight/obese individuals and long-term lipid outcomes--a systematic review. *Obesity Reviews* 2004;5(1):43-50.	Multiple publication of Avenell et al.[2]
Rucker D, Padwal R, Li SK, et al. Long term pharmacotherapy for obesity and overweight updated meta-analysis. *BMJ* 2007;335(7631):1194-99	Journal publication of Padwal et al.[20] with less details
Salem L, et al. Are bariatric surgical outcomes worth their cost? A systematic review. *Journal of the American College of Surgeons* 2005;200(2):270-8.	Focused on economic evaluation
Shekelle PG, et al. *Pharmacological and surgical treatment of obesity. Evidence Report.* Technology Assessment (Summary) 2004;(103):1-6.	For medication part, an older version of(60); for surgery part, most included studies are not RCTs
Slevin E. High intensity counselling or behavioural interventions can result in moderate weight loss. *Evidence-Based Healthcare* 2004;8(3):136-8.	Abstract
Sodlerlund A, et al. Physical activity, diet and behaviour modification in the treatment of overweight and obese adults: a systematic review. *Perspect Public Health* 2009;129(3):132-42.	Did not meet Cook's criteria for SR
Tice JA. Laparoscopic adjustable silicone gastric banding for obesity. Available at: *www medscape com/viewarticle/717883_print 2010* (accessed 31 May 2010).	Most included studies are not RCTs
van Hout G. Psychosocial effects of bariatric surgery. *Acta chirurgica Belgica* 2005;105(1):40-3.	Did not meet Cook's criteria for SR; not a review of RCTs
Vocks S, et al. Meta-Analysis of the effectiveness of psychological and pharmacological treatments for binge eating disorder. *International Journal of Eating Disorders* 2010;43(3):205-17.	Focused on binge eating disorder
Wu T, et al. Long-term effectiveness of diet-plus-exercise interventions vs. diet-only interventions for weight loss: a meta-analysis. *Obesity Reviews* 2009;10(3):313-23.	Did not meet Cook's criteria for SR
Obesity: weight loss without drugs: a balanced diet avoiding high-calorie foods, plus exercise. *Prescrire International* 2007;16(90):162-7.	Not an SR
Orlistat: a second look. At best, a minor adjunct to dietary measures. *Prescrire International* 2002;11(57):10-2.	Not an SR
Weight loss medications for obesity in adults, 3-24-2010, DynaMed.	Not an SR

Abbreviations: RCT = randomized controlled trial; SR = systematic review

APPENDIX T.C: METHODOLOGICAL QUALITY ASSESSMENT

Quality assessment checklist for systematic reviews

(Adapted from various sources[a-d]) (Updated on June 29, 2009)

This checklist contains six quality subsections (grey sections) that, according to the literature, reflect aspects considered essential for a good quality systematic review. If desired, the scores obtained for these six subsections can be used to categorize the review as good quality, average quality, or poor quality, according to the number of criteria met. This additional categorization is optional. The Rating System is flexible in that other criteria can be substituted for some or all of the six criteria in accordance with the priorities and opinions of the assessors.,

Study Question

The research question should be established a priori.

Reported: The objectives of the review are clearly stated in the abstract, introduction, or methods.

Partially reported: The objectives of the review are stated in:

- the abstract, introduction, or methods but are vague or unclear
- a section of the report other than the abstract, introduction, or methods

Not reported: The objectives are not stated in any section of the review.

Inclusion/Exclusion Criteria

The participants, interventions, outcome measures, and types of studies considered for analysis should be established a priori.

Reported: All four elements (participants, interventions, outcome measures, types of studies) are reported in the abstract, introduction, or methods section of the review.

Partially reported: Only three of the four elements are reported in the abstract, introduction, or methods section.

Not reported:

- Fewer than three of the four elements are reported in the abstract, introduction, or methods section.
- The first mention of any of these elements occurs in the results section.

Search Strategy

Electronic databases

Reported: At least one electronic database was searched and the name(s) of the database(s) is/are provided.

Partially reported: At least one electronic database was searched but the name(s) of the database(s) is/are not provided.

Not reported: Electronic databases were not searched or are not mentioned in the review.

Quality subsection 1: At least MEDLINE and one other relevant literature database

Yes: MEDLINE and one other relevant literature database were searched.

Unclear: It was unclear whether MEDLINE and one other relevant literature database were searched because a complete list of all the electronic databases searched is not provided.

No:

- The review stated that neither MEDLINE nor another relevant literature database was searched.
- Neither MEDLINE nor another relevant literature database was mentioned in the complete list of electronic databases searched.
- Only one of the two the databases (MEDLINE or one other relevant database) was searched.

Other sources

Reported: At least one additional resource or method, other than searching electronic databases, was used to identify relevant literature (for example, pearling or review of reference lists in retrieved articles, hand searching of journals).

Partially reported: Other resource or methods were used but details were not provided.

Not reported: The review did not use other resources or methods to identify relevant literature or did not mention them.

Data Extraction

Data extraction method

Reported: The data extraction process is described.

Partially reported: A data extraction process is mentioned but no details are provided.

Not reported: A data extraction process was not used or described.

Quality subsection 2: Standardized method

Yes: The data categories extracted were listed or the use of a standardized data extraction form was mentioned.

Unclear: The review states that a standardized data extraction process was used but does not list the data categories extracted or mention the use of a standardized data extraction form.

No: The data categories extracted were not listed or the use of a standardized data extraction form was not mentioned.

Quality subsection 3: Independent data extraction by at least two reviewers

Yes: Data were extracted independently by at least two reviewers.

Unclear: The number of reviewers who extracted data was not stated.

No: Details of data extraction were not provided or data were extracted by:

- only one reviewer
- one reviewer and checked by another

Quality Assessment

Criteria used to assess the validity of included studies

Reported: A quality assessment tool or checklist was used and details were provided (for example, name or source).

Partially reported: A quality assessment tool or checklist was used but no details were provided.

Not reported:

- A quality assessment tool or checklist was not used or mentioned.
- Studies were only categorized according to a level of evidence hierarchy.

Quality subsection 4:
Independent quality assessment by at least two reviewers

Yes: The quality of the included studies was assessed independently by at least two reviewers.

Unclear: The number of reviewers who appraised study quality was not stated.

No:

Studies were assessed by:

- only one reviewer
- one reviewer and checked by another

Inter-rater agreement

Reported: The review mentions that a consensus method was used or provides a statement of the degree of difference/equivalence between the reviewers or a statistical measure of inter-rater agreement.

Partially reported: The review mentions that inter-rater agreement was measured but does not provide a statement of the degree of difference/equivalence or a statistical measure of inter-rater agreement.

Not reported: The review does not provide any information on inter-rater agreement.

Data Analysis/Synthesis

Only ONE of the three methods for data analysis/synthesis can be assessed. Select the data analysis type according to the definitions below. Only score the quality subsection that pertains to the particular data analysis method used in the review.

Qualitative review: A narrative summary of the study results with no statistical analysis or pooling of results.

Quality subsection 5a:
Study quality used in analysis or discussion of study results

Yes: Results of the included studies were discussed or analyzed in terms of their quality.

Unclear:

- Study quality was assessed, but was either not used at all or was only used to analyze some of the included studies.
- The review mentions selective inclusion of 'quality' studies, but without further assessment of their quality (for example, only RCTs were included but the robustness of their execution was not assessed).

No:

- The results of the included studies were not discussed or analyzed in terms of their quality.
- Study quality was not assessed.

Semi-quantitative review:

Incorporates a statistical analysis of individual studies without pooling the results (for example, relative risks calculated for individual study outcomes) or includes pooling of results using only descriptive statistics (for example, median, mean, mode, frequency).

Quality subsection 5b: Confidence interval/measures of dispersion reported

Yes: Confidence intervals or measures of dispersion (range, standard deviation, standard error of the mean) were reported for all relevant analyses.

Unclear:

- Confidence intervals or measures of dispersion were only reported for some of the relevant analyses.
- Confidence intervals were reported for all relevant analyses, but the level of confidence was not specified (for example, it is unclear whether 95% or 99% confidence intervals were calculated).
- Measures of dispersion were reported for all relevant analyses but the type was not specified (for example, standard deviation or standard error).

No: Confidence intervals or measures of dispersion were not reported.

Meta-analysis:

A pooled effect estimate is calculated for at least two studies. Reviews that contain a meta-analysis of some studies and a qualitative analysis of the remaining studies are considered a 'meta-analysis.'

Quality subsection 5c: Precision of results reported

Yes: Confidence intervals were reported for all pooled effect estimates.

Unclear:

- Confidence intervals were reported for some but not all pooled effect estimates.
- Confidence intervals were reported for all pooled effect estimates but the level of confidence was not specified (for example, it is unclear whether 95% or 99% confidence intervals were calculated).

No: Confidence intervals were not reported.

Quality subsection 5d: Test of study heterogeneity conducted

Yes: A statistical analysis of study heterogeneity was reported for all pooled studies.

Unclear:

- A statistical analysis of study heterogeneity was reported for some but not all pooled studies.
- Heterogeneity was examined visually or a statistical analysis of study heterogeneity was reported for all pooled studies, but the type of model used was not specified (for example, fixed-effect or random-effect).

No: A statistical analysis of study heterogeneity was not conducted.

Test for publication bias

Reported: Publication bias was analyzed or a reason provided for why it was not.

Partially reported:

- The review mentions analyzing publication bias but does not present the results.
- The review states that publication bias was not analyzed but does not explain why.

Not reported: There was no mention of analyzing publication bias.

Concluding Section

Potential methodological limitations

Reported: The methodological limitations or advantages of the review are described in a separate section or paragraph.

Partially reported: The description of the methodological limitations or advantages of the review is cursory (for example, a single sentence or no separate paragraph or section).

Not reported: There is no mention of the potential methodological limitations or advantages of the review.

Clinical application of results

The clinical application of results is considered adequate if all of the following four elements are present in the concluding section (includes discussion) or statement of the review: treatment, treatment effect, patient group, and comparator.

Reported: All four elements are present.

Partially reported: Only three of the four elements are present.

Not reported: Less than three of the four elements are present.

Incorporation of methodological quality

The review should take into account the methodological quality of the included studies when formulating the conclusions.

Reported: The methodological quality of the included studies is mentioned in the concluding section (includes discussion) or statement of the review.

Partially reported: The study types, as designated by a level of evidence hierarchy category, are mentioned in the concluding section (includes discussion) or statement of the review, but not the quality of the studies.

Not reported: The methodological quality of the included studies is not mentioned in the concluding section (includes discussion) or statement of the review.

Quality subsection 6: Conclusions supported by results

Yes: The conclusions drawn by the authors of the review we re supported by the evidence presented in the results section.

Unclear: Some, but not all, of the conclusions drawn by the authors of the review were supported by the evidence presented in the results section.

No: The conclusions drawn by the authors of the review were not supported by the evidence presented in the results section.

Conflict of interest and funding

Conflict of interest

Reported: A statement of conflict of interest (if any) is provided.

Partially reported: A conflict of interest is mentioned but details are not provided.

Not reported: A statement of conflict of interest (if any) is not provided.

Sources of funding

Reported:

- Funding sources are mentioned.
- The review was developed without external funding (for example, authors employed by a university or volunteered time to produce a Cochrane Review).

Partially reported: External funding is mentioned but details are not provided.

Not reported: Funding sources are not mentioned.

Optional Quality Rating System

The quality of systematic reviews can be assessed according to how well their methods exclude bias and confounding by examining the search strategy used, how the data extraction, quality assessment of the included studies, and data analysis/synthesis were conducted, and whether the conclusions of the review match the results. Thus, the quality of the review can be rated numerically with respect to the six quality subsections (grey boxes above), as follows.

Good—six criteria met, or five criteria met and one criterion 'unclear.'

Average—one criterion not met, or one criterion not met and one criterion 'unclear,' or two criteria 'unclear.'

Poor—at least two criteria not met.

N.B. For a criterion to have been 'met,' it must be scored as 'yes' (✓). For meta-analyses, the two applicable quality subsections (5c and 5d) are counted as a single quality criterion. Therefore, to meet the fifth quality criterion for meta-analyses both 5c and 5d must be scored as 'yes' (✓).

References

a. Fishbain D, Cutler RB, Rosomoff HL, Rosomoff RS. What is the quality of the implemented meta-analytic procedures in chronic pain treatment meta-analyses? *Clinical Journal of Pain* 2000;16(1):73-85.

b. Aggressive Research Intelligence Facility – University of Birmingham. ARIF Critical Appraisal Checklist. Available from: *www.bham.ac.uk/arif/ca_process.htm* (accessed 19 February 2002).

c. University of Alberta. Evidence Based Medicine Tool Kit. University of Alberta. Available from: *www.med.ualberta.ca/ebm/main.htm* (accessed 1 November 2000).

d. Greenhalgh T. How to read a paper. Papers that summarise other papers (systematic reviews and meta-analysis). *BMJ* 1997;315:672-5.

Table T.C.1: Results of quality assessment for systematic reviews

Criteria		Avenell[2]	Brown[63]	Colguitt[62]	Curioni[58]
Study question established a priori		●	●	●	●
Inclusion/exclusion criteria		●	●	●	●
Search strategy	Electronic databases	●	●	●	●
	1. At least MEDLINE and one other relevant database	✓	✓	✓	✓
	Other sources	●	●	●	●
Data extraction	Data extraction method	◐	○	●	◐
	2. Standardized method	✓	X	✓	?
	3. Independent data extraction by at least two reviewers	X	?	X	✓
Quality assessment	Criteria used to assess the validity of included studies	●	◐	●	●
	4. Independent quality assessment by at least two reviewers	X	?	✓	✓
	Inter-rater agreement for quality assessment	●	○	●	●
Data analysis/synthesis	Qualitative review	N/A	N/A	●	N/A
	5a. Study quality used in analysis or discussion of study results	N/A	N/A	✓	N/A
	Semi-quantitative review	N/A	N/A	N/A	N/A
	5b. Confidence intervals or measures of dispersion reported	N/A	N/A	N/A	N/A
	Meta-analysis	●	●	N/A	●
	5c. Precision of results reported	✓	✓	N/A	✓
	5d. Test of heterogeneity conducted	✓	X	N/A	✓
Test for publication bias		○	○	N/A	●
Concluding section	Potential methodological limitations/advantages	●	○	●	●
	Clinical application of results	●	◐	●	●
	Incorporation of methodological quality	○	○	●	●
	6. Conclusions supported by results	✓	✓	✓	✓
Conflict/ funding	Conflict of interest (if any)	●	●	●	○
	Sources of funding	●	●	●	○
Quality rating	Six criteria in grey areas	Average	Poor	Average	Good

Table T.C.1: Results of quality assessment for systematic reviews (cont'd)

Criteria		Galani & Schneider[56]	Maciejewski[65]	Padwal[20]	Poobalan[67]
Study question established a priori		●	●	●	●
Inclusion/exclusion criteria		●	◐	●	●
Search strategy	Electronic databases	●	●	●	●
	1. At least MEDLINE and one other relevant database	✓	✓	✓	✓
	Other sources	●	○	●	●
Data extraction	Data extraction method	●	●	●	●
	2. Standardized method	✓	✓	?	✓
	3. Independent data extraction by at least two reviewers	X	✓	✓	✓
Quality assessment	Criteria used to assess the validity of included studies	●	●	●	○
	4. Independent quality assessment by at least two reviewers	✓	?	✓	X
	Inter-rater agreement for quality assessment	●	○	○	N/A
Data analysis/synthesis	Qualitative review	N/A	N/A	N/A	N/A
	5a. Study quality used in analysis or discussion of study results	N/A	N/A	N/A	N/A
	Semi-quantitative review	N/A	N/A	N/A	N/A
	5b. Confidence intervals or measures of dispersion reported	N/A	N/A	N/A	N/A
	Meta-analysis	●	●	●	●
	5c. Precision of results reported	✓	✓	✓	✓
	5d. Test of homogeneity conducted	?	?	✓	X
Test for publication bias		●	○	●	○
Concluding section	Potential methodological limitations/advantages	●	●	●	●
	Clinical application of results	●	●	●	◐
	Incorporation of methodological quality	●	●	●	○
	6. Conclusions supported by results	✓	✓	✓	✓
Conflict/ funding	Conflict of interest (if any)	○	◐	●	●
	Sources of funding	●	○	●	●
Quality rating	Six criteria in grey areas	Average	Average	Good	Average

Table T.C.1: Results of quality assessment for systematic reviews (cont'd)

Criteria		Shaw[57]	Shaw[15]	Li[60]	Tsai[64]
Study question established a priori		●	●	●	●
Inclusion/exclusion criteria		●	●	◐	◐
Search strategy	Electronic databases	●	●	●	●
	1. At least MEDLINE and one other relevant database	✓	✓	✓	✓
	Other sources	●	●	●	●
Data extraction	Data extraction method	●	●	●	○
	2. Standardized method	✓	✓	✓	?
	3. Independent data extraction by at least two reviewers	✓	?	✓	✓
Quality assessment	Criteria used to assess the validity of included studies	●	●	●	●
	4. Independent quality assessment by at least two reviewers	✓	✓	?	✓
	Inter-rater agreement for quality assessment	●	●	○	○
Data analysis/synthesis	Qualitative review	N/A	N/A	N/A	●
	5a. Study quality used in analysis or discussion of study results	N/A	N/A	N/A	X
	Semi-quantitative review	N/A	N/A	N/A	N/A
	5b. Confidence intervals or measures of dispersion reported	N/A	N/A	N/A	N/A
	Meta-analysis	●	●	●	N/A
	5c. Precision of results reported	✓	✓	✓	N/A
	5d. Test of homogeneity conducted	✓	✓	✓	N/A
Test for publication bias		●	○	●	N/A
Concluding section	Potential methodological limitations/advantages	●	●	●	○
	Clinical application of results	◐	●	◐	◐
	Incorporation of methodological quality	○	○	●	○
	6. Conclusions supported by results	✓	✓	✓	✓
Conflict/ funding	Conflict of interest (if any)	●	●	●	●
	Sources of funding	●	●	●	●
Quality rating	Six criteria in grey areas	Good	Good	Good	Average

Table T.C.1: Results of quality assessment for systematic reviews (cont'd)

Criteria		Johansson[59]	Smart[61]	McTigue[66]	Klarenbach[38]
Study question established a priori		●	●	●	●
Inclusion/exclusion criteria		●	●	●	●
Search strategy	Electronic databases	●	●	●	●
	1. At least MEDLINE and one other relevant database	✓	✓	✓	✓
	Other sources	●	○	●	●
Data extraction	Data extraction method	●	○	●	●
	2. Standardized method	?	?	✓	✓
	3. Independent data extraction by at least two reviewers	✓	?	?	X
Quality assessment	Criteria used to assess the validity of included studies	●	○	●	●
	4. Independent quality assessment by at least two reviewers	✓	?	?	✓
	Inter-rater agreement for quality assessment	○	○	○	●
Data analysis/synthesis	Qualitative review	N/A	●	●	N/A
	5a. Study quality used in analysis or discussion of study results	N/A	X	✓	N/A
	Semi-quantitative review	N/A	N/A	N/A	N/A
	5b. Confidence intervals or measures of dispersion reported	N/A	N/A	N/A	N/A
	Meta-analysis	●	N/A	N/A	●
	5c. Precision of results reported	✓	N/A	N/A	✓
	5d. Test of homogeneity conducted	✓	N/A	N/A	✓
Test for publication bias		●	N/A	N/A	●
Concluding section	Potential methodological limitations/advantages	●	○	○	●
	Clinical application of results	◐	●	◐	◐
	Incorporation of methodological quality	●	○	●	●
	6. Conclusions supported by results	✓	✓	✓	✓
Conflict/ funding	Conflict of interest (if any)	●	○	○	○
	Sources of funding	○	●	●	●
Quality rating	Six criteria in grey areas	Good	Poor	Average	Average

APPENDIX T.D: CHARACTERISTICS OF SYSTEMATIC REVIEWS/HTAS

Table T.D.1: Characteristics of the SRs/HTAs

Study objective	Search	Selection criteria
Dietary therapy/physical exercise		
Galani & Schneider, 2007[56] To assess the effectiveness, mid- to long-term (one to six years), of lifestyle interventions in the prevention and treatment of obesity.	**Databases searched:** MEDLINE, EMBASE, Cinhal **Search date:** 1995 to 2005 (due to advancements in research toward conducting high quality studies and better reporting). **Other sources:** reference list and books	**Inclusion criteria:** ***Study:*** RCTs with a follow-up ≥ one year ***Patients:*** adults (≥ 18 years), overweight and obese **Exclusion criteria:** NA
Shaw et al., 2006[57] To assess exercise as a means of achieving weight loss in people with overweight or obesity, using randomized controlled clinical trials.	**Databases searched:** Cochrane library, MEDLINE, EMBASE, Sport Discuss **Search date:** up to 2005 **Other sources:** reference list of review articles and all included studies	**Inclusion criteria:** ***Study:*** RCTs with study duration ≥ three months ***Patients:*** adults (≥ 18 years) with baseline BMI > 25 kg/m^2 ***Intervention:*** exercise (defined as any form of physical activity performed on a repeated basis for any defined period of time) as compared to placebo or another non-pharmacological weight loss interventions **Exclusion criteria:** trials with a drop-out rate > 15%
Curioni & Lourenco, 2005[58] To carry out an SR with meta-analysis of RCTs, assessing the effectiveness of exercise combined with dietary interventions in initial weight loss and its long-term maintenance among overweight and obese people.	**Databases searched:** Cochrane library, MEDLINE, Lilacs (Latin American and Caribbean Literature in Health Science) **Search date:** up to 2003 **Other source:** reference list	**Inclusion criteria:** ***Study:*** RCTs with follow-up ≥ one year ***Patients***: adults (≥ 18 years), BMI ≥ 25 kg/m^2 **Exclusion criteria:** • pregnant women or children or on the use of any medication • studies of behavioural therapy as the only intervention

Table T.D.1: Characteristics of the SRs/HTAs (cont'd)

Behavioural therapy		
Shaw et al., 2005[15] To assess the effects of psychological interventions for overweight or obesity as a means of achieving sustained weight loss.	**Databases searched:** MEDLINE, EMBASE, PsychInfo, PsychLit **Search date:** up to June 2003 **Other sources:** reference list	**Inclusion criteria:** ***Study:*** RCTs with follow-up ≥ three months ***Patients:*** adults (18 years or older) with a baseline BMI > 25 kg/m^2 ***Intervention:*** psychological intervention versus a comparison intervention **Exclusion criteria:** • trials with a drop-out rate > 15% • studies that combined a pharmacological intervention with a psychological intervention
Pharmacotherapy		
Johansson et al., 2009[59] To assess the risk ratio, risk difference, and number needed to harm of drop-out due to adverse events for orlistat, sibutramine, or rimonabant as compared to placebo.	**Databases searched:** MEDLINE, EMBASE, Cochrane controlled trials registration **Search date:** 1990 to May 2008 **Other sources:** reference list	**Inclusion criteria:** ***Study:*** RCTs with a study duration of 12 to 24 months ***Patients:*** adults ***Intervention:*** licensed drugs **Exclusion criteria:** maintenance study; studies that used non-standardized clinical doses of orlistat (180 mg), sibutramine (> 15 mg), or rimonabant (5 mg)
Padwal et al., 2004[20] To assess/compare the effects and safety of approved anti-obesity medications in clinical trials of at least one year duration.	**Databases searched:** MEDLINE (until December 2006), EMBASE (until week 51, 2006), The Cochrane Library (Issue 4, 2006) **Search date:** see above **Other sources:** reference list, contact of drug manufacturers, and clinical experts	**Inclusion criteria:** ***Study:*** RCTs with a follow-up (from the point of randomization) ≥ one year, includes intention to treat analysis ***Patients:*** ≥ 18 years, BMI ≥ 30 kg/m^2, or BMI ≥ 27 kg/m^2 with one or more obesity-related comorbidities ***Intervention:*** sibutramine, orlistat, phentermine, mazindol, diethylpropion, benzphetamine, phendimetrazine, rimonabant ***Comparator:*** placebo **Exclusion criteria:** NA

Table T.D.1: Characteristics of the SRs/HTAs (cont'd)

Li et al., 2005[60] To assess the efficacy and safety of weight loss medications approved by the US Food and Drug Administration, and other medications that have been used for weight loss.	**Databases searched:** MEDLINE, Cochrane Controlled Clinical Trials Register Databases **Search date:** up to 2002 **Other sources:** reference list	**Inclusion criteria:** ***Study:*** RCTs and quasi-RCTs ***Patients:*** adults with a BMI ≥ 27 kg/m² ***Intervention:*** sibutramine, orlistat, phentermine, diethypropion, fluoxine, bupropion, sertraline, topiramate, and zonisamide ***Comparator:*** placebo or another drug **Exclusion criteria:** NA
Surgery		
Klarenbach et al., 2010[38] To assess the evidence on clinical effectiveness and safety, and economic implications of using different bariatric surgery methods in adult patients with severe obesity.	**Databases searched:** MEDLINE (1950 to 3 February 2009), EMBASE (1980 to 3 February 2009), Cochrane Central Register of Controlled Trials (3 February 2009) **Search date:** see above **Other sources:** hand searching and reference list	**Inclusion criteria:** ***Study:*** parallel quasi-RCTs or RCTs ***Patients:*** severely obese adults (16 years or older), with an accepted indication for bariatric surgery: BMI of 40 kg/m² or more (or BMI of 35 kg/m² or more with at least one obesity-related comorbidity) ***Intervention:*** at least one bariatric surgical intervention ***Comparators:*** different bariatric surgical interventions, standard care (diet and exercise), pharmacologic intervention, open and laparoscopic approaches, variant of the same surgical intervention **Exclusion criteria:** intervention: non-surgical bariatric procedures such as intra-gastric balloons
Colquitt et al., 2009[62] To assess the effects of bariatric surgery for obesity on weight, comorbidity, and quality of life.	**Databases searched:** *The Cochrane Library* (Issue 3/2008); MEDLINE (until 29/7/2008); EMBASE (until 29/7/2008); PsychInfo (until 29/7/2008); CINAHL (until 16/7/2008); Science and Social Sciences Citation Index (until 29/7/2008); British Nursing Index (until 6/8/2008). **Search date:** see above **Other sources:** contact experts, reference list	**Inclusion criteria:** ***Study:*** RCTs comparing surgical interventions with other surgical interventions; RCTs, controlled trials, and prospective cohort studies comparing surgery with non-surgical treatment (medical treatment or no treatment); follow-up ≥ one year ***Patients:*** adults with a BMI ≥ 30, young people who fulfill the definition of obesity for their age, sex, and height ***Intervention:*** different surgical procedures ***Comparator:*** usual care (no treatment or medical treatment), different surgical procedures, open, and laparoscopic approaches **Exclusion criteria:** comparison of variations of surgical techniques rather than different procedures; procedures not in current use: jejunoileal bypass procedure, horizontal gastroplasty, vertical gastroplasty, banded gastroplasty that is not adjustable

Table T.D.1: Characteristics of the SRs/HTAs (cont'd)

Multiple strategies		
Tsai, 2009[64] This review examines the results of RCTs in which behavioural weight loss interventions, used alone or with pharmacotherapy, were provided in primary care settings.	**Databases searched:** MEDLINE, EMBASE, Cochrane systemtic review, CINAHL **Search date:** 1950 to January 2009 **Other sources:** reference list	**Inclusion criteria:** ***Study:*** RCTs conducted in the United States ***Patients:*** adults ***Intervention:*** counseling conducted by primary care providers or another provider working in the primary care office **Exclusion criteria:** intervention trials were not primary-care-based; non-US study; pediatric trials; non-intervention trials (e.g., surveys)
Maciejewski et al., 2005[65] To estimate the effect of weight loss interventions on health-related quality of life in RCTs; to conduct a meta-analysis of weight loss treatment on depressive symptoms; and, to examine methodological and presentation issues that compromise study validity.	**Databases searched:** MEDLINE, HealthStar, PsychINFO **Search date:** 1966 to 2003 **Other sources:** NA	**Inclusion criteria:** ***Study:*** RCTs published between 1996 and July 2003 ***Patients:*** adults (≥ 18 years) ***Intervention:*** behavioural therapy, pharmacotherapy, and surgery ***Outcome measures:*** QoL, depressive symptoms **Exclusion criteria:** non-English language publication, studies that focused on pregnancy-related obesity or gestational diabetes
Avenell et al., 2004[2] To review systematically obesity treatments in adults, to identify therapies that impact by achieving weight reduction, risk factor modification, or improved clinical outcomes.	**Databases searched:** 13 databases including MEDLINE, EMBASE, etc **Search date:** MEDLINE (1966 to May 2001), EMBASE (1980 to Week 19 2001) **Other source:** hand search of specific journals	**Inclusion criteria:** ***Study:*** RCTs with follow-up ≥ one year; full text articles ***Patients:*** adults (≥ 18 years) with BMI ≥ 28 kg/m^2 ***Intervention:*** diets, exercise, behavioural therapy, medication, and surgery ***Outcomes:*** weight loss as a main outcome; no comparison for dietary advice alone with exercise alone for weight management **Exclusion criteria:** abstracts
McTigue et al., 2003[66] To examine the evidence of the benefits and harms of screening and of earlier treatment in reducing morbidity and mortality from overweight and obesity.	**Databases searched:** MEDLINE **Search date:** 1994 to 2001 **Other sources:** NA	**Inclusion criteria:** ***Study:*** RCTs with at least one year follow-up (six months for pharmacological studies) reporting weight reduction or health outcomes for treatment and harms questions **Exclusion criteria:** NA

Table T.D.1: Characteristics of the SRs/HTAs (cont'd)

Poobalan et al., 2007[67] To assess the long-term effectiveness of weight loss on all cause mortality in overweight/obese people.	**Databases searched:** MEDLINE, EMBASE, CINAHL **Search date:** 1966 to 2005 **Other sources:** reference list	**Inclusion criteria:** ***Study:*** prospective studies (RCTs and cohort studies) with follow-up ≥ two years ***Patients:*** adult (18 to 70 years), with BMI ≥ 25 kg/m^2 and Caucasian, Afro-American, Japanese American, or British Asian ethnic origins **Exclusion criteria:** general population study, animal study, studies with less than 40% of follow-up

Abbreviations: BMI = body mass index; HTA = health technology assessment; RCT = randomized controlled trial; NA = not available; QoL = quality of life; SR = systematic review

Table T.D.2: Characteristics of the primary studies assessed in SRs/HTAs

SRs/HTAs	Patients		Intervention
Dietary therapy/physical exercise			
Galani & Schneider, 2007[56] 30 RCTs (13 for prevention studies, 17 for treatment)	**13 prevention studies** **N** = 3566 (range from 74–715) **Mean age** (yr): 49 (range from 43–62) **% female**: predominant **Ethnic origin**: Australia, China, England, France, Finland, Italy, Netherlands, Norway, US **Baseline weight** (kg): mean 81 **Baseline BMI** (kg/m²): mean 28.9 (range from 25–29.7) **Comorbidity:** hypertension, impaired glucose tolerance, diabetes	**17 treatment studies** **N** = 8013 (range from 24 to 2161) **Mean age** (year): 49 (range from 34 to 69) **% female**: predominant **Ethnic origin**: Finland, Italy, Sweden, US, UK **Baseline weight** (kg): NA **Baseline BMI** (kg/m²): 34 (range from 30–37) **Comorbidity:** hypertension, T2DM	**Type:** lifestyle intervention including dietary counseling and physical exercise with or without behavioural modification techniques **Duration:** 1 to 6 years **Drop-out rate**: range 3%–50% in prevention studies, and 4%–38% in treatment studies **Length of follow-up:** mean three years
Shaw et al., 2006[57] 41 RCTs	**N** = 3476 **Age** (yr): weighted mean 42.4 in 32 RCTs and range from 20–75 in the remaining nine RCTs **% female**: of 39 RCTs that reported gender distribution, men 100% in 17 RCTs, women 100% in 15 RCTs, and 10 RCTs that included both men and women **Ethnic origin**: 24 RCTs conducted in the United States, four in the Netherlands, three each in Australia and Canada, two in Israel, one each in Denmark, Germany, Norway, and the United Kingdom **Baseline weight** (kg): NA **Baseline BMI** (kg/m²): NA **Comorbidity:** NA		**Type:** walking (21 trials), exercise bicycle (10 trials), jogging (eight trials), weights training (eight trials), commercial aerobic (five trials), treadmill (five trials), stair stepping (two trials), dancing (one trial), ball games (one trial), calisthenics (one trial), rowing (one trial), aqua jogging (one trial) No trials evaluated swimming or water aerobics as weight loss interventions. **Duration:** NA **Drop-off rate**: < 15% in all studies **Length of follow-up:** NA
Curioni & Lourenco, 2005[58] 6 RCTs	**N** = 514 (range from 40–127) **Mean age** (yr): range from 21–65 **% female**: 100% women in three studies, 100% men in one study, both women and men in two studies **Ethnic origin**: four RCTs conducted in US and **two** RCTs in Finand **Baseline weight** (kg): mean varied from 83.5–106 **Baseline BMI** (kg/m²): NA **Comorbidity:** NA		**Type:** any type (not specified) **Duration:** range from 10–52 weeks **Drop-off rate:** mean 16.9% (range 9.4–24%) **Length of follow-up:** 12–24 months

Table T.D.2: Characteristics of the primary studies assessed in SRs/HTAs (cont'd)

Behavioural therapy (BT)		
Shaw et al., 2005[15] 36 RCTs	**N** = 3495 **Mean age** (yr): weighted mean 43.1 in 18 trials that reported mean age; range from 16–75 in the remaining 18 trials that reported only age range **% females:** 100% men (2 trials), 100% women (14 trials), 25% men and 75% women (across 20 trials) **Ethnic origin**: 29 trials conducted in US, one each in Canada, Columbia, Netherlands, Spain, Sweden, Switzerland, the United Kingdom **Baseline weight** (kg): NA **Mean baseline BMI** (kg/m^2): > 25 in most studies **Comorbidity:** diabetes (two trials), impaired glucose tolerance (two trials), mild hypertension (one trial), binge eating disorder (two trials)	**Type:** BT, BT+D/E, CBT, cognitive therapy, hypnotherapy, relaxation **Duration:** median 12 weeks (range from 4 weeks to 12 months) **Intensity:** range from daily to monthly **Drop-out rate:** ≤ 15% in all studies **Length of follow-up:** range 3 to 36 months
Pharmacotherapy		
Johansson et al., 2009[59] 28 RCTs	**N** = 13,457 (orlistat n=7038, sibutramine n=1475, rimonabant n=4944) **Mean age** (yr): range from 41–59 **% female**: greater proportion of women than of men in most studies **Ethnic origin**: predominantly white **Baseline weight** (kg): NA **Mean baseline BMI** (kg/m^2): range from 33–38 **Comorbidity:** hypertension, hypercholesterolemia, T2DM, dyslipidemia, coronary artery disease, risk factors of CVD	**Type:** orlistat, sibutramine, rimonabant **Dosage:** orlistat 360 mg/day, sibutramine (10–15 mg/day), rimonabant (20 mg/day) **Co-intervention:** diet with or without exercise in all studies **Drop-out rate:** 30% for orlistat, 34% for sibutramine, 39% for rimonabant **Length of follow-up:** 12 to 18 months

Padwal et al., 2004[20] 30 RCTs (16 on orlistat, 10 on sibutramine, 4 on rimonabant)		**Orlistat**	**Sibutramine**	**Rimonabant**	**Type**	**Orlistat**	**Sibutramine**	**Rimonabant**
	N = 19,889	10,631	2623	6635	**Dosage**	120 mg t.i.d.	10–20 mg/day; 15 mg/day most commonly used	20 mg/day
	Mean age (yr)	47	45	48	**Co-intervention**	standardized, low fat, hypocaloric diet; encouragement to exercise	dietary modification with or without advice to exercise	dietary modification with or without advice to exercise
	% females	66%	73%	73%				
	Ethnic origin	89% Caucasian	95% Caucasian	87% Caucasian				
	Mean baseline weight (kg)	104	97	102				
	Mean baseline BMI (kg/m^2)	36.3	35.1	36.5	**Drop-out rate (range)**	30% (0–66%)	40% (11%–51%)	40% (32–49%)
	Comorbidity	dyslipidemia, DM, HTN, impaired glucose tolerance	HTN, DM	dyslipidemia, DM, HTN	**Length of follow-up** (yrs)	1–4	1–1.5	1–2

Table T.D.2: Characteristics of the primary studies assessed in SRs/HTAs (cont'd)

<table>
<tr><td>Li et al., 2005[60]
29 RCTs on orlistat</td><td colspan="3">N = NA
Mean age (yr): 48
% female: 73%
Ethnic origin: NA
Baseline weight (kg): NA
Mean baseline BMI (kg/m²): 36.7
Comorbidity: NA</td><td colspan="3">Type: orlistat
Dosage: NA
Co-intervention: diet in all experimental arms in all studies; educational, behavioural, and psycho-social co-interventions in 39% of the studies, and exercise in 18% of the studies
Drop-out rate: NA
Length of follow-up: six to 12 months</td></tr>
<tr><td colspan="7">Surgery</td></tr>
<tr><td rowspan="8">Klarenbach et al., 2010[38]
64 RCTs</td><td></td><td>Surgery vs another surgery or standard care (31 trials)</td><td>Open versus laparoscopic (eight trials)</td><td></td><td>Surgery vs another surgery or standard care (31 trials)</td><td>Open versus laparoscopic (eight trials)</td></tr>
<tr><td>N</td><td>Median 59, range 16–310</td><td>median 60 (range 30–155)</td><td rowspan="2">Type</td><td rowspan="2">AGB, RYGB, sleeve gastrectomy, JB, loop gastric bypass, mini-gastric bypass, BPD, HG, VBG</td><td rowspan="2">RYGB, VBG, AGB</td></tr>
<tr><td>Mean age (yr)</td><td>range 30–48</td><td>range 35–48</td></tr>
<tr><td>% female</td><td>range 44%–97%</td><td>range 68%–94%</td><td rowspan="2">Co-intervention</td><td rowspan="2">no medical treatment</td><td rowspan="2">no medical treatment</td></tr>
<tr><td>Ethnic origin</td><td>NA</td><td>NA</td></tr>
<tr><td>Baseline weight (kg)</td><td>NA</td><td>NA</td><td rowspan="2">Length of follow-up (month)</td><td rowspan="2">median 24 (range 6–60)</td><td rowspan="2">median 12 (range 10–39)</td></tr>
<tr><td>Mean baseline BMI (kg/m²)</td><td>range 34–59</td><td>range 42–51</td></tr>
<tr><td>Comorbidity</td><td>DM, HTN (reported in two trials)</td><td>DM, dyslipidemia, HTN (reported in two trials)</td></tr>
<tr><td>Colquitt et al., 2009[62]
23 RCTs, 3 prospective cohort studies</td><td colspan="3">N: range 204047
Mean age (yr): range 3249
% females: majority
Ethnic origin: NA
Baseline weight (kg): NA
Baseline BMI (kg/m²): range 37–52
Comorbidity: NA</td><td colspan="3">Type: gastric bypass, AGB, sleeve gastrectomy, VBG, biliopancreatic diversion
Co-intervention: NA
Length of follow-up: 12–84 months for RCTs, 10 years for the SOS study</td></tr>
</table>

Abbreviations: AGB = adjustable gastric banding; BMI = body mass index; BPD = biliopancreatic diversion; BT = behavioural therapy; CBT = cognitive behavioural therapy; D = diet; DM = diabetes mellitus; E = exercise; HG = horizontal gastroplasty; HTA = health technology assessment; HTN = hypertension; JB = jejunoileal bypass; kg = kilogram; m = meter; mg = milligram; N = total number; NA = not available; RCT = randomized controlled trial; RYGB = Roux-en-Y gastric bypass; SR = systematic review; T2DM = type 2 diabetes; t.i.d = three times a day; UK = United Kingdom; US = the United States; VBG = vertical banded gastroplasty

APPENDIX T.E: EVIDENCE TABLE ON SAFETY

Table T.E.1: Safety profile

SRs/HTAs	Adverse events		
Dietary therapy/physical exercise			
Galani & Schneider, 2007[56]	Not reported		
Shaw et al., 2006[57]	Not reported		
Curioni & Lourenco, 2005[58]	No data were identified on adverse events.		
Behavioural therapy			
Shaw et al,. 2005[15]	Not reported		
Pharmacotherapy			
Johansson et al., 2009[59]	The median drop-out due to AEs ($AE_{dropout}$) was highest for rimonabant (15.0%; range 12.8 to 17.5%), intermediate for sibutramine (9.3%; range 0% to 12.2%), lowest for orlistat (7.1%; range 0% to12.8%). Every single rimonabant study showed significantly more $AE_{dropout}$ with rimonabant than the placebo group. The risk ratios for $AE_{dropout}$ were significantly elevated for rimonabant (RR 2.00; 95% CI: 1.66 to 2.41) and orlistat (RR 1.59; 95% CI: 1.21 to 2.08), but not sibutramine (RR 0.98; 95% CI: 0.68 to 1.41). Compared to placebo, the risk difference was the largest for rimonabant (RD 7%; 95% CI: 5 to 9%; NNH 14, 95% CI: 11 to 19), followed by orlistat (RD 3%, 95% CI: 1 to 4%; NNH 39, 95% CI: 25 to 83), but no significant difference for sibutramine (RD 0.2%, 95% CI:–3 to 4%; NNH 500). The most common AEs leading to withdrawal were gastrointestinal for orlistat (40%) and psychiatric for rimonabant (47%).		
Padwal et al., 2004[20]	**Orlistat – GI side effects** Predominant in patients treated with orlistat; over 80% of patients experienced at least one GI side effect, with an absolute frequency of 24% (95% CI: 20 to 29%; 14 studies). Most commonly reported side effects: fatty/oily stool, fecal urgency, and oily spotting, each occurring in 15% to 30% of patients in most studies. Approximately 5% of orlistat-treated patients discontinued the therapy because of the side effects.	**Sibutramine – BP and pulse rate** Sibutramine increased systolic BP by 1.7 mmHg (95% CI: 0.1 to 3.3; 7 studies), diastolic BP by 2.4 mmHg (95% CI: 1.5 to 3.3; 7 studies), and pulse rate by 4.5 beats/min (95% CI: 3.5 to 5.6; 7 studies) compared to placebo. Other AEs: insomnia, nausea, dry mouth, and constipation were common, occurring in 7% to 20% of patients treated with sibutramine.	**Rimonabant – psychiatric disorders** Depression, anxiety, irritability, aggression, occurring in 6% of patients treated with rimonabant and was 3% more likely (95% CI: 2 to 5%; 4 studies) compared to placebo.
Li et al., 2005[60]	An increase in diarrhea (RR, 3.40), flatulence (RR: 3.10), and bloating, abdominal pain, and dyspepsia (RR: 1.48) was found in orlistat-treated patients compared to placebo.		

Table T.E.1: Safety profile (cont'd)

Surgery	
Klarenbach et al., 2010[38]	**Hospitalization** Surgical procedure comparisons (11 trials, 1218 patients) AGB patients had significantly shorter hospital stays than RYGB and VBG patients: AGB versus RYGB (MD−1.7 days; 95% CI: −2.0 to −1.3; two trials with 248 patients) and AGB versus VBG (MD−3.1 days; 95% CI: −5.0 to −1.2; three trials with 260 patients). No significant difference in hospital readmission between AGB group and RYGB group (RR 0.10; 95% CI 0.01, 1.73; one trial with 197 patients). Laparoscopic versus open approaches (seven trials, 507 patients) Significantly shorter hospital stays with laparoscopic approach than with open surgery (MD 0.9 days; 95% CI: 1.5 to 0.4; seven trials); no significant difference in incidence of post-operative readmission between RYGB and AGB (RR 0.83; 95% CI: 0.33; 2.07; two trials with 100 patients). **Reoperations and revisions** Surgical procedure comparisons Reoperation (20 trials, 1769 patients): compared with RYGB patients, JB patients had more late reoperations and HG and VBG patients had a greater number of reoperations. No significant difference in early and late reoperation between RYGB and AGB groups (two trials with 248 patients). Failed surgery (12 trials, 1018 patients): AGB groups had more late failed surgeries than RYGB group (RD 8.3; 95%CI 2.8, 14; two trials with 248 patients); HG and VBG had more failed surgeries than RYGB over the course of follow-up. Reversals (seven trials, 696 patients): compared with the RYGB group, the VBG group has significantly more reversals during follow-up; no significant difference between RYGB group and AGB group (two trials with 248 patients). Laparoscopic versus open approaches (seven trials, 519 patients) No significant difference in incidence of early reoperation (four trials with 286 patients) and late reoperation (three trials with 233 patients) between open and laparoscopic RYGB and VBG. No significant difference in incidence of late reversal between open and laparoscopic AGB (one trial with 69 patients). **Gastrointestinal disturbances** Surgical procedure comparisons (16 trials, 1157 patients) Dysphagia: significantly less in the AGB group than in the VBG group (RD −50%; 95% CI: −72 to −29; one trial with 50 patients). Late ulcers: significantly fewer in the AGB than in the RYGB group (RD −9.9%; 95% CI: −16 to −4.0; one trial with 197 patients). Early or late ulcers: significantly fewer in the VBG group than the RYGB group (RD −14%; 95% CI:−23 to −3.7; one trial with 106 patients). Late vomiting: significantly lower risk in the VBG group than the RYGB group (RD −25%; 95% CI:−45 to −5.1; one trial with 40 patients); significantly higher risk in the VBG group than in the HG group (RD 38%; 95% CI:13 to 64; one trial with 45 patients) Laparoscopic versus open approaches (5 trials, 556 participants) Patients who received open RYGB experienced significantly less early vomiting than laparoscopic RYGB (RD 20%; 95% CI: 36 to 4.4; one trial with 51 patients). No significant differences in other variables (late reflux, ulcer, vomiting) between open and laparoscopic RYGB.

	Serious surgical complications Surgical procedure comparisons (20 trials, 3391 patients) *Early complications* Wound infection: the AGB group had a significantly lower risk than the RYGB group (RD −6.3%; 95% CI:−11 to −1.4; one trial with 197 patients). No significant differences in risk of anastomotic leak, bowel obstruction, and hernia when compared AGB with RYGB. *Late complications* Hernia: AGB groups had a significantly lower risk than RYGB groups (RD −4.5%; 95% CI:−8.4 to −0.5; two trials with 248 patients). Stenosis: significantly lower in the AGB group than in the RYGB group (RD −15%; 95% CI: −22 to −8.3; one trial with 197 patients). Slippage or dilatation: AGB groups had a significantly higher risk than RYGB groups (RD 6.1%; 95% CI:1.3 to 11; two trials with 248 patients) and VBG groups (RD 20%; 95% CI: 12 to 28; two trials with 200 patients). Staple-line breakdown: AGB groups had a significantly lower risk than VBG groups (RD −25%; 95% CI:−36; −14; two trials with 153 patients). No significant difference in risk of bowel obstruction between AGB and RYGB (two trials with 248 patients). Myocardial infarction: no trials reported the comparative incidence of myocardial infarction. Laparoscopic versus open approaches (eight trials with 694 patients) *Early complications* Wound infection: significantly fewer with laparoscopic RYGB and AGB than with open RYGB and AGB (RD 7%; 95% CI: 11 to 3; six trials with 478 patients). No significant differences in risk of anastomotic leak, respiratory failure, stenosis, and venous thromboembolic disease between laparoscopic and open RYGB. *Late complications* Hernias: significantly fewer with laparoscopic RYGB and AGB than open RYGB and AGB (RD 17%; 95% CI: 27 to 7.6; six trials with 543 patients). Luminal stenosis: significantly fewer with open RYGB than laparoscopic RYGB (RD 8.8%; 95% CI: 17 to 0.9; one trial with 155 patients). No significant differences in risk of bowel obstruction and staple line breakdown between laparoscopic and open RYGB.
Colquitt et al. 2009[62]	Surgery versus non-surgical interventions Two trials reported adverse events following surgery: operative interventions, revisional surgery, port site infection, and, following conventional therapy: intolerance to medication, acute cholecystitis, need for operative intervention, gastrointestinal problems. Surgical procedure comparison One trial reported that compared to laparoscopic AGB, laparoscopic isolated sleeve gastrectomy had higher rates of early post-operative complications but lower rates of late complications requiring surgery.

Abbreviations: AGB = adjustable gastric banding; BP = blood pressure; CI = confidence interval; DBP = diastolic blood pressure; GI = gastrointestinal; HG = horizontal gastroplasty; HTA = health technology assessment; MD = mean difference; NA = not available; NNH = number needed to harm; RD = risk difference; RR = relative risk; RYGB = Roux-en-Y gastric bypass; SBP = systolic blood pressure; SR = systematic review; VBG = vertical banded gastroplasty

APPENDIX T.F: EVIDENCE TABLES ON EFFICACY/EFFECTIVENESS

Abbreviations for Appendix T.F

AGB	adjustable gastric banding
BMI	body mass index
BP	blood pressure
BPD	biliopancreatic diversion
BT	behavioural therapy
CBT	cognitive behavioural therapy
CI	confidence interval
CrI	credible interval
CV	cardiovascular
D	diet
DBP	diastolic blood pressure
DM	diabetes mellitus
E	exercise
EWL	excess weight loss
FPG	fasting plasma glucose
HbA1c	glycosylated hemoglobin
HBG	horizontal banded gastroplasty
HDL	high-density lipoprotein
HG	horizontal gastroplasty
HrQoL	health-related quality of life
HTA	health technology assessment
JB	jejunoileal bypass
Kg	kilogram
L	litre
LAGB	laparoscopic adjustable gastric banding
LDL	low-density lipoprotein
LISG	laparoscopic isolated sleeve gastrectomy
LRYGB	laparoscopic Roux-en-Y gastric bypass

LSG	laparoscopic sleeve gastrectomy
m	metre
MA	meta-analysis
MD	mean difference
NA	not available
nss	not statistically significant
OR	odds ratio
QoL	quality of life
RCT	randomized controlled trial
RD	risk difference
RR	relative risk
RYGB	Roux-en-Y gastric bypass
SBP	systolic blood pressure
TG	triglyceride
VBG	vertical banded gastroplasty
WC	waist circumference
WL	weight loss

Table T.F.1-1: Weight loss – Dietary therapy/physical exercise

SRs/HTAs	Weight loss (WL)
Galani & Schneider, 2007[56] **Prevention studies:** N of trials: four, high quality studies N of patients: 1168; mean BMI 27 kg/m² **Treatment studies:** N of trials: five, high quality N of pts: 3032; mean BMI 33 kg/m²	Lifestyle interventions versus standard care (not defined) **Weight** (kg): MD − 3.1(P = 0.0001) (prevention studies); MD −5.1 (P < 0.0001) (treatment studies) **BMI** (kg/m²): NA in prevention studies; MD −1.8 (P = 0.001) (treatment studies)
Shaw et al., 2006[57] N of trials: 41 N of patients: 3476, overweight (BMI >25 kg/m²) or obese (BMI ≥30 kg/m²)	Exercise (E) versus no treatment (12 trials) **Weight** (kg): exercise increased WL compared to no treatment. E: −0.5 to −4.0 versus no treatment: −0.1 to +0.7 **BMI** (kg/m²): exercise reduced BMI more than no treatment. E: −0.3 to −0.7 versus no treatment: +0.3 to +0.4 E versus diet (D) (10 trials) **Weight** (kg): Diet resulted in greater WL as compared to exercise. E: +0.5 to +4.0 versus D: −2.8 to −13.6 **BMI** (kg/m²): Diet resulted in greater reduction in BMI as compared to exercise. E: −0.3 to 0.8 versus D: −0.3 to −3.3 E+D versus D (17 trials) **Weight** (kg): E+D resulted in greater (1.1 kg more) WL as compared to D alone. E+D: −3.4 to −17.7 versus D: −2.3 to −16.7 **BMI** (kg/m²): E+D resulted in greater (0.4 kg more) reduction in BMI as compared to D alone. E+D: −0.6 to −4.0 versus D: −0.3 to −4.0 High-intensity E versus low-intensity E (eight trials) **Weight** (kg): increasing the intensity of exercise increased the weight loss if participants were not on a diet; high-intensity exercisers lost 1.5 kg more than low-intensity exercisers; high-intensity E: −1.3 to −8.9 versus low-intensity E: −6.3 to +0.1 **BMI** (kg/m²): insufficient data for analysis High-intensity E versus low-intensity E with D (8 trials) **Weight** (kg): increasing the intensity did not increase the weight loss if participants were on a diet **BMI** (kg/m²): same as above
Curioni & Lourenco, 2005[58] N of trials: six N of patients: 514; BMI unknown	**Weight loss:** individuals in the diet plus exercise group had a mean WL after intervention approximately 20% greater than individuals in the diet group: –13.0±10.4 kg versus –9.9±9.6 (P = 0.063) **Weight maintenance:** individuals in the diet plus exercise group had a mean WL after 1 year approximately 20% greater than individuals in diet group: –0.67±8.3 kg versus –4.5±11.3 (P = 0.058) **% WL from baseline: i**mmediately after intervention: –13±5.5% versus –10±3.6%; after 1 year: –6.8±4.1% versus –4.6±2.5%; weight regain after 1 year: –50±8.2% versus 50±5.9%

Table T.F.1-2: Weight loss – Behavioural therapy[15]

Intervention/Comparator (No. of trials)*	Weight loss (WL)
BT versus no treatment (10)	Qualitative synthesis of four trials: BT: −0.6 kg to −5.5 kg versus no treatment: −2.8 kg to +1.8 kg MA of the remaining six studies: study duration < 12 months (5 studies): BT patients lost 2.5 kg (95% CI 1.7 to 3.3) more than no-treatment patients (P < 0.01); study duration > 12 months (two trials): BT patients lost 2.0 kg (95% CI 2.7 to 1.3) more than no-treatment patients (P < 0.01)
High-intensity versus low-intensity BT (17)	Qualitative synthesis of six trials: both groups lost weight overall; high-intensity BT: −1.4 kg to −8.4 kg versus low-intensity BT: −0.9 kg to −10.5 kg; greater WL in high-intensity BT than low-intensity BT in four trials, while greater WL in low-intensity BT than high-intensity BT in two trials MA of the remaining 11 trials: study duration < 12 months (10 trials): eight studies favored high-intensity BT and two trials favored low-intensity BT; high-intensity BT lost 2.3 kg more than low-intensity BT (95% CI: 1.4 to 3.3) Study duration > 12 months (one trial, follow-up 36 months): high-intensity BT: −1.6 kg versus low-intensity BT: −1.4 kg (P = 0.45)
BT + D/E versus D/E alone (8)	Qualitative synthesis of two trials: BT + D/E: −10 kg versus D/E: +0.5 kg MA of the remaining six trials: five studies favored the intervention groups and one study favored the control groups
Cognitive therapy versus BT (3)	In all three trials, BT groups lost more weight than cognitive therapy group
Cognitive therapy versus placebo (1)	At 6 months: cognitive therapy: +1.35 kg versus + placebo: 0.6 kg
CBT + D/E versus D/E alone (2)	MA of two trials: both groups lost weight overall; 4.9 kg (95% CI: 7.3 to 2.4) more WL in CBT + D/E than in D/E alone
Hypnotherapy versus placebo (1)	At 5 months: hypnotherapy: −2.1 kg versus placebo: −0.2 kg
Relaxation versus placebo (1)	At 6 months: relaxation: −7.9 kg versus placebo: −0.2 kg
CBT versus no treatment (1)	At 6 months: CBT: −0.6 kg versus no treatment: +4.1 kg
CBT versus BT (1)	At 6 months: CBT: −7.0 kg versus BT: −4.5 kg (P < 0.01) At 12 months: CBT: −10 kg versus BT: −4.3 kg (P < 0.01)
CBT + D/E versus CBT alone (1)	At 3 months: CBT + D/E: −1.9 kg versus CBT alone: +0.5 kg

* The number and BMI of patients for each camparison were not available; all patients were overweight or obese

Table T.F.1-3: Weight loss – Pharmacotherapy

Review	Orlistat	Sibutramine	Rimonabant
Padwal et al., 2004[20] **Orlistat studies:** N of trials: 16 N of pts: 10,631; mean BMI 36.3 kg/m² **Sibutramine studies:** N of trials: 10 N of pts: 2623; mean BMI 35.1 kg/m² **Rimonabant studies:** N of trials: four N of pts: 6635; mean BMI 36.5 kg/m²	**Weight or % weight:** all 16 RCTs reported greater (2.9 kg, 95% CI: 2.5 to 3.2 or 2.9%; 95% CI: 2.5% to 3.4%) WL in the orlistat group, as compared to the placebo group. Absolute WL slightly greater in patients with lower baseline CV risk (3.0 kg; 95% CI: 2.4 to 3.6; 7 trials), as compared to patients with higher baseline CV risk (2.8 kg; 95% CI: 2.4 to 3.1; eight trials); similar results for % WL. In patients with diabetes, orlistat reduced weight by 2.6% (95% CI 2.2 to 3.1%; five trials) or 2.3 kg (95% CI 1.6 to 3.0 kg; 4 trials), as compared to placebo. Orlistat increased the frequency of successful 5% responders by 21% (95% CI 18% to 24%; 14 trials) or 10% responders by 12% (95% CI 9% to 14%; 13 trials), as compared to placebo. **BMI:** Orlistat significantly reduced BMI (1.1 kg/m², 95% CI: 0.7 to 1.4; three trials), as compared to placebo. **WC:** Orlistat significantly reduced WC (2.1 cm, 95% CI 1.3 to 2.9; 9 trials)	**Weight or % weight:** patients lost 4.2 kg (95% CI: 3.6 to 4.7; 8 trials) or 4.3% (95% CI: 3.7% to 5.0%; 10 trials) more weight than those taking placebo. Absolute WL for patients at higher CV risk was 4.3 kg (95% CI: 3.7% to 5.0%; 7 trials) versus 4.0 (95% CI: 3.0% to 5.0%; 5 trials) or 3.9% (95% CI: 2.1% to 5.7%; 3 trials) for patients at lower CV risk. Sibutramine increased the frequency of successful 5% responders by 32% (95% CI: 27% to 37%; 7 trials) and 10% responders by 18% (95% CI: 11% to 25%; 7 trails), as compared to placebo. In patients with diabetes, sibutramine reduced weight by 5.0% (95% CI: 3.8 to 6.2%; 3 trials) or 4.9 kg (95% CI: 3.6 to 6.2 kg; three trials), as compared to placebo. Three studies reported that 10% to 30% more sibutramine-treated patients maintained 80% to 100% of the initial WL, as compared to placebo ($P < 0.05$). **BMI:** Absolute reduction in BMI was 1.5 kg/m² (95% CI: 1.3 to 1.8; five trials). **WC:** Absolute reduction in WC was 4.0 cm (95% CI: 3.3 to 4.7; eight trials).	**Weight:** Rimonabant-treated patients lost 4.7 kg (95% CI: 4.1 to 5.3; four trials) more weight than those taking placebo. No sensitivity analysis conducted according to baseline CV risk because all studies enrolled patients with CV risk factors. Rimonabant increased the frequency of successful 5% responders by 33% (95% CI: 29% to 37%; 4 trials) and 10% responders by 19% (95% CI: 15% to 23%; seven studies), as compared to placebo. **WC:** Rimonabant reduced WC by 3.9 cm (95% CI: 3.3 to 4.5; four trials).
Li et al., 2005[60] **Orlistat studies:** N of trials: 29 N of pts: NA; mean BMI 36.7 kg/m²	At 1 year (22 trials): the pooled estimate of the mean WL for orlistat-treated patients as compared to placebo recipients was 2.89 kg (95% CI: 2.27 to 3.51). No effects of quality score and year of publication on outcomes were detected. Sensitivity by drug dose was not possible. Sensitivity analysis by follow-up rate: the pooled estimate of 15 studies with follow-up rates of 70% or more was a mean WL of 2.83 kg (95% CI: 2.0 to 3.6 kg), as compared to placebo; when 80% was used as the cut-off, no effect of completeness of follow-up on outcome was detected.	Only reported results from another meta-analysis	NA

Table T.F.1-4: Weight loss – Surgery

Surgery	Weight loss
Klarenbach et al., 2010[38] **Studies comparing surgery with another surgery or standard care:** N of trials: 31 N of pts: NA; mean BMI ranged from 42 to 58 kg/m^2 **Studies comparing laparoscopic with open surgery:** N of trials: eight N of pts: NA; mean BMI ranged from 42 to 51 kg/m^2	<u>Surgery versus another surgery or standard care (diet and exercise)</u> At 1 year (15 trials, 1103 pts): Network analysis:* Ranking of the effectiveness for reducing BMI (from most to least efficacious): JB, loop gastric bypass, mini-gastric bypass, BPD, sleeve gastrectomy, RYGB, HG, VBG, AGB, and standard care. Network analysis: RYGB produced significantly greater decreases in BMI from baseline than did AGB (MD −6.6; 95% CrI:**: −9.5 to −3.4) and standard care (MD −8.6; 95% CrI: −1.6 to −2.2); direct evidence supported the findings of network analysis for RYGB versus AGB (MD −5.8; 95% CI: −9.7 to −1.9; 2 trials), although statistical heterogeneity was large. At 2 years (10 trials, 813 pts): Ranking of efficacy by network analysis: JB, BPD, mini-gastric bypass, AGB with omentectomy, RYGB, HG, VBG, and AGB. Network analysis: RYGB produced significantly greater decreases in BMI than did VBG (MD −4.1; 95% CrI:−7.0 to −1.9] and AGB (MD −8.0; 95% CrI: −10.9 to −5.1); direct evidence was available and supportive for RYGB versus VBG (−4.7; 95% CI: −6.1 to −3.2; 3 trials), and RYGB versus AGB (−7.2; 95% CI: −8.9 to −5.5; 1 trial) No BMI data were available at 2 years for loop gastric bypass, sleeve gastrectomy, HG, gastrogastostomy, or standard care. At 3 to 5 years (seven trials, 416 pts): Ranking by network analysis: similar to year 1 and year 2: JB, RYGB, VBG, AGB. Network analysis: RYGB produced significantly greater decreases in BMI from baseline than did AGB (MD −7.7; 95% CrI: −15.1; −0.01); direct evidence was available and supportive for RYGB versus AGB (−6.4; 95% CI: −7.9 to −4.9; 2 trials); no other result from network analysis was significant. No data were available during this period for BPD, loop gastric bypass, mini-gastric bypass, AGB with omentectomy, gastrogastostomy, or sleeve gastrectomy. <u>Laparoscopic versus open approaches</u> At 1 year (five trials, 234 pts): Small but significantly greater decrease in BMI in the laparoscopic surgery group as compared to the open surgery group (MD −1.2 kg/m^2; 95% CI: −2.2 to −0.2; five trials) Two trials reported changes in BMI between three and five years; the difference was not statistically significant.

*** Network analysis:** pooling data from studies that are not directly compared but are linked via one or more common comparators.

**** Credible interval (CrI):** used for mixed (direct and indirect) and indirect evidence

Table T.F.1-4: Weight loss – Surgery (cont'd)

Surgery	Weight loss
Colquitt et al., 2009[62]	Surgery versus non-surgical treatment Three RCTs indicated that regardless of the surgical intervention used or the types of patients included, all studies reporting a statistical comparison found statistically significant benefits on measures of weight change as compared to no surgery at 2- to 3-year follow-up. Comparison of different surgeries **LRYGB versus LAGB** One small RCT showed that, on a variety of measures of weight, LRYGB was superior to LAGB. **LRYGB versus LSG** One small RCT showed that BMI and weight loss at 12-month follow-up were similar between LRYGB and LSG group; per cent excess weight loss was greater with sleeve gastrectomy at 12 months (not statistically significant). **LAGB versus LISG** One RCT demonstrated that in all measures of weight change (% of excess weight loss, BMI, body weight) patients undergoing LISG showed more improvement than patients undergoing LAGB. Open versus laparoscopic procedures **Open versus laparoscopic gastric bypass** Four RCTs showed that weight loss was comparable between open and laparoscopic gastric bypass. **Open versus laparoscopic adjustable gastric banding** One RCT showed that open and laparoscopic surgeries to fit adjustable silicone gastric banding led to comparable degrees of significant weight loss.

Table T.F.2: Quality of life (QoL) – All bariatric treatment strategies

SRs/HTAs	QoL
Klarenbach et al., 2010[38] **Studies comparing surgery with another surgery or standard care:** N of trials: 31 N of pts: NA; mean BMI ranged from 42 to 58 kg/m^2 **Studies comparing laparoscopic with open surgery:** N of trials: eight N of pts: NA; mean BMI ranged from 42 to 51 kg/m^2	<u>Surgery versus another surgery or standard care (diet and exercise)</u> Utility scores (a QoL measure that is not disease specific and ranges from 0 to 1): NA SF-36 (generic instrument) (one trial; 197 pts): At 1 year, across all eight domains, no statistically significant differences were found for AGB versus RYGB. Clinically relevant differences could not be excluded. Differences in the mean estimates for the physical functioning and role-physical domains were large and favoured AGB (MD 8.1 and 12.7 respectively). Gastrointestinal Quality-of-Life Index (obesity-specific instrument) (two trials; 160 pts): one trial found a significant difference showing a better QoL in RYGB participants as compared to VBG participants (MD 14.6; 95% CI: 7.2 to 22.1). The other trial found no significant difference between mini-gastric bypass and RYGB participants. <u>Laparoscopic versus open approaches</u> SF-36 (one trial; 96 pts): 3 of 8 domains were significant: compared to open surgery, laparoscopic surgery has better assessment for physical functioning (MD 12.4; 95% CI: 2.9 to 21.9), social functioning (MD 13.2; 95% CI: 2.9 to 23.5), and mental health (MD 7.9; 95% CI: 1.0 to 14.8). Moorehead-Ardelt instrument (obesity-specific instrument) (two trials; 44 to 106 pts depending on the subscale): None of the five domains had significant results.
Colquitt et al., 2009[62]	<u>Surgery versus non-surgical treatment</u> One RCT found statistically significantly greater improvements in five of eight domains of the SF-36 following laparoscopic adjustable gastric banding, as compared to no surgery. <u>Comparison of different surgeries</u> None of the trials reported QoL outcome. <u>Open versus laparoscopic procedures</u> **Open versus laparoscopic gastric bypass** One RCT showed that at three-year follow-up, QoL measures were comparable between open and laparoscopic gastric bypass.
Maciejewski et al. 2005[65] N of trials: 34 (BT, medication, surgery) N of pts: 4054; mean BMI ranged from 25 to 48 kg/m^2	Weight-loss treatments appear to affect HrQoL among different dimensions, and these effects vary over time. Treatment effects on HrQoL as measured by generic measures were positive for at least one domain in every time period, but the domain varied across studies. HrQoL assessed by generic measures was not consistently improved in RCTs of weight loss because only 9 of 34 RCTs showed QoL improvements in one or more domains. For the two types of condition-specific measures, results were inconclusive for all measures except for the obesity-specific scale for obesity related problems. Of the 11 RCTs that included an obesity-specific measure, six trials showed positive treatment effects; however, only two of the 15 RCTs that used non-obesity-specific measures showed positive treatment effects.

Table T.F.3-1: Risk factors/Comorbidities – Dietary therapy/physical exercise

SRs/HTAs	Risk factors/Comorbidities		
Galani & Schneider, 2007[56] **Prevention studies:** N of trials: our, high quality studies N of pts: 1168; mean BMI 27 kg/m^2 **Treatment studies:** N of trials: five, high quality N of pts: 3032; mean BMI 33 kg/m^2	**Intervention versus standard care (not defined):**		
	Risk factors	**Prevention studies (4)**	**Treatment studies (5)**
	SBP (mmHg):	−1.6 (P = 0.068)	−3 (P = 0.0001)
	DBP (mmHg):	−2.0 (P = 0.03)	−2 (P = 0.0001)
	TC (mmol/L):	−0.32 (P = 0.0001)	−1.15 (P = 0.01)
	HDL (mmol/L):	0.01 (P = 0.96)	0.04 (P= 0.02)
	LDL (mmol/L):	−0.22 (P = 0.006)	NA
	TG (mmol/L):)	−0.21 (P = 0.002)	−0.17 (P = 0.02)
	HbA1c (%):	−0.75 (P = 0.37)	NA
	FPG (mmol/L):	−0.35 (P = 0.002)	−0.13 (P = 0.24)
Shaw et al., 2006[57] N of trials: 41 N of pts: 3476; overweight or obese	E versus no treatment (12 trials) **SBP (**mmHg): Exercise did not reduce SBP significantly more than did no treatment. E: −0.8 to −5.0 versus no treatment: −1.0 (nss) **DBP (**mmHg): Exercise reduced DBP 2.1 mmHg more than did no treatment. E: −0.8 to −5.0 versus no treatment: −1.0 to +0.6 **Cholesterol** (mmol/L): Exercise did not reduce cholesterol significantly more than did no treatment. E: −0.1 to −0.3 versus CG: −0.2 to −0.3 (nss) **Triglycerides** (mmol/L): Exercise reduced triglycerides 0.2 more than did no treatment. E: −0.1 to −0.2 versus no treatment: 0 to +0.1 **HDL** (mmol/L): Exercise increased HDL more than did no treatment. E: +0.01 to +0.1 versus no treatment: −1.0 to +0.6 **Glucose** (mmol/L): Exercise reduced glucose 0.2 more than did no treatment. E: −0.1 to −0.4 versus no treatment: −0.2 to +0.1 E versus D (10 trials) **SBP** (mmHg): Diet resulted in greater (2 mmHg more) reduction in SBP, as compared to exercise. E: −0.8 to −9.9 versus D: −2.6 to −11.3 **DBP** (mmHg): No significant difference between D and E on DBP. E: −1.2 to −5.9 versus D: −1.1 to −7.9 **Cholesterol** (mmol/L): Diet resulted in greater reduction in cholesterol, as compared to exercise. E: −0.2 to −0.3 versus D: −0.2 to −0.7 **Triglycerides** (mmol/L): No significant difference between D and E on TG. E: −0.2 to +0.1 versus D: −0.6 to +0.03 **HDL** (mmol/L): No significant difference between D and E. E: +0.01 to +0.1 versus D: −0.01 to +0.1 **Glucose** (mmol/L): Diet resulted in greater (0.1 mmol/L more) reduction in glucose, as compared to exercise. EG: −0.0 to −0.4 versus CG: −0.2 to +0.4 E+D versus D (17 trials) **SBP** (mmHg): Adding exercise to diet did not improve SBP reduction. **DBP** (mmHg): Adding exercise to diet did not improve DBP reduction.		

	Cholesterol (mmol/L): Adding exercise to diet did not improve cholesterol reduction. **Triglycerides** (mmol/L): Adding exercise to diet did not improve TG reduction. **HDL** (mmol/L): Adding exercise to diet did not improve HDL levels. **Glucose** (mmol/L): Adding exercise to diet did not improve glucose levels. High-intensity versus low-intensity E (eight trials) **SBP** (mmHg): Both groups reduced SBP; increased exercise intensity did not reduce SBP significantly more than did low-intensity exercise. **DBP** (mmHg): No consistent effects on DBP; no difference between the groups. **Cholesterol** (mmol/L): Insufficient data for analysis. **Triglycerides** (mmol/L): Decreased in both groups; increased exercise intensity did not reduce TG significantly more than did low-intensity exercise. **HDL** (mmol/L): Increased in both groups; increased exercise intensity increased HDL 0.1 more than did low-intensity exercise. **Glucose** (mmol/L): Reduced in both groups; increased intensity reduced glucose 0.3 more than did low-intensity. High-intensity E: −0.01 to −0.6 versus low-intensity E: −0.3 to +0.5 High-intensity versus low-intensity E with D **SBP** (mmHg): Same as above. **DBP** (mmHg): Same as above. **Cholesterol** (mmol/L): No consistent effects on DBP; increased exercise intensity did not reduce SBP significantly more than did low-intensity exercise. **Triglycerides** (mmol/L): Same as above. **HDL** (mmol/L): Increased in both groups; increased exercise intensity did not increase HDL more than did low-intensity exercise. **Glucose** (mmol/L): Reduced in both groups; increased intensity did not reduce glucose significantly more than did low-intensity.
Curioni & Lourenco 2005[58]	NA

Table T.F.3-2: Risk factors/Comorbidities – Behavioural therapy

Shaw et al., 2005[15]	BT versus no treatment (10 trials) SBP and DBP (two trials): decreased following weight loss Fasting serum glucose, fasting serum cholesterol (one trial): no significant change between the BT and the control groups Fasting serum insulin (one trial): improved in BT group compared to control group (significance not reported) High-intensity versus low-intensity BT (17 trials) HbA1C and FPG (one trial): improved in both groups BT + D/E versus D/E alone (eight trials) SBP and DBP: decreased in both groups (one trial); significant improvement in BT + D/E versus D/E alone (one trial); non-significant improvement in both groups (one trial) Total serum cholesterol and TG: decreased in both groups (one trial); significant improvement in BT + D/E versus D/E alone (one trial) FPG: decreased in both groups (one trial); significant improvement in BT + D/E versus D/E alone (one trial); non-significant improvement in both groups (one trial) Cognitive therapy versus BT (three trials) NA Cognitive therapy versus placebo (one trial) NA CBT + D/E versus D/E alone (two trials) Serum TG: decreased in both groups; decreased significantly more in CBT + D/E versus D/E alone ($P < 0.05$) Hypnotherapy versus placebo (one trial) NA Relaxation versus placebo (one trial) NA CBT versus no treatment (one trial) NA CBT versus BT (one trial) NA CBT + D/E versus CBT alone (one trial) NA

Table T.F.3-3: Risk factors/comorbidities – Pharmacotherapy[20]

Risk factors	Orlistat	Sibutramine	Rimonabant
Blood pressure	Orlistat resulted in placebo-subtracted SBP reductions of 1.5 mmHg (95% CI: 0.9 to 2.2; 13 trials) and DBP reduction of 1.4 mmHg (95% CI: 0.7 to 2.0; 12 trials).	See adverse events	Rimonabant reduced placebo-subtracted SBP by 1.8 mmHg (95% CI: 0.8 to 2.8; three trials) and DBP by 1.2 mmHg (95% CI: 0.5 to 1.9; three trials).
Glycemic parameters	Orlistat reduced the incidence of T2DM from 9.0% to 6.2% (HR 0.63, 95% CI: 0.46 to 0.86) in the XENDOS trial; this benefit was primarily observed in patients with impaired glucose tolerance at baseline.	Inconsistently reported; when reported, no difference from placebo in any study, even in patients with diabetes	Fasting glucose levels were reduced in one trial by 1 mmol/L (95% CI: 0.6 to 1.3) and HbA1c reduced by 0.7% (95% CI: 0.6 to 0.8). No clinically or statistically significant reductions were demonstrated in other studies.
Lipid parameters	Compared to placebo, orlistat reduced total cholesterol levels by 0.32 mmol/L (95% CI: 0.28 to 0.37; 13 trials), LDL cholesterol levels by 0.26 mmol/L (95% CI: 0.22 to 0.30; 13 trials) and HDL cholesterol by 0.03 mmol/L (95% CI: 0.02 to 0.04; 11 trials); the change in TG was not significantly different.	Compared to placebo, sibutramine increased HDL cholesterol levels 0.04 mmol/L (95% CI: 0.01 to 0.08 mmol/L; five trials) and reduced TG levels by 0.18 mmol/L (95% CI: 0.07 to 0.30 mmol/L; four trials)	Compared to placebo, rimonabant increased HDL cholesterol levels by 0.1 mmol/L (95% CI: 0.08 to 0.11; four trials) and reduced TG levels by 0.24 mmol/L (95% CI: 0.17 to 0.30; four trials). Changes in total cholesterol and LDL cholesterol were not significant.
Framingham risk score	No significant difference (one trial)	N/A	N/A
Cardiovascular morbidity	N/A	N/A	N/A
Mortality	N/A	N/A	N/A
Weight maintenance	Weight regain: comparable between the two groups. Weight differential between the two groups after weight loss phase preserved. Changes in serum lipid and glucose values during maintenance phase were similar to weight loss phase in each trial.	N/A	N/A

Table T.F.3-4: Risk factors/Comorbidities – Surgery

Study	Risk factor/comorbidities
Klarenbach et al., 2010[38]	Surgery versus another surgery or standard care (diet and exercise) Six trials (3 to 100 pts depending on the comorbidity) reported resolution or improvement in comorbidity (participants without pre-existing comorbidity at baseline were excluded in the analysis). All risk differences were not statistically significant, and these analyses were not informative because of low power. No trials reported the incidence of knee or hip replacement. Laparoscopic versus open surgery One trial on RYGB patients reported resolution or improvement in comorbidity. Significantly greater resolution of diabetes with open surgery group, as compared to laparoscopic group (RD −50%; 95% CI: −89 to −11; one trial). Significantly greater resolution of dyslipidemia in laparoscopic group, as compared to open surgery group (RD −50%; 95% CI: −84 to −16; one trial).
Colquitt et al., 2009[62]	**Surgery versus non-surgical treatment** One RCT of patients with type 2 diabetes found significantly higher remission of the disease following LAGB than conventional therapy, and two RCTs reporting metabolic syndrome found significantly fewer people with the syndrome 2 years after surgery. **Comparison of different surgeries** LRYGB versus LAGB Similar between the two groups. **Open versus laparoscopic procedures** Open versus laparoscopic gastric bypass One RCT reported that improvement in comorbidities were similar between the two groups.

Table T.F.3-5: Long-term effects of bariatric treatment strategies on overall mortality[67]

Women only	Men only	Women and men combined
No. of studies: two studies conducted in the United States **Participants** ***Study one:*** N =14,407; white, normal weight or overweight ***Study two:*** N = 43,457 (no preexisting diseases, N = 28,388; obesity-related diseases, N = 15,069); white, overweight women **Follow-up** ***Study one:*** median 13.6 years for survivors ***Study two:*** 12 years for survivors; 7.5 years for decedents **Results** ***Study one:*** Compared to women with normal weight (reference group), mortality risk significantly increased in overweight/obese women with weight loss. However, the two groups were not comparable. ***Study two:*** Included women who were at least overweight. Information about participants' intention to weight loss and the presence of any obesity-related diseases were obtained. The "no weight change" subgroup was used as a reference group. For those with obesity-related diseases and intentional weight loss, weight loss greater than 20 pounds within one year significantly improved the mortality risk when compared to similar people with no weight change.	**No. of studies:** three studies, one conducted in each of the United States, Sweden, and the UK **Participants** ***The US study:*** N = 49,337 (no pre-existing disease, N = 36,280; with health problems, N = 13,057); white men with a BMI > 27 kg/m² ***The Swedish study:*** N = 5722, overweight, obese ***The British study:*** N: NA at baseline; 5267 at follow-up; normal weight or overweight men **Follow-up** ***The US study:*** 12.9 years for survivors; 7.3 years for decedents ***The Swedish study:*** 12 years for weight change average; 22 years for whole study ***The British study:*** 7 years **Results** ***The US study:*** Included patients who were at least overweight. The intention of weight loss and the presence of health conditions were separately considered. Compared to the reference group of weight stable men, intentional weight loss greater than 20 pounds for longer than 1 year were detrimental for all men. Unintentional weight loss was also marginally detrimental. ***The Swedish study:*** Compared with similar men who were weight-stable, weight loss was detrimental for non-cancer mortality. However, the intentionality of weight loss was not reported. ***The British study:*** Conducted an analysis on overweight men and adjusted for several variables accounting for demographic variations and probably underlying diseases. Compared with the weight-stable subgroup, intentional weight loss improved mortality risk; however, there was no difference in those with comorbidities or who lost weight unintentionally. Overall, the impact of weight loss on mortality in men is not clear. Two studies indicate weight loss to be detrimental while the most recent cohort showed clear benefits if the weight loss is a personal decision. ***Meta-analysis of three studies:*** Compared with the reference group of weight-stable men, the overall effective weight loss is slightly detrimental with a hazard ratio (HR 1.15; 95% CI: 1.08 to 1.01). When studies with only intentional weight loss are considered, the HR (1.01; 95% CI: 0.99 to 1.09) become non-significant.	**No. of studies:** three studies, one conducted in each of United States, Finland, and Canada **Participants** ***The US study:*** N = 6391, BMI ≥ 25 kg/m² ***The Finnish study:*** N = 4466, BMI ≥ 25 kg/m² ***The Canadian study:*** N = 6781; morbidly obese **Follow-up** ***The US study:*** 9 years after weight change (mean 8 years) ***The Finnish study:*** 18 years after recorded weight change ***The Canadian study:*** maximal 5 years **Results** ***The US study:*** Adjusted for more than 13 variables, and also attempted to account for known underlying diseases. For those who claimed to be trying to lose weight, the effects were marginally beneficial if they remained weight-stable or lost small amounts. **The Finnish study:** Observed that even for those with intentional weight loss,the effect of weight loss was detrimental. ***Meta-analysis of the above two studies:*** Indicated no significant difference between the groups. ***The Canadian study***: Examined the impact of bariatric surgery (RYGB, VBG) on mortality in morbidly obese patients; 7/1035 patients (0.7%) in the surgery group died and 354/5746 patients (6.2%) in the standard treatment group died. Usually surgery is only considered when obesity is life-threatening. Consequently, the surgery group does have a substantially reduced mortality risk as compared to the similar control group who do not undergo surgery. Similarly, the effects of the surgery are difficult to disentangle from any weight loss benefits for this subgroup.

Table T.F.3-6: Conclusions from the systematic reviews/HTAs

SRs/HTAs	Conclusion
Dietary therapy/physical exercise	
Galani & Schneider, 2007[56]	Life style interventions were efficacious in the mid- to long-term prevention and treatment of obesity leading to a significant reduction in body weight and cardiovascular risk factors.
Shaw et al., 2006[57]	Exercise is an effective weight loss intervention, particularly when combined with dietary interventions. Exercise is also an effective intervention for improving a range of secondary outcomes even when weight loss does not occur. No long-term morbidity and mortality benefits were associated with exercise. Exercise was shown to positively impact the intermediate outcomes commonly associated with cardiovascular disease.
Curioni & Lourenco, 2005[58]	Adding exercise to diet produced greater weight loss than diet alone in overweight and obese individuals immediate after the intervention period and after one-year follow-up, but did not produce better long-term maintenance of the lost weight.
Behavioural therapy	
Shaw et al., 2005[15]	People who are overweight or obese benefit from psychological intervention, particularly behavioural and cognitive-behavioural strategies, to enhance weight reduction. Psychological interventions are extremely useful when combined with dietary and exercise strategies. Other psychological interventions are less rigorously useful for their efficacy as weight loss treatments.
Pharmacotherapy	
Johansson et al., 2009[59]	Available weight loss drugs differ markedly regarding risk of discontinuation due to adverse events, as well as differing in the underlying causes of these events. Given the large number of patients eligible for treatment, the low number needed for harm for rimonabant is a concern.
Padwal et al., 2004[20]	Internal validity of studies was limited by high attrition rates. Orlistat, sibutramine, and rimonabant in trials of one year or longer are modestly effective in reducing weight, and have differing effects on cardiovascular risk and adverse effects profiles.
Li et al., 2005[60]	Sibutramine, orlistat, phentermine, diethylpropion (probably), bupropion, fluoxetine, and topiramate all promote weight loss when given along with recommendations for diet. Sibutramine and orlistat are the two most-studied drugs. The amount of extra weight loss attributable to these medications is modest (less than 5 kg at one year), but this amount still may be clinically significant.
Surgery	
Klarenbach et al., 2010[38]	Although data from large, adequately powered, long-term RCTs are lacking, bariatric surgery seems to be more effective than standard care for the treatment of severe obesity in adults. Procedures that are mainly diversionary (e.g., BPD) result in the greatest amounts of weight loss, hybrid procedures (e.g., RYGB) are of intermediate effectiveness, and restrictive procedures (e.g., AGB) result in the least amounts of weight loss. RYGB and AGB tended to lead to trade-offs between the risk of adverse events and the need for procedure conversion or reversals. The evidence base was limited for sleeve gastrectomy.
Colquitt et al., 2009[62]	Surgery is more effective than conventional management. Certain procedures produce greater weight loss, but data are limited. The evidence on safety is even less clear. Due to limited evidence and the poor quality of the trials, caution is required when interpreting comparative safety and effectiveness.
Multiple strategies	
Tsai, 2009[64]	Current evidence does not support the use of low-intensity to moderate-intensity physician counseling for obesity, by itself, to achieve clinically meaningful weight loss. Available data do not indicate how best to incorporate PCPs into more intensive approaches for achieving this goal. PCP counseling, plus pharmacotherapy, or intensive counseling (from a dietitian or nurse), plus meal replacements may help patients achieve this goal.

Maciejewski et al., 2005[65]	HrQoL outcomes, including depression, were not consistently improved in RCTs of weight loss. The overall quality of these clinical trials was poor. Better-designed RCTs using standardized HrQoL measures are needed in order to determine the extent to which weight loss improves HrQoL.
Avenell et al., 2004[2]	Orlistat, sibutramine, and metformin appear beneficial for the treatment of adults with obesity. Exercise and/or behavioural therapy appear to improve weight loss when added to diet. Low-fat diets with exercise, with or without behavioural therapy, are associated with the prevention of type 2 diabetes and hypertension. Long-term weight loss was also associated with reduced risk of developing diabetes, and may be beneficial for cardiovascular disease.
McTigue et al., 2003[66]	Limited evidence suggests that counseling interventions may promote modest weight loss in the overweight (BMI 25–29.9 kg/m^2). Effective treatments for people with a BMI >30 kg/m^2 include intensive counseling and behavioural interventions for lifestyle change, and pharmacotherapy. Surgery is effective in reducing weight for people with a BMI of 35 kg/m^2 or greater.
Poobalan et al., 2007[67]	Considering the methodological limitations, benefits of weight loss on all-cause mortality for overweight/obese patients are meager. The most important explanations are intentionality, self-reporting of weight loss, and the time lapse between last recorded weight loss measurement and the mortality outcome.

APPENDIX G: SUMMARY OF SWEDISH OBESITY SUBJECT (SOS) STUDY

Table T.G.1: Patient characteristics

	Intervention group	Control group	Difference
Total number	2010	2037	
Mean age (yrs)	46.1	47.4	1.3 (P<0.001)
Mean baseline weight (kg)	119.2	116.9	+ 2.3 (P<0.001)
Smoking (%)	27.9	20.2	+ 7.7 (P<0.001)
Treatment received	**Bariatric surgery** VBG (N = 1369) Non-adjustable or adjustable banding (N = 376) Gastric bypass (N = 265)	**Conventional treatment** Received customary non-surgical obesity treatment for their given centre of registration. No attempt was made to standardize the conventional treatment, which ranged from sophisticated lifestyle intervention and behavioural modification to no treatment. No anti-obesity drugs were approved in Sweden until 1998.	

Source: Colquitt et al., 2009[62]; Sjostrom et al., 2009[70]

Abbreviations: BMI = body mass index; CI = confidence interval; DM = diabetes; kg = kilogram; GBP = gastric bypass; HDL = high-density lipoprotein; HR = hazard ratio; HrQoL = health-related quality of life; HTN = hypertension; N = number; TG = ***triglyceride***; VBG = vertical banded gastroplasty; WC = waist circumference; yrs = years

Table T.G.2: Effects of bariatric surgery on weight loss and HrQoL

Weight change/HrQoL	Surgery	Control	Effect size/P-value (95% CI)
% weight change at 2 yrs	-23.4 (N = 1845)	0.1 (N = 1660)	Difference 22.2 (21.6 to 22.8), P < 0.001
% BMI change at 2 yrs	-23.3 (N = 1845)	0.1 (N = 1845)	22.1 (21.5 to 22.7), P < 0.001
Weight at 10 years (kg)	100.5 (±17.7) (N = 655)	115.2 (±19.9) (N = 621)	P < 0.0001
Weight change at 10 yrs (kg)	-19.7 (±15.8) (N = 655)	1.3 (±13.8) (N = 621)	P < 0.0001
Weight % change at 10 yrs	-16 (±12.1) (N = 655)	1.5 (±9.9) (N = 621)	
BMI at 10 yrs	35.3 (±5.4) (N = 655)	40.6 (±5.9) (N = 621)	
Change in BMI at 10 yrs	-6.7 (±5.4) (N = 655)	0.7 (±4.9) (N = 621)	P < 0.0001
% weight loss at 10 yrs for each surgical procedure (proportion of patients followed)	GBP: 25±11% (58/265) VBG: 16±11% (746/1369) Gastric banding: 14±14% (237/376)		
% weight loss at 15 yrs for each surgical procedure (proportion of patients followed)	GBP: 27±12% (10/265) VBG: 18±11% (108/1369) Gastric banding: 13±14% (52/376)		
HrQoL Current health perceptions from the General Health Rating Index Social interaction from the Sickness Impact Profile Overall mood from the Mood Adjective Check List Obesity-related Problems scale Hospital Anxiety and Depression scale	At 2 years, the surgery group had significant improvement in all HrQoL measures as compared to patients receiving conventional treatment.		

Table T.G.3: Effects of bariatric surgery on risk factors/comorbidities

Risk factors/comorbidities		Surgery	Control	Effect size/P-value (95% CI)
Diabetes	Incidence at 2 yrs	15/1489 (1%)	112/1402 (8%)	OR 0.14 (0.08-0.24), P < 0.001
	Incidence at 10 yrs	36/517 (7%)	129/539 (24%)	OR 0.25 (0.17-0.38), P < 0.001
	Recovery of DM at 2 yrs	246/342 (72%)	52/248 (21%)	OR 8.42 (5.68-12.5), P < 0.001
	Recovery of DM at 10 yrs	42/118 (36%)	11/84 (13%)	3.45 (1.64-7.28), P < 0.001
Hypertension	Incidence at 2 yrs	149/623 (24%)	223/770 (29%)	OR 0.78 (0.60-1.01), P = 0.06
	Incidence at 10 yrs	88/215 (41%)	137/279 (49%)	OR 0.75 (0.52-1.08), P = 0.13
	Recovery of HTN at 2 yrs	409/1204 (34%)	185/880 (21%)	1.72 (1.40-2.12), P < 0.001
	Recovery of HTN at 10 yrs	81/424 (19%)	38/342 (11%)	OR 1.68 (1.09-2.58), P = 0.02
Hyper-triglyceridemia	Incidence at 2 yrs	58/731 (8%)	176/801 (22%)	OR 0.29 (0.21-0.41), P < 0.001
	Incidence at 10 yrs	38/225 (17%)	75/281 (27%)	OR 0.61 (0.39-0.95), P = 0.03
	Recovery of HTG at 2 yrs	683/1102 (62%)	187/850 (22%)	OR 5.28 (4.29-6.49), P < 0.001
	Recovery of HTG at 10 yrs	185/402 (46%)	79/331 (24%)	OR 2.57 (1.85-3.57), P < 0.001
Cardiovascular disease medication	On medication at baseline	N = 150	N = 125	
	% on medication at 2 years	61.7	91.2	RR 0.69 (0.60, 0.80), P < 0.05
	% on medication at 6 years	64.7	86.4	RR 0.77 (0.67, 0.88), P < 0.0 5
	Not on medication at baseline	N = 360	N = 330	
	% on medication at 2 years	3.1	10.1	RR 0.28 (0.14, 0.56), P < 0.05
	% on medication at 6 years	13.3	16.7	RR 0.80 (0.56, 1.16)

Table T.G.4: Effects of bariatric surgery on cancer, mortality, and adverse events

	Surgery group	Control group	Effect size/P-value (95% CI)
Cancer incidence			
Total:	126/2010	173/2037	0.71 (P = 0.003)
First-time cancer (10 years):	117	169	HR 0.67, 95% CI 0.53 to 0.85, P = 0.0009
In women:	79	130	HR 0.58, 95% CI 0.44 to 0.77, P = 0.0001
In men:	38	39	HR 0.97, 95% CI 0.62 to 1.52, P = 0.90
Mortality (at mean follow-up of 10.9 years)			
Overall mortality:	101/2010 (5.0%)	129/2037 (6.3%)	
Deaths due to cardiac events:	13/2010	25/2037	
Deaths due to cancer:	29/2010	47/2037	
Adverse events			
Mortality 90-days post surgery:	5/2010 (0.25%)(4 peritonitis with organ failure; 1 sudden death)	2/2037 (0.10%) (1 pancreatic cancer; one alcohol-related)	
No. of patients with complications:	151/1164 (13%)		
Post-operation requiring reoperation:	26/1164 (2.2%)		
Reoperation or conversion:	N = 1338 (for at least 10-year follow-up) Banding: 31% VBG: 21% Gastric bypass: 17%		

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SECTION THREE: ECONOMIC EVALUATION

Charles Yan, PhD, Andy Chuck, PhD, MPH

ECONOMIC ANALYSIS (E)

Objectives and Policy Questions

The objective of the economic analysis was to address the following issues:

1. Cost comparisons (effectiveness or utility analyses) in the short-term and in the long-term and the potential for one treatment strategy to replace another in a given sub-population.
2. Unit cost estimates, including physician billings, hospitalization or facility operational costs, other service costs and capital costs, for the procedure as well as related health services.
3. Estimates of patient and public demand, including prevalence and incidence of condition(s); utilization rates of standard or alternative treatments, where data exist; and estimates of the use of the new technology taking into account service capacity, where feasible, as well as appropriate clinical indicators for use.

Issue 1 was addressed by a systematic review of the economic literature to determine the comparative cost-effectiveness of alternative interventions for obesity. Issue 2 was addressed by conducting a secondary analysis of provincial health service utilization data to estimate the direct health services cost associated with bariatric surgery in Alberta. Issue 3 was addressed by conducting a secondary analysis of provincial health utilization data linked with the 2007 Canadian Community Health Survey (CCHS) to estimate the economic burden of disease associated with obesity in Alberta.

Methods

Review of economic studies

Search strategy

Selected databases were searched for economic evaluation studies of bariatric services published from 2000 to April 2010. Core Databases searched include MEDLINE, EMBASE, CINAHL, and Web of Science, along with the Cochrane Database of Systematic Reviews (CDSR) and the Centre for Reviews and Dissemination Databases (DARE, NHS EED, and HTA). Refer to Table E.A.1 in Appendix E.A for the detailed search strategy.

Selection criteria

The search was limited to human and English-language publications. Studies investigating the economic, health service utilization, or cost impact of bariatric services for adults on the health system were included. Opinion articles (for example, opinions or letters to the editor) and abstracts were excluded. The selection of potentially relevant studies was reviewed by one reviewer.

A recent 2010 CADTH report of bariatric surgeries[1] has been published that included a systematic review of relevant health economic literature relating to bariatric surgeries and a primary cost-effectiveness model comparing alternative bariatric surgical procedures, including standard care. Articles that were reviewed by the CADTH report[1] are not reviewed here; but rather a synthesis of their findings will be conducted. However, findings from the primary cost-effectiveness model will be reviewed in this report.

Data extraction

Data extracted from studies include study design, objective, perspective, timelines, bariatric interventions under investigation, country, health and cost outcomes, results from marginal analysis, and study conclusions.

Quality assessment criteria

An informal quality assessment of economic studies was conducted using criteria adapted from Drummond et al.[2] and Drummond et al.[3] The purpose of providing a quality assessment of economic studies in this report is to identify the components included in the studies and to provide a general assessment of the quality of the economic studies reviewed. The quality of potentially relevant studies was assessed by one reviewer.

Secondary analysis of Provincial Health Utilization databases

Source of information

Information on costs and resource utilization were retrieved from three provincial health utilization databases between 2004 and 2008 fiscal years. The Alberta Physician Claims Database (PCD) provided information related to billing services to physicians for medically insured services in Alberta. The Alberta Discharge Abstracts Database (DAD) provided information related to hospital inpatient procedures. The Ambulatory Care Classification System (ACCS) provided information related to outpatient procedures. Note that cost data in the DAD and ACCS include patient-specific drug and supply costs, functional centre direct costs such as salaries (excluding physician services), medical and surgical supplies, and functional center indirect costs such as administration and support services (Alberta Case Cost Report, Alberta Health and Wellness, December 2009).

Analysis

The analysis consisted of two components. The first was an estimate of the direct health service costs of bariatric surgery. Patients who received bariatric surgery in 2005–2006 were identified using the Canadian Classification of Health Interventions (CCI) codes (see below) that corresponded to bariatric surgery. Total physician and inpatient costs for each patient with a corresponding CCI code were calculated by aggregating all costs of physician and inpatient services provided within the dates of admission and discharge. A mean cost per bariatric surgery was then calculated by divided the total cost of bariatric surgery across all patients by the number of patients in the cohort.

The second component was a pre-post analysis comparing the health service utilization before and after surgery. For the cohort of patients who received bariatric surgery in 2005–2006, total physician, inpatient, and outpatient visits and costs were calculated across all patients, over a period of 2 years before and 2 years after surgery. Total physician, inpatient, and outpatient visits and costs were divided by the number of patients in the cohort to provide a mean visit and a cost per patient. The mean visit and costs before and after surgery were then compared to each other. Note that all costs were adjusted to reflect 2006 dollars using the Alberta Consumer Price Index (CPI). Furthermore, visits or costs that were greater than three times its standard deviation in each year were censored from the analysis.

Definition of bariatric surgical patients

Table E.1 outlines the CCI codes that correspond to a specific type of bariatric surgery. Patients were included in the analysis if they had any one of these codes listed in the principal intervention field in the DAD.

Table E.1: CCI code description for bariatric surgeries

Open approach	Laparoscopic approach	Description
1.NF.78.XP	1.NF.78.EJ	Using vertical banded technique
1.NF.78.WJ	1.NF.78.GB	Using vertical (sleeve) gastrectomy technique
1.NF.78.SH	1.NF.78.DQ	Using gastric bypass technique with gastroenterostomy (e.g., Roux-en-Y)
1.NF.78.SJ	1.NF.78.DO	Using gastric bypass technique with gastroenterostomy and biliopancreatic bypass [to terminal ileum] (e.g., biliopancreatic diversion)
1.NF.78.SI	1.NF.78.DI	Using gastric bypass technique with enteroenterostomy and biliopancreatic bypass [to terminal ileum] (e.g., duodenal switch)

Secondary analysis of Provincial Health Utilization databases and CCHS data

Source of information

Information on health service utilization was retrieved from the three provincial health utilization databases identified above. Health utilization data from 2007 was linked with epidemiologic (BMI), demographic (age, gender, income, and education), behavioural (smoking status and physical activity), and health status (presence of diabetes, hypertension, COPD, and back problems) data contained in the 2007 CCHS.

Analysis

Six separate multivariate regression models were developed to estimate the impact of BMI on physician visits, physician costs, outpatient visits, outpatient costs, combined physician and outpatient costs, and inpatient admissions. Note that inpatient costs were unavailable in the dataset. BMI was divided into four categories characterizing underweight, normal weight, overweight, and obese (as defined in the S section of this report). Furthermore, each model was adjusted for age, gender, income, education, smoking status, physical activity, and the presence of diabetes, hypertension, COPD, and back problems. All analyses were conducted with STATA 9.1 (Statacorp LP, College Station, Texas). Statistical significance was defined at $p < 0.05$.

Calculation of health service utilization and costs

Adjusted estimates of mean physician visits, outpatient visits, and inpatient admissions in 2007 by BMI category were estimated from the regression models. Using normal weight as a point of reference, differences in adjusted mean costs and visits were calculated for underweight, overweight and obesity. Total economic burden was then calculated by multiplying the incremental adjusted mean difference with the prevalence of Albertans who are underweight, overweight, or obese (refer to Appendix E.B for complete details).

Literature review findings

Search results

Eight hundred eighty-one published documents were identified from the literature search. After reviewing their titles and abstracts, 130 studies were retrieved for further evaluation. Of the 130 studies, 29 full text articles met the final inclusion/exclusion criteria. See Figure E.A.1 in Appendix E.A for the progress through the selection of potentially relevant studies.

Eleven studies[1,4-13] compared bariatric surgeries with various forms of bariatric surgical procedures or with non-surgical treatments. Nine[5-13] of the 11 studies were reviewed in the CADTH report.[2] The remaining 18 studies examined various non-surgical interventions, including pharmacotherapy (PT), lifestyle modification (LM), and weight management programs (WMP). Table E.2 shows a matrix of the number of articles retrieved by the specific interventions included in the articles. Some studies included a combination of bariatric interventions.

Table E.2: Number of retrieved articles by bariatric intervention*

Comparator	Intervention						
	Surgery**		PT	LM	WMP	PT+LM	PT+WMP
Surgery	3	1					
LM	7	2		4	2	8	
WMP							1
Placebo			2	4	2	2	

* One article could have evaluated more than one intervention. Thus the sum of the numbers listed in the table could exceed the number of articles retrieved for review.
** The first column lists the articles reviewed in the CADTH report; the second column lists the articles not being reviewed in the CADTH report.

Evidence from published literature

Evidence from the selected studies is summarized in Table E.A.2 in Appendix E.A.

Surgery versus surgery or non-surgical interventions

In the CADTH report,[1] a decision analytic model was developed to evaluate the cost-effectiveness of bariatric surgeries in comparison with lifestyle modification and other bariatric surgical alternatives for adult patients with a BMI ≥ 40 kg/m^2 or a BMI ≥ 35 kg/m^2 with obesity-related morbidity. The analysis was conducted from a payer's perspective. Cost categories considered were the pre-treatment consultation from family physicians and dieticians, hospitalization of surgery, follow-up, and the treatment of surgical complications and obesity-related morbidities. Timelines for the analysis were varied at 1 year, 10 years, 20 years, and lifetime. At a 1-year time horizon the model compared surgical interventions (RYGB, LAGB, sleeve, and BPD) with lifestyle modification and between each other. At a time horizon greater than one year, the model evaluated Roux-en-Y gastric bypass (RYGB) or laparoscopic adjustable gastric banding (LAGB) in comparison with lifestyle modification (LM).

At 1 year, as compared to LM, the cost per unit BMI reduced was $2990 for RYGB, $5764 for LAGB, $2184 for sleeve, and $3064 for biliopancreatic diversion (BPD). In a pair-wise comparison

[2] Eleven economic studies are reviewed in the CADTH report; two of them are not included in our search results due to their publication date being earlier than 2000.

between surgical interventions, the cost per QALY gained was $673 for sleeve versus LAGB and $10,714 for BPD versus RYGB. Furthermore, RYGB was less effective and more costly compared to sleeve (that is, sleeve dominated RYGB). At 10 years, 20 years, and lifetime, compared to LM, the cost per QALY gained was $21,595, $13,674, and $9398, respectively, for RYGB; and $37,910, $21,240 and $12,212, respectively, for LAGB. Furthermore, when the proportion of patients with obesity-related morbidity was increased, compared to LM, the cost per QALY gained for RYGB decreased. The study concluded that bariatric surgeries were more cost-effective than lifestyle modification for the treatment of patients with severe obesity. However, within surgical interventions, it was uncertain which surgical intervention had the greatest cost-effectiveness due to limitations in available data.

Anselmino et al.[4] used a decision analytic model to evaluate the cost-effectiveness of adjustable gastric banding (AGB) and gastric bypass procedures (GBP) compared to medically guided diet (conventional treatment) for treating obese patients (BMI ≥ 35 kg/m^2) with type 2 diabetes (T2DM). The study was conducted from a payer's perspective over a 5-year time horizon in three European countries (Austria, Italy, and Spain) and included the cost of pre-surgery assessment, surgical procedures, hospitalization, follow-up, physician visits, and the treatment for surgery-related complications and T2DM. In Austria and Italy, AGB and GBP were less costly and more effective than conventional treatment (CT) (that is, they dominated CT). In Spain, compared to CT, the cost per QALY gained was $1964[3] for AGB and $3593 for GBP. The study concluded that compared to CT, AGB and GBP were cost-effective interventions for the treatment of severely obese patients.

Summary of CADTH report

Nine studies[5-13] were already reviewed by the CADTH report and are summarized below. The studies assessed the cost-effectiveness of a bariatric surgery in comparison with either another surgical alternative or standard care for patients with a BMI ≥ 40 kg/m^2 or a BMI ≥ 35 kg/m^2 with obesity-related morbidity. The majority of these studies took a payer's perspective; three[8,9,11] took a societal perspective.

For studies that evaluated surgical interventions versus standard care, the cost per QALY gained ranged between $5000 and $40,000, indicating the bariatric surgical interventions were cost-effective. Craig et al.[10] reported the cost-effectiveness ratios for GBP by age groups; they ranged from $5646 to $16,834 for women and $11,188 to $37,223 for men. Surgery was the least cost-effective for elderly patients. In the study by Salem et al.,[6] RYGB was associated with a cost less than $26,140 per QALY gained, as compared to standard care.

For obese patients with T2DM, bariatric surgery was found to be more cost-effective than standard care in two studies.[7,13] Ackroyd et al.[7] reported $2406 per QALY gained for LGBP and $3308 per QALY gained for LAGB in the UK; in France and Germany, the bariatric interventions were more effective and less costly. Keating et al.[13] showed that LAGB was associated with a gain of 0.7 life year and 1.2 QALYs at a lower cost ($2614 in savings).

For studies that evaluated surgical interventions with other surgical interventions, Paxton et al.,[9] van Mastrigt et al.,[11] and Clegg et al.[12] provided direct comparisons across bariatric surgical alternatives. Paxton et al. assumed that weight loss was comparable between open gastric bypass and laparoscopic gastric bypass, and hence conducted a cost-minimization analysis. They reported the

[3] To facilitate the comparison, all currencies are converted to Canadian dollars using the exchange rates released by the Bank of Canada on August 11, 2010.
Table E.A.2 for costs in original currencies.

latter to be more cost-effective, driven by fewer post-operative complications, and noted a difference in health care and productivity costs. van Mastrigt et al.[11] compared vertical banded gastroplasty (VBG) with Lap-Band over a 1-year horizon, based on an RCT enrolling 100 patients. This study indicated that VBG was associated with an extra $143 per additional per cent excess weight loss. In the Clegg study, AGB and gastric bypass were shown to be more cost-effective than VBG, with a cost of $10,131 and $1217, respectively, per QALY gained.

In conclusion, the CADTH report[1] stated that, compared to lifestyle modification, bariatric surgery was cost-effective for patients with severe obesity and, furthermore, was less costly and more effective for those with T2DM. However, the report suggested that no conclusion was achieved regarding the cost-effectiveness between the surgical alternatives, due to limitations in the reviewed primary studies.

Pharmacotherapy (PT) versus lifestyle modification (LM), weight management program (WMP), or no treatment

Eight studies[14-21] compared PT plus LM with LM alone. Two studies[22,23] evaluated PT alone versus no treatment and one study[24] evaluated PT plus WMP versus WMP alone. Van Baal et al.[14] conducted a Markov model to compare low-calorie diet (LCD) alone with no treatment and to compare LCD plus orlistat with no treatment for adult patients between 20 and 70 years of age with a BMI $\geq$ 30 kg/m^2. The analysis was conducted in the Netherlands from a payer's perspective over a lifetime horizon. Estimates of short-term efficacy were derived from published literature, and long-term efficacy rates were based on the assumption that 23% of weight loss achieved after 1 year would be maintained over the patient's lifetime. This analysis considered the cost of health care (including GP and dietitian time), orlistat acquisition, and the treatment for obesity-related morbidity. Compared with no treatment, the cost per life year gained and the cost per QALY gained were $22,177 and $24,140, respectively, for LCD alone, and $72,286 and $79,299 for LCD plus orlistat. The study concluded that LCD should be the first option for the treatment of obesity for adults aged 20 to 70 years with a BMI $\geq$ 30 kg/m^2.

Lacey et al.[15] constructed a decision-tree model to assess the cost-effectiveness of LCD plus orlistat, as compared to LCD alone for patients aged 18 years or older with a BMI $\geq$ 28 kg/m^2 and no diagnosed T2DM. The analysis was conducted in Ireland from a payer's perspective using an 11-year horizon. Estimates of efficacy were derived from five RCTs. The treatment period was 12 months. For patients with less than 5% weight loss at the third month, the orlistat treatment would be discontinued. Costs considered in the analysis were the acquisition cost of orlistat, the cost of the LCD program, and the cost associated with monitoring and treatment of obesity-related morbidity. Compared to LCD alone, the cost per QALY gained was $22,864 for LCD plus orlistat. The study concluded that orlistat is effective and cost-effective compared to LCD alone.

Iannazzo et al.[16] constructed a Markov model to assess the long term (10 years) clinical and economic impact of orlistat in combination with LM (LCD and exercise) versus LM alone for adult patients in Italy with a BMI $\geq$ 30 kg/m^2. Clinical evidence applied in the analysis was based on a large RCT, and costing was conducted from a societal perspective. Cost categories included the orlistat acquisition, glucose tolerance test for impaired glucose tolerance (IGT), treatment of diabetes, and treatment of obesity. The patients paid the cost of the orlistat, while other costs were paid by the Italian National Health Service. The study indicated that orlistat plus LCD and exercise was associated with a cost of $101,564 per QALY gained, compared to LM alone. When orlistat was given only to obese IGT patients, the cost decreased to $28,631per QALY gained. The study

concluded that adding orlistat to LM was associated with best value-for-money in the sub-group of obese patients with IGT.

Roux et al.[21] compared the cost-effectiveness of usual care with four weight loss strategies—diet only, diet and orlistat; diet and exercise; and a combination of diet, exercise, and behaviour modification—for women aged ≥ 35 years with a BMI ≥ 25 kg/m^2. A first-order Monte Carlo model was applied to simulate the natural history of obesity over a lifetime horizon. The study was conducted from a societal perspective in the US, with clinical evidence mainly derived from RCTs. The medical costs considered in the analysis were the costs of medication, physician services, laboratory and diagnostic tests, and the costs of obesity-related morbidity and mortality. Non-medical costs such as fitness and travel costs as well as the costs of patients' time were also included. Results indicated the treatment option with the lowest cost per life year (LY) saved or per QALY gained was the combination of diet, exercise, and behaviour modification; as compared to usual care, the cost of the combined treatment was $63,153 per LY saved and $13,174 per QALY gained. The study concluded that the weight loss program combining diet, exercise, and behaviour modification was the most cost-effective for overweight and obese women.

Hampp et al.[17] constructed a decision analytic model to assess the clinical and economic impact of rimonabant in combination with LM (LCD and exercise) for adult patients with a BMI ≥ 30 kg/m^2 or a BMI ≥ 27 kg/m^2 with treated or untreated dyslipidaemia or hypertension. Five treatment alternatives were:

- rimonabant at a daily dose of 20mg plus LM for 1 year;
- rimonabant plus LM for one year followed by placebo plus LM for 1 year;
- rimonabant plus LM for 2 years;
- placebo plus LM for 2 years;
- no intervention,

The time horizon of the analysis was 5 years. The study applied clinical evidence demonstrated in a large RCT and healthcare costs from a US payer's perspective. The cost categories included the costs of medications, dietician and physician visits, and treatment for myocardial infarction and diabetes. Results indicated that rimonabant plus LM for one year and of rimonabant plus LM for 1 year followed by placebo plus LM for 1 year were dominant options in that they were more costly and less effective, as compared to the other alternatives. The cost of for rimonabant treatment for 2 years was $75,255 per QALY gained as compared to LM, and $55,349 per QALY gained as compared to no intervention. The study concluded that adding rimonabant to LM reduced the incidence of obesity-related morbidity and improved health-related quality of life, but at a considerable cost.

Brennan et al.,[18] Warren et al.,[19] and Ara et al.[20] constructed decision-tree models to evaluate the clinical impact and cost-effectiveness of sibutramine in combination with lifestyle counselling for patients with a BMI ≥ 30 kg/m^2, as compared to lifestyle counselling alone. These studies adopted a payers' perspective and had a 5-year horizon (1 year sibutramine treatment plus 4 years follow-up). The Brennan study was performed in Germany, the Warren study in the UK and the US, and the Ara study in four European countries (Finland, Germany, Switzerland, and the UK). Clinical evidence applied in these studies was based on an RCT. The costs considered in these studies were of sibutramine treatment, fatal and nonfatal coronary heart disease (CHD), and diabetes. Compared with lifestyle counselling alone, the cost of sibutramine per QALY gained was $18,484 in Germany (as showed in the Brennan study); $9723 in the US and $7841in the UK (as showed in the Warren

study); and $16,384 in Finland, $18,486 in Germany, $14,476 in Switzerland, and $7439 in the UK (as shown in the Ara study). These studies achieved the consistent conclusion that adding sibutramine to LM was a cost-effective option, compared to LM alone.

Ruof et al.[22] conducted a decision analytic model to evaluate the cost-effectiveness of orlistat in comparison with placebo for obese patients in Sweden and Switzerland with T2DM. This model was conducted from a payers' perspective over an11-year horizon. A meta-analysis was conducted to pool results from even RCTs, including 1249 and 1230 patients in the orlistat and placebo groups, respectively. Patients with weight loss greater than 5% at 12 weeks would continue the treatment for 1 year, while the treatment would be discontinued for those who failed to achieve a 5% weight loss. The economic analysis considered costs of medication and treatment for obesity- and diabetes-related morbidities. Results indicated that the orlistat treatment was associated with $18,881 and $18,341, in Sweden and Switzerland respectively, per QALY gained. The study supported the use of orlistat for overweight and obese patients with T2DM.

Lamotte et al.[23] constructed a Markov model to evaluate the cost-effectiveness of orlistat for obese patients with T2DM, as compared to no treatment. The population was divided into four sub-groups:

- patients with event-free profiles;
- patients with arterial hypertension but without hypercholesterolaemia at the beginning of the study;
- patients with hypercholesterolaemia but without arterial hypertension at the beginning of the study;
- patients with arterial hypertension and hypercholesterolaemia.

The study adopted a payers' perspective and was conducted over a 10-year horizon in Belgium. The costs included were of medications and obesity-related morbidity (including microvascular complications and macrovascular complications). Results indicated that, as compared to no treatment, the cost of orlistat per LY saved, for the above-listed subgroups, was $26,953, $9989, $9964, and $4669, respectively. The study concluded that orlistat was a cost-effective option for the treatment of obese patients with T2DM.

Malone et al.[24] used data from a RCT enrolling 501 patients to assess the cost-effectiveness of sibutramine plus a WMP for the treatment of overweight and obese patients, as compared to a WMP alone. The patient population comprised individuals aged 18 years or older with a BMI $\geq$ 30 kg/m^2 or a BMI between 27 and 29.9 kg/m^2 with one or more co-morbidities, including diabetes, hypertension, or hyperlipidaemia. The WMP was a physician-supervised, multidisciplinary program, including five monitored care visits and two education programs. The study was conducted from a payer's perspective and the time horizon was 24 months (12 months before enrolment and 12 months after enrolment). Cost categories included the costs of hospitalization, outpatient visits, physician visits, and prescription medications. Results showed that the weight loss at 12 months was 13.7 pounds for sibutramine plus a WMP and five pounds for a WMP alone. Compared with WMP alone, the cost of sibutramine plus a WMP was $44 per pound lost. The study concluded that adding sibutramine to a WMP generated a significant weight loss but there were no savings in healthcare costs, compare to a WMP alone.

Weight management program (WMP) versus no intervention or usual care

Gustafson et al.[25] assessed the cost-effectiveness of a 16-week weight loss program for low-income women in the US in comparison with no intervention, using clinical and resource use data collected from an RCT. The study adopted a payers' perspective and was conducted over lifetime. Study population comprised women between 40 and 60 years of age with a BMI between 25 kg/m^2 and 45 kg/m^2 and an income ≤ 200% of the federal poverty level, 46% of whom had high blood pressure, 29% of whom had high cholesterol, and 67% of whom were obese. The weight-wise intervention consisted of weekly counselling sessions during a 16-week period, with a focus on consuming nine or more fruit and vegetable servings daily and lifestyle change through self-monitoring, problem-solving, and goal-setting. Cost categories were the costs of staff time, program materials, rental space and utilities/overhead. Results indicated that the WMP was associated with $1947 per life year saved, as compared to no intervention. The study concluded that the weight-wise intervention was a cost-effective option.

Gusi et al.[26] used data from an RCT to assess the cost-effectiveness of a walking program in Spain over a 6-month period, compared to best care. The study population comprised women 60 years or older with a BMI between 25 kg/m^2 and 39.9 kg/m^2 or 6 to 9 points in the 15-item Geriatric Depression Scale. The cost analysis was conducted from a payer's perspective and considered health system costs, including personnel time, facilities, medications and consultation. The walking program consisted of walks with a group in public park or forest tracks, guided by the qualified exercise leaders, for 50 minutes, three times per week over 6 months. Individuals in best care received routine care with a recommendation to increase physical activity. Results indicated that the program was associated with a cost of $419 per QALY gained, as compared to best care. The study concluded that the walking program was cost-effective for depressed or overweight elderly women.

Bemelmans et al.[27] conducted a Markov model to evaluate the clinical and economic impact of a community-based intervention and an intensive LM to reduce overweight prevalence, as compared to no intervention. The community-based intervention offered social support such as self-help groups, risk factor screening and/or counselling to 90% of general population, and the intensive LM was offered to 10% of the population and targeted at overweight individuals. The study adopted a payer's perspective and was conducted over an 80-year horizon. Cost categories were the costs of the interventions and treatment for obesity-related morbidity. Results indicated that, compared to no intervention, the cost was $6878 per LY gained and $6743 per QALY gained for the community-based intervention, $11,328 per LY gained and $9980 per QALY gained for the intensive LM, and $8092 per LY gained and $7687 per QALY gained for the combination of both programs. The study concluded that both community-based intervention and intensive lifestyle modification were cost-effective for preventing and reducing overweight, and that the former was slightly more cost-effective.

Lifestyle modification (LM) versus other LM or no intervention

Besides the studies (described above) that evaluated LM versus other bariatric services, four studies[28-31] compared LM versus other LM or no treatment.

Olsen et al.[28] used data from an RCT enrolling 401 patients to assess the cost-effectiveness of nutritional counselling by a GP or a dietician for patients with a BMI ≥ 30 kg/m^2 and with a high risk for ischaemic heart disease (IHD), as compared to no counselling. The counselling by GPs consisted of general advice plus written information on health and diet, and the counselling by dieticians focused on principles of good nutrition and advice about food shopping, cooking

methods, meal planning, and exercise. The study adopted a societal perspective and was conducted over a 1-year horizon. The direct cost was the time cost spent by the GPs and dieticians, and the indirect cost was the time cost spent to attend the nutritional counselling. Results indicated that, as compared to no counselling, the cost was $1487 per LY saved and $10,858 per LY saved for GP and dietician counselling, respectively. For patients without IHD, as compared to no counselling, the cost decreased to $845 per LY saved and $4248 per LY saved, respectively. The study concluded that nutritional counselling by a GP or a dietician was cost-effective for obese patients with a high risk of IHD, and that intervention by a GP was superior to that by a dietician.

Tsai et al.[29] used data from an RCT enrolling 132 patients to evaluate the cost-effectiveness of LCD in comparison with standard diet for the treatment of patients with severe obesity (BMI ≥ 43 kg/m^2). The time horizon of the study was 12 months. The study adopted a societal perspective in the US. Patients in study and control groups received weekly counselling sessions during the first month and monthly sessions over the next 5 months. Patients in the LCD group were counselled to consume less than 30 grams per day of carbohydrate, while those in control group were counselled to follow the National Cholesterol Education Program Step 1 diet. Direct medical costs included the costs of time spent by dieticians, physician visits, and laboratory tests. The productivity cost considered in the analysis was the cost of lost work time. The base-case analysis showed that LCD generated an additional QALY of 0.04 at a lower cost. However, results from a bootstrap analysis indicated the difference in costs and QALYs was not statistically significant between comparators. The study, therefore, concluded that LCD was not more cost-effective for weight loss, as compared to the standard diet.

Sevick et al.[30] used an RCT enrolling 318 patients to conduct a cost-effectiveness analysis of diet, exercise, and a combination of diet and exercise, as compared to LM, for the treatment of elderly patients aged ≥ 60 years with a BMI ≥ 28 kg/m^2 and knee osteoarthritis. The study was conducted from a payer's perspective over an 18-month horizon. The costs considered in the analysis included home visits, dietary classes, telephone time, gym space, and equipment. Results indicated that, compared to lifestyle control, the cost per percentage of baseline body weight loss was $37, $50, and $63, for diet, exercise, and combined diet and exercise, respectively. The study concluded that combined exercise and diet was the most cost-effective option to improve physical function, pain, and stiffness for obese patients with knee osteoarthritis.

Galani et al.[31] constructed a Markov model to assess the economic impact of an LM for preventing and treating obesity, compared to standard care. The study population comprised individuals aged ≥ 25 years with a BMI between 25 kg/m^2 and 35 kg/m^2 and examined three sub-groups based on BMI levels:

- overweight with a BMI 25 kg/m^2 to 29.9 kg/m^2;
- moderately obese with a BMI 30 to 35 kg/m^2;
- borderline with a BMI 30 kg/m^2.

The model adopted a societal perspective and was conducted in Switzerland over a lifetime horizon. Individuals in the LM group attended dietician and supervised exercise sessions during the first 3 years and undertook moderate daily exercise for at least 30 minutes. Standard care consisted of basic dietary counselling and physical exercise sessions for obese patients, and no intervention for overweight patients. Clinical evidence came from published cohort studies and RCTs. The costs of interventions and obesity-related morbidities, including hypertension, T2DM, hypercholesterolaemia, coronary heart disease, and stroke, were considered. Results were reported over a range of age/sex

groups. Compared with standard care, the costs per QALY gained of LM ranged from $910 for 55-year-old men to $6255 for 25-year-old women for overweight patients; from dominant (due to more effective and less costly) in 35-year-old women and 55-year-old men to $3164 in 25-year-old women for moderate obese patients, and the costs from dominant (due to more effective and less costly) in all males to $3008 in 25-year-old women for borderline patients. The study concluded that LM was cost-effective option in long run.

Quality assessment

The quality of the selected studies was assessed using criteria adapted from Drummond et al.[2,3] The assessment considered the methodological approaches applied to enhance the internal validity and transferability of the studies. This included a data extraction of the following:

- study question;
- study type;
- perspective;
- time horizon;
- reliability of clinical evidence;
- cost calculation;
- methods of handling uncertainty.

Overall, the studies met our quality criteria. Cost categories included in the studies were consistent with the stated perspective. Evidence of effectiveness came from RCTs, which provided greater internal validity of clinical inputs used in the studies. However, measures of health-related quality of life (HRQOL), which was the measure of health benefit, were not sufficiently described in the studies. Consequently, the measures of health benefit may not accurately reflect the populations included in these studies.

It is also important to mention that it is uncertain how generalizable the results are to the Alberta context. Studies were conducted in various European countries, Australia, and the US, and, although they generally met our quality criteria, they did not provide the detail necessary to determine whether their analysis is comparable to the epidemiological and health system characteristics of Alberta.

Results from Analysis of Provincial Health Utilization Data

Costs of bariatric surgery

Table E.3 presents the number of the surgical patients, by city, in 2006. Two hundred seventeen patients, having a mean age of 39 years, and 87% of whom were women, underwent a bariatric surgical procedure in Alberta.

Table E.4 shows the mean cost of bariatric surgery in 2006. Mean costs per bariatric surgery for inpatient and physician services were $10,763 and $2189, respectively. When combining both inpatient and physician services, the mean cost was $12,176 per bariatric surgery.

Table E.3: Distribution of surgical patients by city in 2006

City	No. of surgical patients
Calgary	1
Edmonton	89
Medicine Hat	100
Red Deer	27
TOTAL	**217**

Table E.4: Bariatric surgery costs per patient in 2006

	Mean	Std. Err.	95% CI	
Inpatient (n = 88)*	$10,763.16	$535.51	$9698.78	$11827.54
Physician (n = 172)*	$2,189.39	$55.71	$2,079.42	$2,299.37
Overall (n = 80)*	$12,175.79	$586.75	$11,007.89	$13,343.69

*** Note:** Of 217 bariatric surgery patients in 2006, cost data were available for 172, 88, and 80 patients in the PCD, DAD, and both databases respectively. Analysis of inpatient, physician, and overall data were based on separate analysis of patients contained in those datasets.

Abbreviations: n = number; Std. Err. = standard error; 95% CI = 95% confidence interval.

Impact of bariatric surgery on healthcare costs and utilizations

Table E.5 shows the mean costs and health utilizations across the 217 bariatric surgery recipients, between 2004 and 2008. Note that the cohort represents patients who received a bariatric surgery in 2006. In 2007 and 2008, health services costs and visits were greater than in 2004 and 2005. However, the marginal change in health service costs and visits between 2004 and 2005 (that is, pre-surgery) was positive, indicating an increase in costs and visits prior to surgery. In contrast, the marginal change in health service costs and visits between 2007 and 2008 was negative, indicating a decrease in health service costs and visits post-surgery.

Table E.5: Mean costs and utilizations between 2004 and 2008

Costs							
Services	**2004**	**2005**	**2006***	**2007**	**2008****	**Difference: 2005 versus 2004**	**Difference: 2008 versus 2007**
Inpatient	$346	$530	$12,795	$2513	—	$183	—
Outpatient	$247	$274	$716	$551	$432	$27	-$118
Physician	$503	$623	$2634	$957	$800	$120	-$157
Overall	$365	$1426	$16,145	$4020	—	$1061	—
Visits							
Inpatient	0.08	0.09	1.00	0.34	0.32	0.02	-0.03
Outpatient	1.01	1.44	3.03	1.96	1.87	0.44	-0.09
Physician	9.91	11.24	20.49	14.55	12.30	1.33	-2.26

* Bariatric surgery was conducted in 2006.

** No cost data is available for hospitalization in 2008.

Results from Analysis of Provincial Health Utilization and CCHS data

Table E.**6** shows the adjusted mean costs and visits from the six separate regression models. When combining physician and outpatient costs, the mean cost per obese resident in Alberta is $696. This is followed by costs of $545 for overweight, $523 for underweight, and $480 for normal weight residents. Compared to normal weight, obesity, overweight, and underweight are associated with increases of $217, $65, and $44, respectively.

Based on information from the 2007 CCHS survey, for Alberta residents:

- 463,000 were obese;
- 843,000 were overweight;
- 58,000 were underweight.

The economic burden of obesity in 2007 was estimated to be $100 million in Alberta when including both physician and outpatient services. This was followed by a cost for overweight of $55 million and for underweight of $2.5 million. Furthermore, for obese individuals, the factors of female gender, older age, lower income, lower education, no physical activity, and the presence of comorbidities were associated with increased economic burden (see Figure E.1). A similar pattern is observed when analyzing health service visits (see Figure E.2.).

Table E.6: Economic burden of obesity in 2007

Mean cost/visit per resident by BMI						
BMI	**Outpatient and physician cost**	**Physician cost**	**Outpatient cost**	**Physician visits**	**Outpatient visits**	**Inpatient admissions**
Underweight	$523.24	$362.43	$192.35	7.272	0.705	0.066
Normal weight	$479.53	$315.77	$150.09	6.574	0.611	0.052
Overweight	$544.91	$372.93	$189.38	7.632	0.812	0.066
Obese	$696.44	$492.34	$245.68	9.877	1.130	0.081
Incremental costs or visits compared to normal weight						
Underweight	$43.71	$46.65	$42.25	0.698	0.094	0.015
Overweight	$65.37	$57.16	$39.29	1.058	0.201	0.014
Obese	$216.90	$176.57	$95.58	3.303	0.519	0.029
Economic burden of obesity (costs are in millions and visits are per 1000)						
Underweight versus normal weight	$2.53	$2.70	$2.44	$0.33	5.45	0.85
Overweight versus normal weight	$55.10	$48.18	$33.11	$91.84	169.56	11.72
Obese versus normal weight	$100.47	$81.79	$44.28	$530.24	240.44	13.61

Figure E.1: Cost comparison by demographic, behaviour, and comorbidity categories

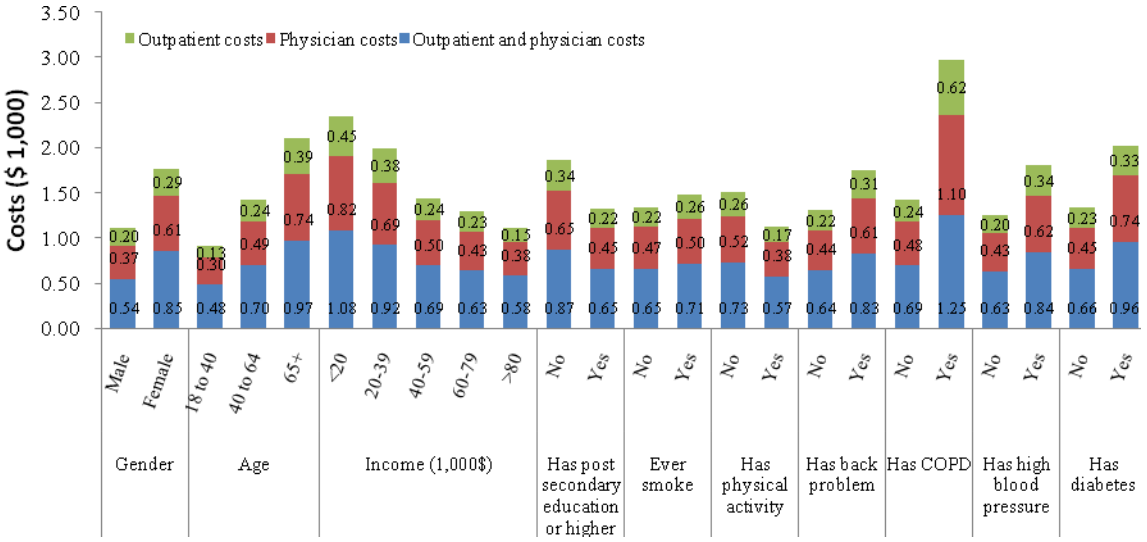
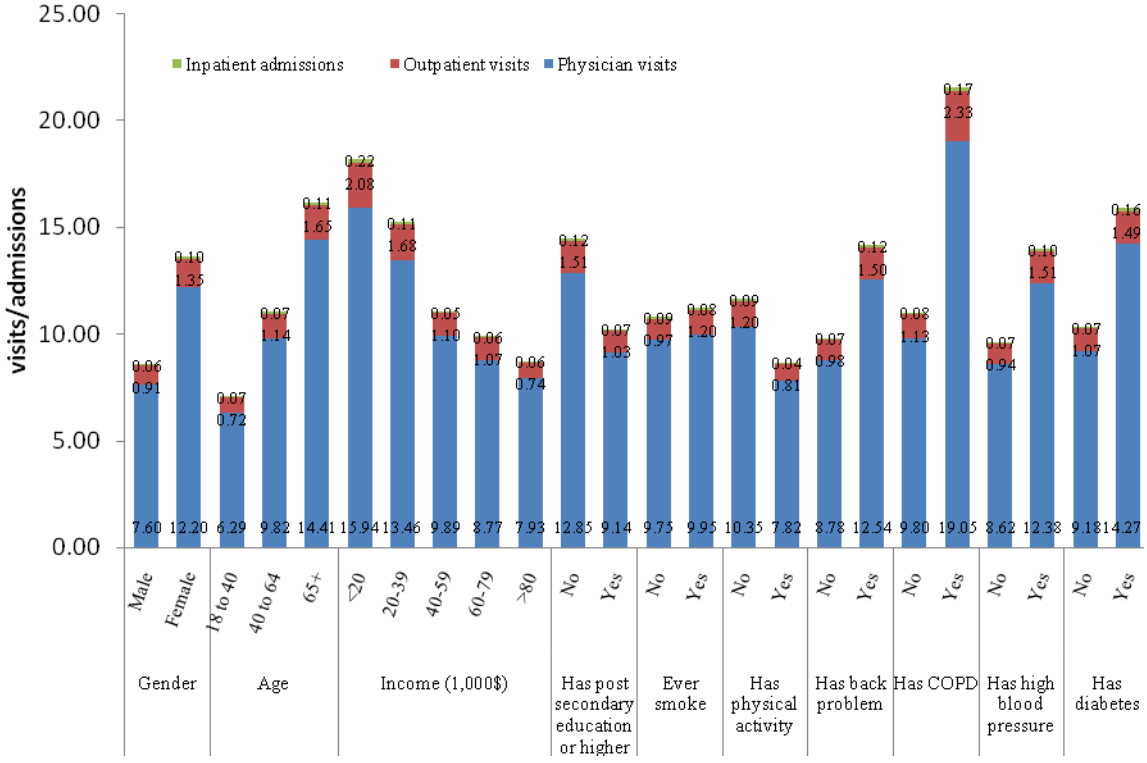


Figure E.2: Health utilization comparison by demographic, behaviour, and comorbidity categories



Discussion

The objectives of the economic analysis were:

- to determine the comparative cost-effectiveness of various bariatric treatment strategies for obesity in adults;
- to assess the economic burden of obesity in Alberta;
- to estimate the direct health services cost associated with bariatric surgery.

Four types of bariatric interventions were identified in the literature review. These include bariatric surgical procedures, pharmacotherapy, lifestyle modification, and weight management programs. The CADTH report constructed a Markov model to evaluate the cost-effectiveness of bariatric surgery versus lifestyle modification or other bariatric surgical intervention for patients with a BMI $\geq$ 40 kg/m^2 or a BMI $\geq$ 35 kg/m^2 with obesity-related comorbidities. This model applied clinical evidence based on a systematic review and cost data collected from the provinces of Alberta and Ontario and, therefore, can be generalized to an Alberta context. The model demonstrated that bariatric surgery is cost-effective for patients with severe obesity, compared to lifestyle modification. Compared to lifestyle modification, the lifetime cost per QALY gained was $9398 for RYGB and $12,212 for LAGB. Moreover, surgery was particularly cost-effective for patients with obesity-related comorbidities. However, within bariatric surgical interventions, due to limitations in the data available for analysis, the most effective type of bariatric surgery could not be identified.

For studies that evaluated bariatric surgical procedures in comparison with lifestyle modification, bariatric surgery was demonstrated to be cost-effective for patients with a BMI $\geq$ 40 kg/m^2 or a BMI $\geq$ 35 kg/m^2 with obesity-related comorbidity. Results from the CADTH review[1] of the economic literature indicated that bariatric surgery was associated with a cost per QALY gained of $5000 to $40,000. Furthermore, there is evidence to indicate that the surgery is more cost-effective for obesity patients with T2DM.[4,7,13] Still, within bariatric surgical procedures, it is uncertain from the literature which bariatric surgery is the most cost-effective.

For studies that evaluated pharmacotherapy in comparison with no intervention, lifestyle modification or WMP, the pharmacotherapy was associated with the improvement in health benefit for treating patients with a BMI $\geq$ 30 kg/m^2 or a BMI $\geq$ 27 kg/m^2 with T2DM. However, the cost-effectiveness of the comparisons varied, depended upon the specific medical conditions and interventions being evaluated.

For orlistat, as compared to no intervention, the cost per QALY gained was less than $18,881 for patients with T2DM; and compared with lifestyle modification, the cost per QALY gained was $28,631 for patients with impaired glucose tolerance (IGT). This suggested that orlistat treatment for obese patients with obesity-related morbidity was cost-effective. For the treatment of obese patients without obesity-related morbidity, and in comparison with LM alone, one study showed that orlistat plus LM was cost-effective[15] but three studies showed that the medication generated its health benefits at a greater cost, and therefore was less cost-effective.[14,16,21]

Of the studies evaluating sibutramine, three studies showed that, as compared to LM alone, the cost per QALY gained, plus LM, was less than $18,486, suggesting the medication was cost-effective.[18-20] By contrast, one study showed that the cost per QALY gained for sibutramine plus LM was $75,255 as compared to LM alone, and $55,349 as compared to no intervention, suggesting the medication was not cost-effective.[17] Moreover, as compared to WMP, one study showed that sibutramine plus WMP generated a significant weight loss, but at no cost savings.[24]

For studies that evaluated WMP, the specific interventions and patient population included in the evaluations varied. In a study conducted in the United States, a weight-wise intervention program was compared to no intervention for low-income women with a BMI between 25 kg/m^2 and 45 kg/m^2. In another study, conducted in Spain, a walking program was compared with best care (that is, routine care with a recommendation to increase physical activity) for moderately depressed elderly women with a BMI between 25 kg/m^2 and 39.9 kg/m^2. However, in a study conducted in the Netherlands, a community-based intervention program was compared with intensive LM for the general population and overweight individuals. All these studies showed that the WMPs were cost-effective, when compared with no intervention or best care.

For studies that evaluated various LM programs in comparison with other LM programs or no treatment, the patient populations and interventions under examination varied. For instance, some included GP or dietician counselling versus no counselling for patients with a BMI ≥ 30 kg/m^2 and with a high risk for ischaemic heart disease (IHD),[28] while others compared LCD versus standard diet for patients with a BMI ≥ 43 kg/m,[2,29] or diet and exercise versus lifestyle education for patients with a BMI ≥ 28 kg/m^2 and knee osteoarthritis,[30] or lifestyle intervention versus standard care for patients with a BMI between 25 kg/m^2 and 35 kg/m.[2,31] (Refer to Results section for further details regarding these interventions.) Overall, the studies showed that LM was cost-effective with a cost per QALY gained less than the conventional cost-effectiveness threshold of $50,000.

The analysis of provincial health utilization data linked with the CCHS indicated that, compared to the costs for individuals of normal weight, the health service costs associated with obesity are increased by $217. This translates to an estimated $100 million economic burden of disease associated with obesity. Furthermore, higher cost and resource utilization were associated with factors including female, older age, lower household income, lower education, physical inactivity, and the presence of comorbidities.

The analysis of provincial health utilization data indicated that the mean cost of inpatient and physician services associated with bariatric surgery in 2006 was $12,176 per surgery. This analysis showed that health service utilization and costs for the two years following surgery were greater than for the two years preceding surgery. However, when examining the marginal change in health service utilization and costs, the analysis showed an upward trend in the two years preceding surgery and a downward trend in the two years following surgery. Although this may suggest that bariatric surgery may alter the upward trajectory of health service utilization for severely obese patients who underwent surgery, it is important to note that the value in 2008 was still greater than that observed in 2005. Hence, it is uncertain whether the decrease is simply a return to pre-surgical levels. Still, these results are consistent with findings published elsewhere. In a US study[32] that examined the healthcare utilization of inpatient services before and after RYGB, it was found that the rate of hospitalization in the year post-operation was more than double compared to the rate in the year preceding RYGY. Furthermore, in an observational study conducted in Québec,[33] a downward trend was found in hospital costs over the five years following bariatric surgery.

Importantly, the cost estimate of bariatric surgery does not include services that may have been provided prior to admission and after discharge from hospital (for example, pre-surgical counselling conducted prior to admission to hospital and post-surgical support following discharge) due to unavailability of data at the time of the analysis. However, the CADTH review of bariatric surgery did conduct a budget impact for RYGB or LAGB.[1] Cost categories included the cost of pre-surgical consultation (including bariatric specialist time, dietician follow-up, and laboratory and other testing) post-surgical follow-up with a bariatric specialist, surgery, hospital stay, and surgical complication. Cost categories did not include capital expenses for improving capacity, such as additional dedicated

surgical suites, and so on. The budget impact analysis was based on multiplying the estimated cost per surgical procedure by the difference between the number of surgeries needed to treat the population of potentially eligible patients and the current volumes of bariatric surgeries being conducted in Canada (that is, the volume of additional bariatric surgeries required).

The cost per surgical procedure in 2009 was estimated to be $21,839 for RYGB and $14,586 for LAGB. Within a 5-year time horizon, assuming that the number of patients eligible for bariatric surgery was 1%, 2%, or 5% of the severely obese population, the number of additional bariatric surgeries required in Canada was 3423, 10,540, and 31,893, corresponding to a budget impact of $74.75 million, $230.19 million, and $696.52 million for RYGB and $49.92 million, $153.74 million, and $465.20 million for LAGB. Alberta accounted for 9.6% of the eligible patients in Canada; using this as a weight for estimating, the budget impact in Alberta would correspond to aproximately $7.17 million, $22.09 million, and $66.86 million for RYGB and $4.79 million, $14.75 million, and $44.65 million for LAGB.

Conclusion

Evidence generated from the literature review showed that bariatric interventions were associated with improved health outcomes, but at additional costs. This indicates that bariatric interventions will not result in cost savings to the health system and their value must be assessed in terms of the amount of health outcome gained for the dollars invested. Furthermore, the extent to which the evidence is generalizable to the Alberta context is unknown.

Bariatric surgery was demonstrated to be a cost-effective option for patients with a BMI $\geq$ 40 kg/m^2 or a BMI $\geq$ 35 kg/m^2 with obesity-related morbidity, compared to lifestyle modification, because the associated costs per additional health gains were considered good value for money spent. This surgical intervention is more attractive for patients with obesity-related morbidities such as T1DM. However, within bariatric surgical interventions, there is limited evidence to identify which type of surgery is the most cost-effective.

Pharmacotherapy was associated with an improvement in health benefit for patients with a BMI $\geq$ 30 kg/m^2 or a BMI $\geq$ 27 kg/m^2 with obesity-related morbidity, compared to lifestyle modification. There is great variation in the cost-effectiveness of pharmaceutical therapy, likely due to the variation in the specific components of lifestyle modification.

Compared to no intervention, weight management programs or lifestyle modification were found to be cost-effective because the associated costs per additional health gains were considered good value for money. Importantly, however, there can be significant variation in the specific characteristics included in either lifestyle modification or weight management programs; this limits the generalizability of this finding.

In Alberta, in terms of inpatient and physician services:

- in 2006 the mean total cost of bariatric surgery was estimated to be $12,176;
- in 2007 the economic burden of obesity was estimated to be $100 million.

Caveats

It is important to evaluate the evidence in light of the following caveats.

1. Cost-effectiveness was addressed using evidence from the published literature. With the exception of the CADTH review,[1] the extent to which the evidence from the published literature can be generalized to the Alberta context is unknown due to local differences in clinical practice, epidemiology, and costs.
2. The analysis of provincial health utilization data was limited to two years preceding and two years following surgery. Due to the short time horizon before and after surgery, it is uncertain whether the trends of increasing health service utilization prior to surgery and decreasing health service utilization after surgery were reliable and valid (that is, the downward trend could simply be the health service utilization returning to levels observed prior to surgery). It should be noted that no data was available beyond 2008, and that historical data going back further than 2 years is less relevant to the current Alberta context, due to the evolving nature of bariatric surgical techniques.
3. The cost estimate for bariatric surgery only reflects the resources corresponding to the specific CCI coding and therefore does not include services that may have been provided prior to admission and after discharge from hospital (for example, pre-surgical counselling conducted prior to admission to hospital and post-surgical support following discharge). Hence the analysis underestimates the costs of bariatric surgery.
4. Bariatric surgical procedures using laparoscopic versus open approaches were not differentiated in the analysis of provincial health utilization databases, due to data quality issues regarding the coding of the surgical procedures. Consequently, the impact of laparoscopic procedures on health service utilization and costs as compared to the impact of traditional bariatric surgical approaches on those same elements is unknown.
5. No inpatient cost data was available in the dataset that links health service utilization data with the epidemiologic data contained in the 2007 CCHS, and the economic burden of obesity in Alberta only included costs associated with physician and outpatient services. Consequently, the estimated burden of obesity in Alberta is underestimated.

APPENDIX E.A: LITERATURE SEARCH SUMMARY: BARIATRIC SERVICES – EFFECTIVENESS

The IHE Research Librarian conducted the literature search for publications published between 2000 and April 8, 2010. The search was further limited to human studies and publications on economic studies. Explain any other limits. The search was developed and carried out prior to the study selection process. In addition to the strategy outlined below, reference lists of retrieved articles were reviewed for potential studies.

Table E.A.1: Search strategy

Database	Edition or date searched	Search Terms ††
The Cochrane Database of Systematic Reviews www.thecochranelibrary.com	2000 – 2010 Issue 3	#1 (obes* OR superobes*):ti,ab,kw, from 2000 to 2010 #2 (diet OR lifestyle OR "life style" OR exercise OR walking OR behavioural OR behavioral OR cognitive OR psychological OR modification):ti #3 "weight loss" OR "weight reduction" OR "weight management" OR "physical activity":ti,ab,kw #4 (sibutramine OR orlistat OR "appetite suppressants" OR "antiobesity agents" OR counseling OR "cognitive therapy" OR "behavioral therapy" OR psychotherapy OR counseling OR "patient education"):ti,ab,kw #5 (surger* or "gastric band" or "gastric bypass" or "lap band" or lagb):ti #6 (#1 AND (#2 OR #3 OR #4 OR #5)) #7 (child not adult):ti #8 (#6 AND NOT #7) #9 (cost* OR economic* OR expenditures OR fiscal OR pharmacoeconomic):ti,ab,kw #10 (#9 AND #8) **8 Results**
MEDLINE (includes in-process and non-MEDLINE citations) OVID Licensed Resource	2000 – April 8, 2010	1. exp obesity/ 2. (superobes* or obes* or bariatric* or weight).ti. 3. 1 or 2 4. (unplanned weight or unintended weight or involuntary weight or antipsychotic or schizophreni* or bipolar or Parkinson* or Alzheimer* or smoking or dementia or bulimi* or anorexi* or urinary incontinence or ui or pelvic floor or asthma or adhd or attention-deficit or apnea or cancer or colorectal or gastroesophageal or fatty liver of osteoarthritis or arthritis or urologic* or mood disorders or birth weight or diarrhea or kidney or gallstone*).m_titl. 5. 3 not 4 6. exp Bariatrics/ 7. surger*.ti. 8. gastric bypass.ti. 9. roux en y.ti.

		10. biliopancreatic diversion*.ti. 11. gastric band*.ti. 12. lap band*.ti. 13. lagb.ti. 14. anastomosis, roux-en-y/ or biliopancreatic diversion/ or gastrectomy/ 15. gastrectom*.ti. 16. intragastric balloon*.ti. 17. Weight Loss/ 18. Anti-Obesity Agents/ 19. Appetite Depressants/ 20. diethylpropion/ or phenmetrazine/ or phentermine/ or phenylpropanolamine/ 21. Sibutramine.tw. 22. (reductil or meridia or sibutrex).tw. 23. Orlistat.tw. 24. (xenical or alli or tetrahydrolipstatin).tw. 25. diet therapy/ or diet, carbohydrate-restricted/ or diet fads/ or diet, fat-restricted/ or diet, reducing/ 26. diet.ti. 27. Exercise/ 28. Exercise Therapy/ 29. exercise.ti. 30. Physical Fitness/ 31. lifestyle.ti. 32. life style.ti. 33. physical activity.ti. 34. walking.ti. 35. Behavior Therapy/ 36. Cognitive Therapy/ 37. Psychotherapy/ 38. Psychotherapy, Group/ 39. Counseling/ 40. counseling.ti. 41. behavio?ral.ti. 42. weight management.ti. 43. psychological.ti. 44. Patient Education as Topic/ 45. Health Education/ 46. modification.ti. 47. or/6-46 48. limit 47 to "all child (0 to 18 years)" 49. limit 48 to "all adult (19 plus years)" 50. 47 not (48 not 49) 51. limit 50 to animals 52. 50 not 51

		53. limit 52 to yr="2000 - 2010" 54. 5 and 53 55. exp "Costs and Cost Analysis"/ 56. (economic adj1 (evaluat* or analys* or study or studies or assess* or consequence*)).tw. 57. (cost-benefit or benefit-cost or cost effectiv* or cost utility).tw. 58. (cost minimization or cost minimisation or cost consequence* or cost offset*).tw. 59. ((cost or costs) adj2 analys*).tw. 60. "cost of illness".tw. 61. (cost* or economic* or expenditures or fiscal or pharmacoeconomic or spending).ti. 62. or/55-61 63. 54 and 62 **422 results**
CRD Databases (DARE, HTA & NHS EED) http://nhscrd.york.ac.uk	2000 – April 8, 2010	# 1 obes* OR superobes* RESTRICT YR 2000 2010 # 2 diet:ti OR lifestyle:ti OR exercise:ti OR walking:ti OR behavioural:ti OR behavioral:ti OR cognitive:ti OR psychological:ti OR modification:ti # 3 "weight loss" OR "weight reduction" OR "weight management" OR "physical activity" # 4 sibutramine OR orlistat OR "appetite suppressants" OR "antiobesity agents" OR counseling OR "cognitive therapy" OR "behavioral therapy" OR psychotherapy OR counseling OR "patient education" #5 MeSH Bariatric Surgery Explode 1 #6 surger*:ti OR "gastric band*":ti OR "gastric bypass":ti OR "lab band*":ti OR LAGB:ti #7 child*:ti NOT adult:ti #8 #2 OR #3 OR #4 OR #5 OR #6 #9 #1 AND #7 #10 #9 NOT #7 #11 cost* OR economic* OR expenditures OR fiscal OR pharmacoeconomic # 12 #11 AND #10 **145 results**
EMBASE Licensed Resource (Ovid Platform)	2000 – April 8, 2010 (2010 Week 13)	1. *obesity/ 2. *morbid obesity/ 3. *diabetic obesity/ 4. *abdominal obesity/ 5. or/1-4 6. (superobes* or obes* or bariatric* or weight).ti. 7. (unplanned weight or unintended weight or involuntary weight or antipsychotic* or schizophreni* or bipolar or Parkinson* or Alzheimer* or smoking or dementia or bulimi* or anorexi* or urinary incontinence or ui or pelvic floor or asthma or adhd or attention-deficit or apnea or cancer or colorectal or

		gastroesophageal or fatty liver or osteoarthritis or arthritis or contaceptive* or erectile or urologic* or mood disorders or birth weight or diarrhea or kidney or gallstone*).ti. 8. (5 or 6) not 7 9. exp bariatric surgery/ 10. exp stomach surgery/ 11. surgery.ti. 12. gastric bypass.ti. 13. roux en y.ti. 14. biliopancreatic diversion*.ti. 15. gastrectom*.ti. 16. intragastric balloon*.ti. 17. bariatrics/ 18. weight reduction/ 19. antiobesity agent/ 20. exp anorexigenic agent/ 21. sibutramine/ 22. sibutramine.tw. 23. (reductil or meridia or sibutrex).tw. 24. orlistat.tw. 25. (xenical or alli or tetrahydrolipstatin).tw. 26. diet therapy/ 27. diet restriction/ or caloric restriction/ 28. diet therapy/ or diabetic diet/ or low calory diet/ or low fat diet/ 29. diet.ti. 30. exercise/ or aerobic exercise/ or anaerobic exercise/ or aquatic exercise/ 31. fitness/ 32. exercise.ti. 33. exp physical activity/ 34. physical activity.ti. 35. yoga/ or pilates/ 36. lifestyle.ti. 37. life style.ti. 38. walking.ti. 39. behavior therapy/ 40. cognitive therapy/ 41. psychotherapy/ 42. behavior modification/ 43. group therapy/ 44. counseling/ or nutritional counseling/ 45. counseling.ti. 46. behavi?ral.ti. 47. weight management.ti. 48. psychological.ti.

		49. patient education/ or health education/ 50. modification.ti. 51. or/9-50 52. limit 51 to (child or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>) 53. limit 52 to adult <18 to 64 years> 54. 51 not ((52 not 53) or school.mp.) 55. (exp vertebrate/ or animal/ or exp experimental animal/ or nonhuman/ or animal.hw.) not (exp human/ or human experiment/) 56. (rat or rats or mouse or mice or hamster or hamsters or animal or animals or dog or dogs or cat or cats or bovine or sheep).ti,ab,sh. not (exp human/ or human experiment/) 57. 55 or 56 58. 54 not 57 59. limit 58 to yr="2000 - 2010" 60. 8 and 59 61. "COST"/ 62. exp Economic Evaluation/ 63. health economics/ 64. PHARMACOECONOMICS/ 65. ((economic or cost*) adj2 (evaluat* or analys* or study or studies or assess* or consequence*)).tw. 66. ((cost-benefit or benefit-cost or cost effectiv* or cost utility) adj2 (analys* or evaluat* or assess* or study or studies)).tw. 67. (cost minimization or cost minimisation or cost consequence* or cost offset*).tw. 68. "cost of illness".tw. 69. or/61-68 70. 60 and 69 **402 results**
Web of Science ISI Interface Licensed Resource	2000 – April 8, 2010	#1 TS=(obes* OR superobes*) Databases=SCI-EXPANDED, SSCI, A&HCI Timespan=2000-2010 #2 TI=(surger* OR gastric bypass OR roux en y OR biliopancreatic diversion* OR gastric band* OR LAGB OR gastrectom* OR intragastric balloon* OR "weight loss" OR "weight reduction" OR "weight management" OR diet OR lifestyle OR "life style" OR exercise OR walking OR physical activity OR behavioural OR behavioral OR cognitive OR psychological OR modification) OR TS=(sibutramine OR orlistat OR "appetite suppressants" OR "antiobesity agents" OR counseling OR "cognitive therapy" OR "behavioral therapy" OR psychotherapy OR counseling OR "patient education") #3 #1 AND #2 #4 TI=(antipsychotic* OR schizophreni* OR smoking OR "fatty liver" OR bipolar OR "mood disorders" OR athritis OR osteoarthritis OR anorexi* OR bulimi* OR adhd OR asthma OR colorectal OR cancer OR "pelvic floor" OR apnea OR gastroesophageal OR kidney OR diarrhea OR gallstone* OR

		urologic OR dementia OR alzheimer* OR Parkinson*) #5 #3 NOT #4 #6 TI=((child* OR adolescent OR pediatric OR child OR juvenile OR youth OR school*) NOT adult) #7 #5 NOT #6 #8 TI=(dog OR dogs OR sheep* OR lamb OR lambs OR rat OR rats OR cats OR mice OR mouse OR murine OR rabbit* OR animal* OR pig OR pigs OR piglet* OR porcine) #9 #7 NOT #8 #10 TI=(cost* OR economic* OR expenditures OR price OR fiscal OR pharmacoeconomic OR spending) #11 #9 AND #10 **(129 results)**
CINAHL	2000 – April 8, 2010	S1 (MH "Obesity") S2 (MH "Obesity, Morbid") S3 TI (superobes* or obes* or bariatric* or weight) S4 TI "unplanned weight" or "unintended weight" or "involuntary weight" or "birth weight" S5 TI antipsychotic* or schizophreni* or bipolar or dementia or alzheimer* or Parkinson* or mood disorders or bulimi* or anorexi* S6 TI smoking or urinary or ui or pelvic floor or asthma or adhd or attention-deficit or apnea or cancer or colorectal or gastroesophageal or fatty liver or osteoarthritis or arthritis or urologic* or diarrhea or kidney or gallstone* S7 (S1 OR S2 OR S3) not (S4 OR S5 OR S6) S8 (MH "Weight Loss") S9 (MH "Weight Reduction Programs") S10 (MH "Antiobesity Agents+") S11 (MH "Sibutramine") S12 TX reductil or meridia or sibutrex or sibutramine or orlistat or xenical or alli or tetrahydrolipstatin S13 (MH "Diet, High Protein") or (MH "Diet, Ketogenic") or (MH "Diet, Low Carbohydrate") or (MH "Diet Fads") S14 (MH "Diet Therapy") S15 (MH "Physical Activity") S16 TI diet or exercise or lifestyle or life style or physical activity or fitness or walking S17 (MH "Behavior Therapy+") or (MH "Behavior Modification") or (MH "Counseling") or (MH "Nutritional Counseling") or (MH "Psychotherapy") or (MH "Psychotherapy, Group") S18 TI counseling or behavioral or behavioural or psychological or weight management or modification S19 (MH "Health Education") or (MH "Patient Education") S20 (MH "Bariatric Surgery+") S21 TI surgery or gastric bypass or gastric band* or roux en y or intragastric balloon* or lagb or lap band* or gastrectom* or biliopancreatic diversion*

		S22 S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 S23 S7 AND S22 Limiters - Publication Year from: 2000-2010 S24 (MH "Costs and Cost Analysis") S25 (MH "Cost Benefit Analysis") S26 (MH "Economic Aspects of Illness") S27 (MH "Health Care Costs") S28 (MH "Economics") or (MH "Economics, Pharmaceutical") S29 TI cost* OR economic* OR expenditures OR fiscal OR pharmacoeconomic S30 S24 or S25 or S26 or S27 or S28 or S29 S31 S30 AND S22 **199 results**
NEOS Library www.library.ualberta.ca/catalogue		
Clinical Practice Guidelines		
AMA Clinical Practice Guidelines www.topalbertadoctors.org/TOP/CPG/CPGTopics.htm		
CMA Infobase http://mdm.ca/cpgsnew/cpgs/index.asp		
National Guideline Clearinghouse www.ngc.gov		
Alberta Health and Wellness www.health.gov.ab.ca		
Health Canada www.hc-sc.gc.ca		
CDC – Centers for Disease Control and Prevention		
US Medicare Coverage Database www.cms.hhs.gov/mcd/search.asp?		
Aetna Clinical Policy Bulletins www.aetna.com/about/cov_det_policies.htm		
BlueCross BlueShield www.bluecares.com/		
Aggressive Research Intelligence Facility (ARIF) www.bham.ac.uk/arif		
TRIP Database www.tripdatabase.com		
Grey Literature		
NLH – National Library for Health www.library.nhs.uk		
AETMIS www.aetmis.gouv.qc.ca		

CCOHT www.ccohta.ca		
Institue for Clinical and Evaluative Sciences (ICES) www.ices.on.ca/		
ECRI (HTAIS Database) www.ecri.org		
Health Technology Assessment Unit At McGill www.mcgill.ca/tau/		
Medical Advisory Secretariat www.health.gov.on.ca/english/providers/program/mas/mas_mn.html		
NZHTA		
MHRA		
NICE		
Google www.google.com		

Note: ††

"*", "#", and "?" are truncation characters that retrieve all possible suffix variations of the root word e.g. surg* retrieves surgery, surgical, surgeon, etc.

Figure E.A.1: Progress through the selection of potentially relevant studies

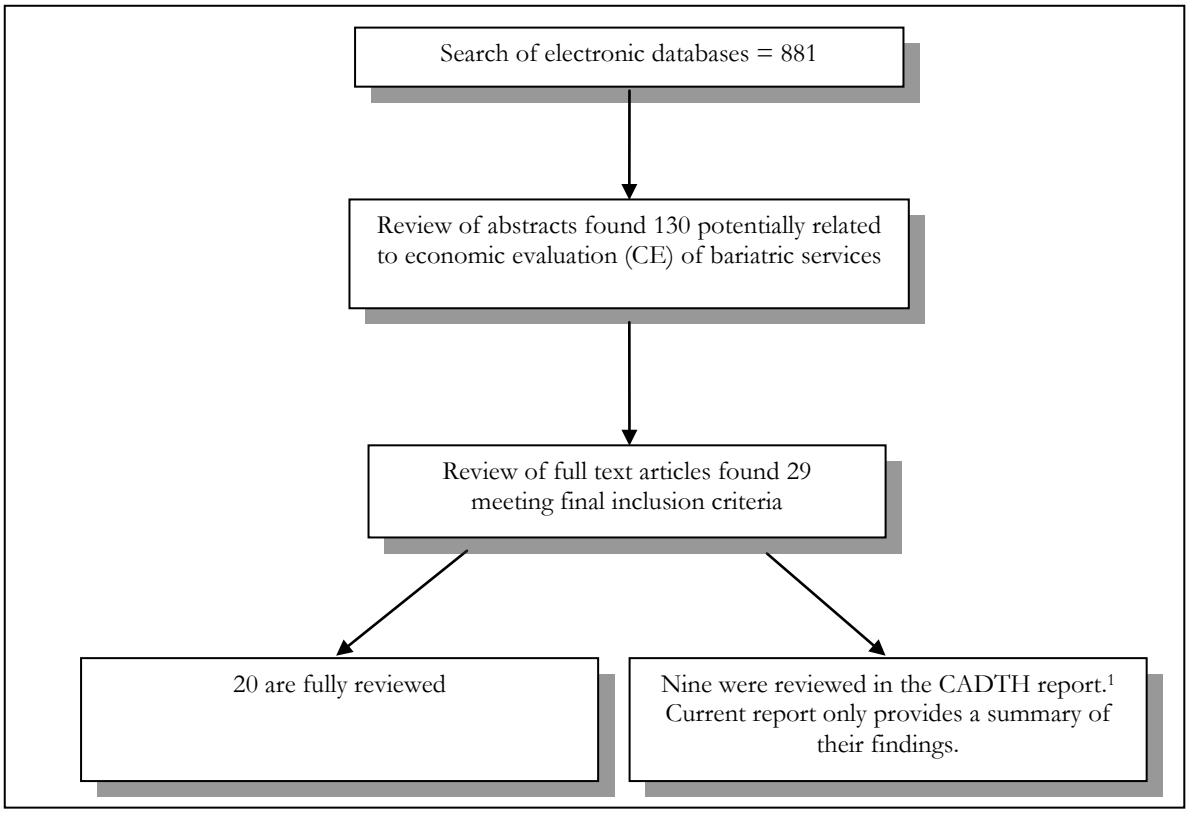


Table E.A.2: Evidence table of reviewed economic studies

#	Components	Description
1	**Study**[1]	Authors/publish year: Klarenbach/2010; country: Canada; study type: CUA; setting: secondary care; study perspective: payer
	Objective	To evaluate the cost-effectiveness of bariatric surgeries in comparison with lifestyle modification and other bariatric surgical alternatives.
	Population	Adult patients with a BMI ≥ 40 kg/m² or a BMI ≥ 35 kg/m² with obesity-related comorbidity.
	Intervention	The RYBG was compared with lifestyle modification or other surgical procedures including LAGB, sleeve gastrectomy, and biliopancreatic diversion with duodenal switch.
	Time Horizon/ discount rate	1, 10, 20 years, and lifetime/5%
	Currency/price year	CAD/2009
	Result	
	Health outcomes	Markov model was built up to explore the health outcomes with using clinical data collected from a literature review. At one year, compared to lifestyle modification, the reduction in BMI was 8.56 kg/m² for RYGB, 2.80 kg/m² for LAGB, 9.7 kg/m² for sleeve and 10.85 kg/m² for BPD. At 10 years, 20 years, and over lifetime, the QALY was 6.19, 9.37, and 12.42, respectively, for lifestyle modification; 7.33, 11.11, and 14.72, respectively, for RYGB; and 6.56, 9.95, and 13.2, respectively, for LAGB.
	Costs	Cost categories were the pre-treatment consultation from family physicians and dieticians, hospitalization of surgery, follow-up, and the treatment of surgical complications and obesity-related morbidities. At one year, the cost was $1349 for lifestyle modification, $26,935 for RYGB, $17,487 for LAGB, $22,536 for sleeve, and $34,587 for BPD. At 10 years, 20 years, and over lifetime, the cost was $16,406, $26,534, and $38,454, respectively, for lifestyle modification; $41,106, $50,282, and $60,106, respectively, for RYGB; and $30,422, $38,879, and $48,021, respectively, for LAGB.
	Marginal analysis	At one year, compared to lifestyle modification, the incremental cost-effectiveness ratio (ICER) ($ per BMI reduced) was $2990 for RYGB, $5764 for LAGB, $2184 for sleeve, and $3064 for BPD. At 10 years, 20 years, and over lifetime, compared to lifestyle modification, the ICER ($ per QALYs gained) was $21,595, $13,674, and $9398, respectively, for RYGB; and $37,910, $21,240, and $12,212 for LAGB. At one year, compared to LAGB, the ICER ($ per QALYs gained) was $673 for sleeve, $10,714 for BPD; and RYGB was associated with less QALYs gained (−1.17) at greater costs (an additional $4349).
	Conclusion	Bariatric surgeries were more cost-effective than lifestyle modification for the treatment of patients with severe obesity. However, within surgical interventions, the surgical intervention with the greatest cost effectiveness was uncertain due to limitations in available data.

2	**Study**[4]	Authors/publish year: Anselmino/2009; country: Austria, Italy and Spain; study type: CEA, CUA; setting: secondary care; study perspective: payer
	Objective	To assess cost-effectiveness and budget impact of AGB and GBP versus CT.
	Population	BMI ≥ 35 kg/m^2 with T2DM.
	Intervention	AGB and GBP versus CT. CT were defined as the medically guided diet for 1 year, followed by watchful waiting.
	Time Horizon/ discount rate	5 years; 3.5% for costs and health outcomes
	Currency/price year	€/2009
	Result	
	Health outcomes	QALY, BMI year, and T2DM free-year. Results were not reported.
	Costs	Compared with CT, AGB was associated with €2.942 million savings per 1000 patients in Austria and €1.107 million savings in Italy. In Spain, the cost of AGB versus CT was €1.497 million per 1000 patients. Compared with CT, GBP was associated with €1.938 million savings per 1000 patients in Austria and €1.67 million savings in Italy. In Spain, the cost of GBP versus CT was €3.57 million per 1000 patients.
	Marginal analysis	In Austria and Italy, AGB and GBP dominated CT in that they were less costly and more effective. In Spain, the ICER was €1456/QALY, €25.9/MBI year and €611/T2MD free-year for AGB versus CT; and €2,664/QALY, €44.2/MBI year and €1362/T2MD free-year for GBP versus CT.
	Conclusion	Compared to CT, AGB and GBP generated improved health outcomes and were cost-effective.
3	**Study**[28]	Authors/publish year: Olsen/2005; country: Denmark; study type: CEA; setting: primary and secondary care; study perspective: society
	Objective	To assess the cost-effectiveness of nutritional counselling for obese patients with high risk for ischaemic heart disease (IHD).
	Population	BMI ≥ 30 kg/m^2, waist circumference > 102 cm for men and > 88 cm for women with dyslipidaemia or T2DM.
	Intervention	The study compared nutritional counselling by a GP or a dietician (which comprised five sessions) to no counselling. The counselling by GPs consisted of general advice plus written information on health and diet, while that by dieticians focused on principles of good nutrition and advice on food shopping, cooking methods, meal planning, and exercise.
	Time Horizon/ discount rate	12 months
	Currency/price year	Danish kroner (Dkr)/2001

	Result	
	Health outcomes	Of a total of 401 participants, 243 were in dietician group and 158 in GP group; 377 were without IHD (243 in GP group and 134 in dietician group). Life years gained: 0.0274 versus 0.0919 in dietician versus GP group; 0.0919 versus 0.1608 for those without IHD
	Costs	Total costs: Dkr 1642 versus 755 in dietician versus GP group
	Marginal analysis	Compared with no counselling, the ICER was Dkr 8,213 and Dkr 59,987 per LY gained in GP and dietician group, respectively; for patients without IHD, ICER decreases to Dkr 4670 and Dkr 23,469, respectively.
	Conclusion	Nutritional counselling by a GP or a dietician was cost-effective for obese patients with a high risk of IHD. Intervention by a GP was superior to that by a dietician.
4	**Study**[24]	Authors/publish year: Malone /2005; country: US; study type: CEA; setting: secondary care; study perspective: payer
	Objective	To assess the cost-effectiveness of sibutramineplus a WMP for overweight and obese patients.
	Population	Individuals aged 18 years or older with a BMI ≥ 30 kg/m² or a BMI of 27 kg/m² to 29.9 kg/m² with one or more co-morbidities, including diabetes, hypertension, or hyperlipidaemia.
	Intervention	Sibutramine plus a WMP was compared with WMP alone. The WMP was a physician-supervised, multidisciplinary program, including five monitored care visits.
	Time Horizon/ discount rate	12 months/NA
	Currency/price year	US$/2004
	Result	
	Health outcomes	Of 501 patients included in the study, 281 were randomized to the intervention group and 220 to the control group (WMP alone). The groups were not comparable in terms of patient demographics and BMI at baseline. In the intervention versus control group, the mean weight loss at 12 months was 13.7 versus 5 pounds; per cent change in weight was -6% versus -2.2%; and per cent having weight loss of at least 10% was 19.6% versus 10%.
	Costs	The median increase in total costs from 12 months before enrolment to 12 months after enrolment was $1279 in the intervention group and $271 in the control group; the median increase in obesity-related costs was $408 versus $31 in both groups.
	Marginal analysis	When total costs were considered, the mean ICER of intervention over control group was $194 per additional pound reduced; $399 per percentage change in weight loss. When obesity-related costs were considered, the mean ICER of intervention over control group was $44 per additional pound reduced; $101 per percentage change in weight loss.
	Conclusion	Adding sibutramine to a WMP led to a significantly greater reduction in weight, but no savings in costs.

5	**Study**[14]	Authors/publish year: van Baal /2008; country: Netherlands; study type: CUA; setting: primary care; study perspective: payer
	Objective	To assess the cost-effectiveness of orlistat in combination with low-calorie diet for the treatment of obesity.
	Population	Individuals aged between 20 and 70 years with a BMI ≥ 30 kg/m^2, not being treated for obesity.
	Intervention	No intervention was compared to treatment with orlistat plus low-calorie diet and treatment with low-calorie diet alone.
	Time Horizon/ discount rate	Lifetime/1.5% for effects and 4% for costs
	Currency/price year	€/2005
	Result	
	Health outcomes	QALY gained: 31,000 and 17,000 in medication and diet group for the targeted population of 1.14 million; LY: 34,000 versus 18,000 in medication and diet group for the 1.14 million
	Costs	Direct healthcare costs were considered and no productivity costs were considered. Incremental costs: €1,136 versus €302 million for the 1.14 million populations in medication and diet group.
	Marginal analysis	ICER of diet over no intervention: €16,400 per LY gained and €17,900 per QALYs gained; ICER of medication plus diet over no intervention: €53,600 per LY gained and €58,800 per QALYs gained.
	Conclusion	The study suggested that a low-calorie diet was the first option for the treatment of obesity.
6	**Study**[22]	Authors/publish year: Ruof /2005; country: Sweden and Switzerland; study type: meta-analysis/CEA; setting: primary care; study perspective: healthcare system
	Objective	To assess clinical and economic effects of orlistat on obese patients with T2DM.
	Population	Patients with obesity and T2DM.
	Intervention	Treatment with orlistat was compared with placebo.
	Time Horizon/ discount rate	11 years/3%
	Currency/price year	€/2001
	Result	
	Health outcomes	Meta-analysis was conducted to pool results from seven RCTs; 1249 and 1230 patients were included in orlistat and placebo groups, respectively. After 12 weeks, 23% of patients in orlistat group achieved a weight reduction of more than 5%; these patients demonstrated a mean decrease in H1C of 1.16% and a weight loss of 8.6 kg.

	Costs	The cost analysis considered medication costs and direct healthcare costs of obesity- and diabetes-related complications. Total costs: not reported
	Marginal analysis	The ICER was €14,000 and €13,600 per QALY gained, in Sweden and Switzerland, respectively.
	Conclusion	The analysis supported the use of orlistat for overweight and obese patients with T2DM.
7	**Study[23]**	Authors/publish year: Lamotte/2002; country: Belgium; study type: CEA; setting: primary care; study perspective: healthcare consumer
	Objective	To assess clinical and economic consequences of treating obese patients with T2DM with orlistat as compared to no treatment.
	Population	Patients with obesity and T2DM.
	Intervention	Treatment with orlistat was compared with placebo.
	Time Horizon/ discount rate	10 years/3%
	Currency/price year	€/2000
	Result	
	Health outcomes	A Markov model that incorporated obesity- and diabetes-related complications was constructed to predicted health outcomes and costs over a long run for four sub-groups: patients with event-free profiles, those with arterial hypertension and without hypercholesterolaemia at the beginning of the study, those with hypercholesterolaemia but without arterial hypertension at the beginning of the study, and those with arterial hypertension and hypercholesterolaemia. Compared to placebo, orlistat generated an incremental LY of 0.08, 0.204, 0.227, and 0.474 for the sub-groups, respectively.
	Costs	Compared to placebo, the incremental costs for those patient groups were €1608, €1514, €1678, and €1641, respectively.
	Marginal analysis	Compared to placebo, the cost per LY saved was €19,986, €7,407, €7388, and €3462, respectively.
	Conclusion	Orlistat was a cost-effective option for the treatment of obese patients with T2DM.
8	**Study[15]**	Authors/publish year: Lacey/2005; country: Ireland; study type: CUA; setting: primary care; study perspective: healthcare system
	Objective	To assess the cost-effectiveness of the adding orlistat to a calorie-controlled diet overweight and obese patients.
	Population	Individuals aged 18 or older with a BMI ≥ 28 kg/ m^2, no diagnosed T2DM, and being able to lose 2.5 kg during 4 weeks before starting treatment.
	Intervention	The orlistat in combination with a calorie-controlled diet was compared with diet alone for overweight and obese patients.
	Time Horizon/ discount rate	11 years/3%

	Currency/price year	€/2003
	Result	
	Health outcomes	Clinical evidence was derived from five RCTs that included 1386 patients. Compared with diet alone, the QALY gain was 0.028 in orlistat patients and 0.09 in orlistat responders.
	Costs	The incremental cost associated with orlistat versus diet alone was €478.
	Marginal analysis	The ICER for orlistat versus diet was €16,954 per QALY gained.
	Conclusion	Orlistat is effective and cost-effective in obese patients if, after 3 months of treatment, only treatment responders continue treatment.
9	**Study[16]**	Authors/publish year: Iannazzo/2008; country: Italy; study type: CUA; setting: primary care; study perspective: society
	Objective	To assess the cost-effectiveness of orlistat in combination with lifestyle modification for the treatment of obesity.
	Population	Individuals aged ≥ 35 years with a BMI ≥ 30 kg/m^2
	Intervention	Orlistat in combination with lifestyle modification was compared with lifestyle modification alone. The lifestyle modification included a reduced-calorie diet and exercise.
	Time Horizon/ discount rate	10 years/3.5%
	Currency/price year	€/NA
	Result	
	Health outcomes	A Markov model that incorporated impact of obesity and diabetes on cardiovascular mortality was constructed to simulate the clinical and economic outcomes of the interventions. Compared to placebo, orlistat led to a QALY gain of 0.046 (6.084 versus 6.13) and a LY gain of 0.014 (8.011 versus 8.026).
	Costs	The extra cost-per-patient in orlistat over placebo group was €2948 (€12,580 versus €15,530).
	Marginal analysis	The incremental cost per QALY gained with orlistat over placebo was €75,310.
	Conclusion	Adding orlistat to lifestyle modification provided the best value-for-money in the sub-group of obese patients with IGT.
10	**Study[17]**	Authors/publish year: Hampp/2008; country: US; study type: RCT/CUA; setting: primary care; study perspective: payer
	Objective	To assess the clinical and economic impact of rimonabant in combination with lifestyle modification for the treatment of obesity.
	Population	Individuals aged ≥ 18 years with a BMI ≥ 30 kg/ m^2 or a BMI ≥ 27 kg/m^2 with treated or untreated dyslipidaemia or hypertension.
	Intervention	Five alternatives were examined: rimonabant at a daily dose of 20 mg plus lifestyle interventions for one year; rimonabant plus lifestyle interventions for 1 year followed by placebo plus lifestyle interventions for 1 year; rimonabant plus lifestyle intervention for 2 years; placebo plus lifestyle interventions for 2 years; and no intervention. The lifestyle intervention was low-calorie diet and exercise.

	Time Horizon/ discount rate	5 years/3%
	Currency/price year	US$/2006
	Result	
	Health outcomes	The incidence of coronary heart disease (CHD) was reduced from 1.16% with no treatment by 0.042% with placebo and by 0.083% with rimonabant for 2 years. The incidence of diabetes was reduced from 5.06% with no treatment by 0.192% with placebo and by 0.470% with rimonabant for 2 years. QALYs gained were 0.0984 with rimonabant for 2 years, 0.0403 with placebo, and 0.0000 with no treatment.
	Costs	The total costs per patient for each non-dominated strategy were: $6060.27 with rimonabant for 2 years, $1878.61 with placebo, and $851.41 with no treatment.
	Marginal analysis	The rimonabant plus lifestyle interventions for one year and rimonabant plus lifestyle interventions for 1 year followed by placebo plus lifestyle interventions for 1 year were dominated options in that they generated lower QALYs gained at higher costs, compared to other alternatives. The ICER of rimonabant for 2 years was $71,973.43 per QALY gained over placebo and $52,935.52 per QALY gained over no treatment.
	Conclusion	Rimonabant in combination with lifestyle interventions had the potential to decrease the incidence of obesity-related morbidity and to improve health-related quality of life, but at a considerable cost.
11	**Study[18]**	Authors/publish year: Brennan /2006; country: Germany; study type: CUA; setting: primary care; study perspective: payer
	Objective	To assess the clinical impact and cost-effectiveness of sibutramine in combination with diet and lifestyle counselling for the treatment of obesity.
	Population	Individuals with a BMI ≥ 30 kg/m² without co-morbidities.
	Intervention	Sibutramine in combination with diet and lifestyle advice was compared with diet and lifestyle counselling alone.
	Time Horizon/ discount rate	5 years/5%
	Currency/price year	€/2003
	Result	
	Health outcomes	The incremental QALY relating to weight loss, diabetes, and CHD of sibutramine over placebo was 51.5 (20,290 with sibutramine versus 20,238 with placebo) for a cohort of 1000 patients.
	Costs	The incremental costs were €706,148 (€2,302,468 with sibutramine versus €1,596,320 with placebo) for a cohort of 1000 patients.
	Marginal analysis	The ICER of sibutramine over placebo was €13,706 when considering the costs and benefits associated with weight loss and reductions in CHD and diabetes events.
	Conclusion	Adding sibutramine to lifestyle modification was a cost-effective option, compared to lifestyle modification alone.
12	**Study[19]**	Authors/publish year: Warren/2004; country: UK and US; study type: CUA; setting: primary care; study perspective: payer

	Objective	To assess the clinical impact and cost-effectiveness of sibutramine in combination with diet and lifestyle counselling for the treatment of obesity.
	Population	Individuals with a BMI ≥ 30 kg/m^2.
	Intervention	Sibutramine in combination with diet and lifestyle counselling was compared with diet and lifestyle counselling alone.
	Time Horizon/ discount rate	5 years/6% in UK and 3% in US for costs, and 1.5% in UK and 3% in US for benefits
	Currency/price year	£ and US$/2000
	Result	
	Health outcomes	The incremental QALY relating to weight loss, diabetes, and CHD of sibutramine over placebo was 58.9 for the UK cohort of 1000 patients and 52.91 for the US cohort of 1000 patients.
	Costs	The incremental costs were £281,791 in UK and $491,999 in the US for a cohort of 1000 patients.
	Marginal analysis	The ICER of sibutramine over placebo was £4780 in the UK and $9299 in the US when considering the costs and benefits associated with weight loss and reductions in CHD and diabetes events.
	Conclusion	Adding sibutramine to diet and lifestyle modification was a cost-effective option in both the UK and the US, compared to diet and lifestyle modification alone.
13	**Study[20]**	Authors/publish year: Ara/2007; country: Finland, Germany, Switzerland, and UK; study type: CUA; setting: primary care; study perspective: payer
	Objective	To assess the clinical impact and cost-effectiveness of sibutramine in combination with diet and lifestyle counselling for the treatment of obesity.
	Population	Individuals with a BMI ≥ 30 kg/m^2.
	Intervention	Sibutramine in combination with diet and lifestyle counselling was compared with diet and lifestyle counselling alone.
	Time Horizon/ discount rate	5 years/3.5% in UK and 5% in Finland, Germany, and Switzerland
	Currency/price year	€/2004
	Result	
	Health outcomes	The incremental QALYs per 1000 patients relating to weight loss, diabetes, and CHD of sibutramine over placebo were 50.5 for Finland, 51.5 for Germany, 54.4 for Switzerland, and 59.0 for the UK.
	Costs	The total incremental costs per 1000 patients were €614,031 for Finland, €706,148 for Germany, €583,742 for Switzerland, and €325,183 for the UK.
	Marginal analysis	The ICER of sibutramine over placebo was €12,149 for Finland, €13,707 for Germany, €10,734 for Switzerland, and €5516 for the UK.
	Conclusion	The study suggested that adding sibutramine to diet and lifestyle modification was a cost-effective option and could be considered as a viable alternative alongside diet and exercise.
14	**Study[29]**	Authors/publish year: Tsai/2005; country: US; study type: CUA; setting: primary care;

		study perspective: society
	Objective	To compare the cost-effectiveness of the diet counselling strategies for patients with severe obesity.
	Population	Patients with a BMI ≥ 43 kg/m^2.
	Intervention	Low-carbohydrate diets were compared with standard diets. Patients in both groups received weekly counselling sessions during the first month and monthly sessions during the next 5 months. Patients in the intervention group were counselled to consume less than 30 grams of carbohydrate per day, while those in control group were counselled to follow the National Cholesterol Education Program Step 1 diet.
	Time Horizon/ discount rate	1 year
	Currency/price year	US$/2001
	Result	
	Health outcomes	Low-carbohydrate diets generated an additional QALY of 0.04, as compared to standard diets.
	Costs	The total cost associated with low-carbohydrate diets was less than that with standard diets, with a difference of $49.
	Marginal analysis	Low-carbohydrate diets were a dominant option due to higher QALYs gained at lower costs. However, the bootstrap analysis indicated that the difference in costs and QALYs was not statistically significant.
	Conclusion	The low-carbohydrate diet was not more cost-effective for weight loss than was the standard diet.
15	**Study[30]**	Authors/publish year: Sevick/2009; country: US; study type: CEA; setting: primary care; study perspective: payer
	Objective	To assess the cost-effectiveness of exercise and diet for the treatment of obesity.
	Population	Elderly patients aged ≥ 60 years with a BMI ≥ 28 kg/m^2 and knee osteoarthritis.
	Intervention	The interventions of diet, exercise, and combined exercise and diet were compared with healthy lifestyle control. Participants in the lifestyle control group were scheduled a monthly meeting for one hour during the first three months, including presentations and physician talks on topics pertaining to osteoarthritis, one session on exercise, and one session on dietary weight loss. Thereafter, monthly or bimonthly phone contact was made.
	Time Horizon /discount rate	18 months/5%
	Currency/ price year	US$/2000
	Result	
	Health outcomes	The percentage of baseline body weight lost was 1.2%, 4.9%, 3.7%, and 5.7% for lifestyle control, diet, exercise, and combined diet and exercise, respectively.
	Costs	The cost-per-patient per month was $32, $160, $152, and $304 for lifestyle control, diet, exercise, and combined diet and exercise, respectively.
	Marginal analysis	Compared to lifestyle control, the cost per percentage of baseline body weight lost was $35, $48, and $60 for diet, exercise, and combined diet and exercise, respectively.

	Conclusion	Combined exercise and diet was the most cost-effective option for improving physical function, pain, and stiffness for obese patients with knee osteoarthritis.
16	**Study**[21]	Authors/publish year: Roux/2006; country: US; study type: CUA; setting: outpatient care; study perspective: society
	Objective	To assess the cost-effectiveness of weight loss programs in overweight and obese adult US women.
	Population	Adult women aged ≥ 35 years with a BMI ≥ 25 kg/m^2.
	Intervention	Usual care was compared with four weight loss strategies: diet only, diet and pharmacotherapy, diet and exercise, and combined diet, exercise, and behaviour modification. Exercise consisted of three 45-minute sessions per week and two monthly review sessions. Pharmacotherapy comprised of orlistat (120 mg) three times per day for initial 6 months, and half that dose for next 6 months. Behaviour modification consisted of cognitive counselling for 1 hour every 2 weeks.
	Time Horizon/ discount rate	Lifetime/3%
	Currency/price year	US$/2001
	Result	
	Health outcomes	Combined diet, exercise, and behaviour modification was the most effective option with 24.17 discounted LY and 18.426 discounted QALY, followed by diet and exercise (24.129 LY and 18.255), diet and pharmacotherapy (24.128 and 18.248), diet only (24.12 and 18.169) and usual care (24.119 and 18.183).
	Costs	The lifetime cost was $124,200 for the combined diet, exercise, and behaviour modification, $123,240 for diet and exercise, $122,660 for diet and pharmacotherapy, $122,440 for diet only, and $121,120 for usual care.
	Marginal analysis	The combined diet, exercise, and behaviour modification dominated other options with an ICER over usual care of $60,400 per LY gained and $12,640 per QALY gained.
	Conclusion	The weight loss program combining diet, exercise, and behaviour modification was the most cost-effective for overweight and obese women.
17	**Study**[25]	Authors/publish year: Gustafson/2009; country: US; study type: CEA; setting: primary care; study perspective: payer
	Objective	To assess the cost-effectiveness of a 16-week weight loss program.
	Population	Women aged between 40 and 60 years with a BMI between 25 kg/m^2 and 45 kg/m^2 and income ≤ 200% of the federal poverty level.
	Intervention	The weight-wise intervention was compared with a wait-listed control group. The weight-wise intervention consisted of weekly counselling sessions during a 16-week period, with a focus on consuming nine or more fruit and vegetable servings daily and lifestyle change through self-monitoring, problem-solving, and goal-setting.
	Time Horizon/ discount rate	Lifetime/3%
	Currency/price year	US$/2007

	Result	
	Health outcomes	The intervention was associated with a decrease of 4.4 kg in weight and 6.2 mmHg in systolic blood pressure, as compared to the control.
	Costs	Costs of weight-wise intervention were $242 per person. Control group was assumed to be with zero cost.
	Marginal analysis	The ICER was $1862 per LY gained.
	Conclusion	The weight-wise intervention was a cost-effective approach.
18	**Study**[26]	Authors/publish year: Gusi/2008; country: Spain; study type: CUA; setting: primary care; study perspective: healthcare system
	Objective	To assess the cost-effectiveness of a walking program compared to best care.
	Population	Women aged ≥ 60 years with a BMI between 25 kg/m^2 and 39.9 kg/m^2 or 6 to 9 points in the 15-item Geriatric Depression Scale.
	Intervention	The walking program consisted of walks with a group in public park or forest tracks, guided by the qualified exercise leaders, for 50 minutes, three times per week over 6 months. The individuals in best care group received routine care and a physical activity recommendation.
	Time Horizon/ discount rate	6 months/na
	Currency/price year	€/2005
	Result	
	Health outcomes	The mean QALY was 0.395 and 0.263 in intervention versus control group, with an incremental QALY of 0.132.
	Costs	The mean incremental cost per person in the intervention over control group was €41.
	Marginal analysis	The ICER was €311 per QALY gained.
	Conclusion	The walking program was cost-effective for depressed or overweight elderly women, compared to best care.
19	**Study**[31]	Authors/publish year: Galani/2007; country: Switzerland; study type: CEA, CUA; setting: primary care; study perspective: society
	Objective	To assess the lifetime health and economic impact of a lifestyle intervention for preventing and treating obesity, as compared to standard care.
	Population	Individuals aged ≥ 25 years with a BMI between 25 kg/m^2 and 35 kg/m^2. The population was assessed in three sub-groups based on BMI: overweight with a BMI 25 kg/m^2 to 29.9 kg/m^2, moderately obese with a BMI 30 kg/m^2 to 35 kg/m^2, and bordline with a BMI 30 kg/m^2.
	Intervention	Individuals in lifestyle intervention group attended dietician and supervised exercise sessions during the first 3 years. The intervention consisted of recommendations to limit total intake of fat to less than 30% of energy consumption and of saturated fat to less than 10%, to increase fibre to at least 15g/1000kcal, and to undertake moderate daily exercise for at least 30 minutes. The dietician also advised about food types. Standard care consisted of basic dietary counselling and physical exercise sessions for obese patients and of no intervention for overweight patients.

	Time Horizon/ discount rate	Lifetime/3%
	Currency/price year	Swiss Francs (CHF)/2006
	Result	
	Health outcomes	The lifestyle intervention over the standard care in overweight, borderline, and moderately obese patients was associated with 0.01 LY gained for both men and women. The lifestyle intervention over standard care was associated with QALY gained of 0.23 in overweight women and 0.25 in overweight men, 0.25 in borderline women and 0.28 in borderline men, and 0.26 in moderately obese women and 0.29 in moderately obese men.
	Costs	The incremental costs of the lifestyle intervention over standard care were CHF 510 in overweight women and CHF 405 in overweight men, CHF 80 in borderline women and CHF 6 in borderline men, and CHF 207 in moderately obese women and CHF 127 in moderately obese men.
	Marginal analysis	Results of the marginal analysis were reported by age/sex groups. For overweight patients, the ICER was from CHF 17,149 in 55-year-old men to CHF 295,863 in 25-year-old women per LY gained, and from CHF 914 in 55-year-old men to CHF 6286 in 25-year-old women per QALY gained. For moderately obese patients, the ICER was from dominant (due to more effective and less costly) in 45-year-old and 55-year-old men to CHF 171,544 in 25-year-old women per LY gained, and from dominant in 35-year-old women and 55-year-old men to CHF 3180 in 25-year-old women per QALY gained. For borderline patients, the ICER was from dominant in all male age groups to CHF 142,619 per LY gained in 25-year-old women, and from dominant in all male age groups to CHF 3,023 per QALY gained in 25-year-old women.
	Conclusion	The lifestyle interventions were cost-effective in long-run.
20	**Study**[27]	Authors/publish year: Bemelmans/2008; country: Netherlands; study type: CEA, CUA; setting: community; study perspective: healthcare system
	Objective	To evaluate the clinical and economic impact of a community intervention and an intensive lifestyle program for prevention of overweight.
	Population	Individuals with a BMI ≥ 25 kg/m^2
	Intervention	Community-based intervention and intensive lifestyle modification were evaluated in comparison with no intervention. The community-based intervention offered social support such as self-help groups, risk factor screening, and/or counselling to 90% of the general population, while the intensive lifestyle modification was offered to 10% of the population and targeted at overweight individuals.
	Time Horizon/ discount rate	20 years and 80 years/4%
	Currency/price year	€/2004

	Result	
	Health outcomes	The target population comprised 12 million and 0.65 million individuals in community-based intervention and intensive lifestyle programs, respectively. Of the target population, which comprised 12 million and 0.65 million individuals in community-based intervention and intensive lifestyle programs, respectively, the combined intervention generated 110,000 LYs and 150,000 QALYs saved over 20 years, and 1.3 million LYs and 1.22 million QALYs saved over 80 years, as compared to no intervention.
	Costs	The total costs were presented graphically.
	Marginal analysis	Compared to no intervention, the ICER was €5,100 per LY gained and €5,000 per QALY gained with the community-based intervention alone, €8,400 per LY gained and €7,400 per QALY gained with intensive lifestyle modification alone, and €6,000 per LY gained and €5,700 per QALY gained with the combination of both programs.
	Conclusion	Both community-based intervention and intensive lifestyle modification were cost-effective for preventing and reducing overweight; the former was slightly more cost-effective.

APPENDIX E.B

Table E.B.1 Estimate of economic burden of obesity

S1 Outlined regression results

Variable	Outpatient and physician cost	Physician cost	Physician visit	Outpatient cost	Outpatient visits	Inpatient visits
BMI	22.716***	17.263***	0.320***	12.022***	0.084***	0.021***
Age	11.682***	10.732***	0.192***	10.297***	0.026***	0.012***
Female	115.699***	89.703***	1.634***	20.4	0.069	-0.005
Income	-24.317	-29.264*	-0.373	-43.731**	-0.266**	-0.026
High school & over	-26.581	-22.935	-0.577	29.222	0.113	-0.006
Ever smoked	40.332	17.909	-0.023	25.196	0.188	0.029
Has physical activity	-25.649	-38.907	-0.634*	-72.139*	-0.228	-0.001
Has COPD	164.875*	236.529***	2.820***	173.009**	0.262	-0.134
Has back problem	54.586*	56.304**	1.560***	16.189	0.198	0.028
Has high blood pressure	-34.628	-17.222	-0.205	14.867	0.001	-0.039
Has diabetes	71.861	83.380**	1.381**	-66.891	-0.289	-0.001
N	3660	3660	3660	1660	1667	311
Adj R-squared	0.41	0.34	0.46	0.39	0.29	0.75

Legend: * p < .05; ** p < .01; *** p < .001

Note: Graph investigation and linear test showed costs/visits are linear in body mass index. So the impact of BMI on costs/visits was assessed using linear regression, adjusted by age, gender, etc.

S2 Mean costs/visits per patient

BMI	Outpatient and physician costs	Physician costs	Physician visit	Outpatient costs	Outpatient visits	Inpatient visits
Underweight	$ 872.07	$604.04	12.120	$701.26	2.571	1.163
Normal weight	$ 856.38	$565.05	11.764	$643.82	2.620	1.239
Overweight	$ 969.94	$664.62	13.602	$712.31	3.054	1.357
Obese	$1150.34	$813.22	16.315	$803.15	3.694	1.442

Note: Mean costs/visits were predicted using results from the regression models above.

S3 # of residents/patients by BMI

BMI	# population	CCHS	PCD and ACCS	PCD	ACCS	DAD
Underweight	57,796	175	105	105	48	10
Normal weight	1,116,229	3586	2008	2004	836	150
Overweight	842,883	2994	1682	1680	796	145
Obese	463,222	1883	1140	1140	576	106

Note: Second column is Alberta residents, represented by the sample in the CCHS survey; third column is residents completing the CCHS survey (i.e., the sample); remaining columns are patients in the databases.

CCHS = Canadian community health survey; PCD = physician claim database; ACCS = Ambulatory Care Classification System; DAD = discharge abstract database

S4 Economic burden of obesity

Mean cost/visits per resident

BMI	Outpatient and physician costs	Physician costs	Physician visit	Outpatient costs	Outpatient visits	Inpatient admission
Underweight	$523.24	$362.43	7.272	$192.35	0.705	0.066
Normal weight	$479.53	$315.77	6.574	$150.09	0.611	0.052
Overweight	$544.91	$372.93	7.632	$189.38	0.812	0.066
Obese	$696.44	$492.34	9.877	$245.68	1.130	0.081

Note: The mean cost/visit was adjusted to residents completing CCHS, using patient costs or visits listed in S2. The method is:

$$\frac{cost\ in\ S2 \times patient\ \#\ in\ S3}{residents\ in\ CCHS\ (S3)}$$

Incremental costs/visits over normal weight

BMI	Outpatient and physician costs	Physician costs	Physician visit	Outpatient costs	Outpatient visits	Inpatient admission
Underweight	$43.71	$46.65	0.698	$42.25	0.094	0.015
Overweight	$65.37	$57.16	1.058	$39.29	0.201	0.014
Obese	$216.90	$176.57	3.303	$95.58	0.519	0.029

Note: This table presents the difference between normal weight and other BMI categories.

Economic burden of obesity (costs are in millions and visits are per 1000)

Underweight versus normal weight	$2.53	$2.70	40.33	$2.44	5.45	0.85
Overweight versus normal weight	$55.10	$48.18	891.84	$33.11	169.56	11.72
Obese versus normal weight	$100.47	$81.79	1530.24	$44.28	240.44	13.61

Note: Multiplying Alberta residents with obesity in S3 by the marginal cost/visit between obese and normal weight.

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Paula Corabian contributed to study conception and design, data analysis and interpretation, and approved the final version for publication.

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Christa Harstall contributed to study conception and design, revision of manuscript for critical content, and approved the final version for publication.

Charles Yan contributed to study conception and design, statistical analysis, economic expert review of the literature, revision of manuscript for critical content, and approved the final version for publication.

Anderson (Andy) Chuck contributed to study conception and design, statistical analysis, economic expert review of the literature, manuscript preparation, and approved the final version for publication.

This report summarizes available key information on the use of bariatric treatments for adult obesity in Alberta and North America (mainly Canada). This analysis was intended to describe the profile of adult obesity (definition, progression, epidemiology, and population dynamics of affected individuals in Alberta and in Canada) and patterns of care for this condition (focusing on bariatric treatments recommended by evidence-based clinical practice guidelines), as well as to identify potential inequities in health status or care across population groups. Also considered were social factors associated with the use of multidisciplinary programs involving bariatric treatments for adult obesity in Alberta.

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