

**TITLE: Bariatric Surgery for Adolescents and Young Adults: A Review of Comparative Clinical Effectiveness, Cost-Effectiveness, and Evidence-Based Guidelines**

**DATE:** 03 August 2016

**CONTEXT AND POLICY ISSUES**

Rates of overweight and obesity in Canadian children showed a statistically significant overall decline in Canada over the 2004 to 2013 period from 30.7% to 27.0%, with rates of obesity remaining stable at 13%.<sup>1</sup> While this decline is encouraging, median body mass index (BMI) and weight of Canadian children still remain above averages for the World Health Organization (WHO) growth charts.<sup>1</sup>

Adolescent obesity is associated with several chronic diseases including diabetes, sleep apnea, cardiovascular disease, non-alcoholic steatohepatitis, polycystic ovarian syndrome, and musculoskeletal disorders.<sup>2,3</sup> Further, the risk of obesity-related morbidity and mortality increases over time, suggesting that children who develop obesity early may be at higher risk of experiencing complications than individuals who develop obesity later in life.<sup>4</sup> Obesity in adolescence is significantly associated with an increased risk of severe obesity in adulthood.<sup>5</sup> Currently, the majority of obese adolescents are treated with lifestyle interventions focused on behavioral and dietary modifications delivered by a multidisciplinary team. These interventions may have short-term benefits, but data to support long-term benefits is lacking.<sup>6</sup>

Bariatric surgery is a catch-all term for a variety of surgical weight loss procedures that involve modification of the gastrointestinal tract. These procedures either reduce the stomach volume, or the nutrient absorptive capacity of the intestines.<sup>7</sup> The most common procedures in Canada include gastric bypass, in which the size of the stomach is reduced and part of the small intestine is bypassed; sleeve gastrectomy in which the majority of the stomach is removed; and gastric banding, in which an adjustable band is placed around the upper portion of the stomach to reduce its overall size. For patients with persistent severe obesity, who have failed non-surgical methods of weight-loss, bariatric surgery can be an effective weight-loss strategy and may improve common obesity-related comorbidities.<sup>7</sup> However, bariatric surgery is also associated with substantial risk of morbidity and mortality. Reported side-effects include surgical complications bowel obstruction, ulcers, gallstones, scar tissue formation, band-related

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complications, and re-surgery.<sup>7,8</sup> Approximately 6% of patients are readmitted within 30 days of surgery,<sup>7</sup> and post-surgical mortality rates have been estimated at 0.1 to 2%.<sup>7</sup> Complication rates are higher in patients with greater obesity or more complex comorbidities.<sup>7</sup> Further, the success of the procedure is also dependent on experience of the operating surgeon, clinic volume, patient related factors (e.g., sex and age), whether care is provided at a specialized tertiary care centre, and respiratory status.<sup>9</sup> After bariatric surgery, patients require lifetime monitoring.

Outcomes may be different for adolescents and young adults than for adults as biological, psychological, and social factors are distinct during these developmental periods. Further, there may be medical or ethical dilemmas associated with providing bariatric surgery before adulthood.<sup>10-12</sup> There is also uncertainty regarding the relative benefits and risks of delaying surgery.<sup>13</sup> A systematic review reported that pre-operatively, a large proportion of adolescents who undergo bariatric surgery have depression and anxiety symptoms, and may suffer from eating disorders.<sup>14</sup> Eligibility criteria based on BMI cut-offs may encourage weight gain in patients who want the surgery but don't quite meet the threshold, so it has been discussed that patients of younger age and lower BMI should be considered as well.<sup>15</sup>

National Institute of Health and Care Excellence (NICE) guidelines from the United Kingdom (UK)<sup>16</sup> and International Pediatric Endosurgery Group (IPEG) guidelines<sup>17</sup> state that weight loss surgery should only be considered in exceptional circumstances for obese children, and that the child must be physically mature and have failed 6 months of multidisciplinary lifestyle intervention. Eligibility criteria are stricter for youth than for adults. That is, only severely morbidly obese or morbidly obese children with serious comorbidities that would improve with weight loss are typically considered.<sup>16,18,19</sup> Also, guidelines stipulate that surgery must be carried about by a multidisciplinary team with pediatric expertise.<sup>16,17</sup> The high rate of obesity coupled with increasing numbers of surgeries performed may increase awareness and interest in the procedure.<sup>8</sup>

The Canadian Institute for Health Information (CIHI) reported that from 2012 to 2013 approximately six thousand bariatric surgeries, costing \$48 million CAD (excluding physician compensation and non-hospital costs), were performed in Canada; a fourfold increase over six years.<sup>7</sup> The majority of evidence on obesity and bariatric surgery in Canada is based on adult populations; however, the number of younger patients interested in and undergoing surgery has grown.<sup>20</sup> Bariatric surgery has been demonstrated to improve weight loss, health, and psychosocial outcomes in adolescents;<sup>14,21</sup> however, there is limited knowledge regarding its effect relative to alternative surgical procedures or non-surgical interventions. Thus, this review seeks to assess the comparative clinical and cost-effectiveness of bariatric surgery versus viable comparators in the adolescent and young adult population, and to review current evidence-based guidelines regarding the use of bariatric surgery in the adolescent population.

## RESEARCH QUESTIONS

1. What is the comparative clinical effectiveness of bariatric surgery versus alternative surgical procedures or non-surgical treatments for obese patients with a mean age of 18 years or younger?
2. What is the cost-effectiveness of bariatric surgery for obese patients with a mean age of 18 years or younger?

3. What are the evidence-based guidelines regarding bariatric surgeries for obese patients with a mean age of 18 years or younger?

## KEY FINDINGS

Five systematic reviews, two economic evaluations, two reviews of guidelines, and six primary evidence-based guidelines were identified regarding the clinical and cost-effectiveness, and guidelines for the use of bariatric surgery in adolescents and young adults. Very few comparative clinical studies have been conducted in the area of adolescent bariatric surgery. The limited available evidence suggests superior weight loss, and resolution of comorbidities compared to non-surgical interventions, and potential superior weight loss with Roux-en-Y gastric bypass versus other procedures. Complications are common, and the effect of surgery on outcomes such as quality of life, psychosocial outcomes, long-term weight loss and complications, and mortality remain uncertain. Cost-effectiveness data is lacking, but limited evidence suggests that bariatric surgery is cost-effective several years after intervention, but not immediately. Evidence-based guidelines reflect the limited evidence-base in the low strength of their recommendations. Most guidelines suggest that under specific circumstances, bariatric surgery may be indicated for adolescent patients, but that patients must meet a strict clinical and psychiatric profile, and that the procedure requires substantial support from a multidisciplinary team with pediatric expertise, and sufficient community and family involvement.

## METHODS

### Literature Search Methods

A limited literature search was conducted on key resources including MEDLINE via Ovid, PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, economic studies, and guidelines. The search was also limited to English language documents published between January 1, 2011 and July 5, 2016.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

### Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

**Table 1: Selection Criteria**

<b>Population</b>	Obese or morbidly obese patients with a mean age of 21 years or less, with or without comorbidities
<b>Intervention</b>	Gastric bypass, adjustable gastric banding, or gastric sleeve surgery alone or in combination with non-surgical treatment
<b>Comparator</b>	Q1 and 2: Non-surgical treatment (e.g., lifestyle interventions such as diet and exercise programs, excluding non-advice interventions such as physician advice); Pharmaceutical weight loss treatments (e.g., sibutramine, orlistat); Alternative surgical interventions (i.e., comparative studies between surgery types) Q3: No comparator necessary
<b>Outcomes</b>	Q1: Clinical effectiveness and safety (e.g., benefits and harms to the patient, quality of life, mortality, change in comorbidities, adverse events, change in weight); Q2: Cost-effectiveness outcomes Q3: Evidence-based guidelines regarding the use of bariatric surgery in adolescent and young adult populations
<b>Study Designs</b>	Health technology assessments, systematic reviews, meta-analyses, economic evaluations, evidence-based guidelines

### Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2011. Health technology assessments, systematic reviews (SRs) and meta-analyses were excluded if they were superseded by an update, or a more recent review of the same primary studies. Systematic reviews with unique primary studies were excluded if the studies were limited to non-comparative studies, case series, or case reports, in the interest of appraising higher quality evidence and acknowledgement of their limitations, including small sample sizes, high risk of selection bias, and inability to demonstrate causality. Similarly SRs with unique primary studies that did not meet the inclusion criteria were excluded. Economic studies that reported direct costs and that were not formal cost-effectiveness evaluations were excluded. Guidelines that were not developed using a systematic, evidence-based process were not included. Due to the large volume of literature identified, a decision was made to restrict the final selection of articles to HTAs, SRs, MAs, economic evaluations, and evidence-based guidelines; primary RCTs and non-randomized studies were not evaluated for this report.

### Critical Appraisal of Individual Studies

The included SRs and reviews of guidelines were critically appraised using AMSTAR criteria.<sup>22</sup> The methods used when conducting the literature search, study selection, quality assessment, data extraction, and for summarizing the data were assessed. Economic studies were assessed using the Drummond checklist.<sup>23</sup> Study design, data collection, analysis, and interpretation of the results were evaluated. Evidence-based guidelines were assessed with the AGREE II instrument.<sup>24</sup> The scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence were assessed. Summary scores were not calculated for the included studies; rather, a narrative review of the strengths and limitations of each included study is presented.

## SUMMARY OF EVIDENCE

### Quantity of Research Available

A total of 755 citations were identified in the literature search. Following screening of titles and abstracts, 721 citations were excluded and 34 potentially relevant reports from the electronic search were retrieved for full-text review. Nine potentially relevant publications were retrieved from the grey literature search.

#### *Excluded Studies*

Of these 43 potentially relevant articles, 28 publications were excluded. Five articles were commentaries or non-systematic narrative reviews;<sup>25-29</sup> five reviews or guidelines had unclear methodology;<sup>30-34</sup> one guideline did not provide adolescent specific recommendations,<sup>35</sup> one study had irrelevant outcomes;<sup>36</sup> nine studies had patients with irrelevant populations and/or patients outside of the specified age range,<sup>37-45</sup>; one was not published in English;<sup>46</sup> four systematic reviews had no unique primary studies,<sup>47-50</sup> and two systematic reviews did not identify any comparative evidence.<sup>14,21</sup>

#### *Included Studies*

Fifteen publications met the inclusion criteria and were included in this report. This includes four systematic reviews or health technology assessments of clinical evidence,<sup>51-54</sup> one SR on both clinical and economic evidence,<sup>13</sup> two primary economic evaluations,<sup>55,56</sup> two reviews of guidelines,<sup>57,58</sup> and six primary evidence-based guidelines.<sup>59-64</sup> Study selection is presented in a PRISMA flowchart in APPENDIX 1.

Additional references of potential interest are provided in APPENDIX 6.

### Summary of Study Characteristics

Detailed study characteristics are presented by study type in APPENDIX 2.

There was some overlap among the primary studies included in the SRs (see APPENDIX 3). Of the 82 primary studies reviewed, 22 were common to at least two reviews, and 60 were unique to one review. The majority of the included studies were non-comparative case series or observational studies and did not meet the inclusion criteria of this report. Discrepancies in the included studies were due to differences in included study designs and other selection criteria, search time frames, and comparators set by the individual SRs.

#### *Clinical Evidence*

##### *Study Design*

Five SRs<sup>13,51-54</sup> were identified regarding the comparative clinical effectiveness of bariatric surgery versus non-surgical treatments for adolescent or young adult patients requiring treatment for obesity. One SR also addressed cost-effectiveness.<sup>13</sup> The SRs were published in 2015,<sup>52,54</sup> 2014,<sup>53</sup> 2013,<sup>51</sup> and 2011.<sup>13</sup> Search dates were from 2000 to current (date not specified, earlier than date of publication in 2015),<sup>54</sup> database inception to July 2014,<sup>52</sup> inception to March 2013,<sup>53</sup> inception to January 2013,<sup>51</sup> and inception to September 2010.<sup>13</sup>

### *Country of Origin*

The SRs were conducted by authors in the United States (US),<sup>54</sup> the United Kingdom,<sup>13,51,52</sup> Sweden.<sup>53</sup>

### *Patient Population*

All of the SRs dealt with children, adolescents or young adults, with different age ranges including patients < 21 years,<sup>52,54</sup> patients 13 to 18 years,<sup>53</sup> patients with a mean age of between 6 and 18 years,<sup>51</sup> and patients ≤ 19 years.<sup>13</sup> Patient eligibility criteria was generally poorly described (i.e., in terms of prior care and comorbidities), but all patients were eligible for bariatric surgery and had baseline BMI in the range of obesity. Specific BMI (kg/m<sup>2</sup>) ranges varied from 41.4 to 51.4,<sup>54</sup> 42.3 to 63.5,<sup>52</sup> >35,<sup>53</sup> 38.5 to 60.2,<sup>51</sup> and 37.7 to 67.<sup>13</sup>

### *Interventions and Comparators*

This report was limited to studies investigating the comparative effectiveness of gastric bypass (GB), adjustable gastric banding (AGB), or gastric sleeve (GS) versus non-surgical or alternative surgical strategies. The identified SRs evaluated laparoscopic adjustable gastric banding (LAGB),<sup>13,51-54</sup> Roux-en-Y gastric bypass (RYGB),<sup>13,51,52,54</sup> and regular or vertical sleeve gastrectomy (VSG).<sup>13,51,52,54</sup> Comparators of interest included alternative surgical procedures (LAGB, GB, RYGB, BPD, GS, VSG),<sup>51,52</sup> and alternative non-surgical treatment (including diet, physical activity, lifestyle, and pharmaceutical interventions) and prevention strategies.<sup>13,52-54</sup>

### *Outcomes*

Outcomes related to bariatric surgery included weight loss,<sup>51,53,54</sup> resolution of morbidities (e.g., metabolic syndrome or hyperlipidemia),<sup>13,53,54</sup> psychological and social outcomes (including quality of life),<sup>52,53</sup> mortality,<sup>53,54</sup> long-term morbidity,<sup>53</sup> short term complications,<sup>53</sup> and harms.<sup>13</sup> Follow-up ranged from a minimum of 6 months,<sup>51</sup> minimum of one year,<sup>13</sup> the perioperative period (within 30 days post surgery) to long-term (duration not specified),<sup>54</sup> one month to at least 5 years,<sup>52</sup> and six months to 10 years.<sup>53</sup>

### *Cost-Effectiveness Evidence*

#### *Study Design*

One SR of primary economic evaluations<sup>13</sup> and two primary economic evaluations<sup>55,56</sup> presented evidence regarding the cost-effectiveness of bariatric surgery versus non-surgical treatments for adolescent or young adult patients requiring treatment for obesity. The SR also addressed clinical effectiveness as previously discussed.<sup>13</sup> One primary evaluation was a cost-utility analysis,<sup>55</sup> and the other was a cost-effectiveness analysis.<sup>56</sup>

#### *Country of Origin and Perspective*

The SR was conducted by authors in the UK.<sup>13</sup> Both primary economic evaluations were conducted in the US context.<sup>55,56</sup> A US healthcare system perspective was adopted by one evaluation,<sup>55</sup> and the other took a modified societal perspective.<sup>56</sup>

### *Patient Population*

The SR looked at obese patients under the age of 19.<sup>13</sup> The patient populations in the primary evaluations included a real-life group of obese adolescent patients (n = 11) who attended a single clinic, and the US youth population eligible for bariatric surgery.<sup>56</sup>

### *Interventions and Comparators*

The SR assessed various bariatric surgery procedures compared to alternative non-surgical treatment and prevention strategies.<sup>13</sup> The cost-utility analysis<sup>55</sup> evaluated RYGB with or without concomitant hiatal hernia repair compared to no surgery over a time horizon of seven years. Whether no surgery was comprised of other obesity management strategies was unclear.<sup>55</sup> The cost-effectiveness analysis investigated the impact of four-fold increased nationwide access to adolescent bariatric surgery over a time horizon of 10 years. One study assumed that weight lost would be regained at a rate of 5% per year for the first 5 years followed by a plateau; that BMI remained unchanged in the non-surgical group; and that medical care would be reduced with lower BMI.<sup>55</sup> One study assumed a lag period (18 to 36 months) before a reduction in BMI was achieved, and that the surgical change (weight loss) persisted over the 10 year study period.<sup>56</sup>

### *Outcomes*

The SR of primary economic evaluations presented results as cost in Australian dollars per disability adjusted life year (DALY).<sup>13</sup> One primary evaluation presented results as cost in United States dollars (USD) per quality adjusted life year (QALY),<sup>55</sup> the other presented results as cost per unit of BMI reduced.<sup>56</sup>

### *Evidence-Based Guidelines and Reviews of Evidence-Based Guidelines*

Two reviews of guidelines,<sup>57,58</sup> and six primary evidence-based guidelines<sup>59-64</sup> were identified regarding the use of bariatric surgery in obese adolescents and young adults requiring treatment. The two reviews identified a total of 22 primary guidelines, of which three were common to both reviews.

### *Clinical Society and Country of Origin*

The two reviews of guidelines<sup>57,58</sup> were conducted by authors in the US<sup>58</sup> and UK.<sup>57</sup> They identified a total of seven<sup>58</sup> and 15<sup>57</sup> guidelines. One review<sup>58</sup> only included guidelines from the US and Canada, while the other did not restrict by country of origin.

The individual primary guidelines were conducted by the Canadian Task Force on Preventive Health Care,<sup>59</sup> the International Federation for the Surgery of Obesity and Metabolic Disorders – European Chapter,<sup>60</sup> the National Institute of Clinical and Health Excellence (NICE) in the UK,<sup>64</sup> the Institute of Clinical Systems Improvement (ICSI) in the US,<sup>61</sup> the National Health and Medical Research Council (NHMRC) in Australia,<sup>65</sup> and the National Heart, Lung and Blood Institute in the US.<sup>63</sup>

### *Guideline Development and Methodology*

The two reviews included primary guidelines that used a range of guideline development approaches, with the majority employing a comprehensive SR of the evidence and a formal

grading system to form recommendations. Primary guidelines were developed using various tools to assess the quality of the literature and to determine strength of recommendations including GRADE,<sup>59,61,64</sup> the Oxford Centre for Evidence-Based Medicine classification system,<sup>60</sup> NHMRC levels of evidence and grades for recommendation,<sup>62</sup> and criteria adapted from the American Academy of Paediatrics Steering Committee on Quality Improvement and Management.<sup>63</sup> Recommendations were developed by review of the evidence grading by an expert panel,<sup>59-64</sup> and in one case, consideration of implementation issues, resource implications, values of patients and caregivers.<sup>61</sup> Guideline validation included external review by experts, stakeholders, and public,<sup>59,61,62</sup> four-week public consultation,<sup>64</sup> or was not reported.<sup>60,63</sup>

### *Targeted Users and Patient Population*

The two reviews evaluated guidelines aimed at medical practitioners providing care for obese patients and presented recommendations relevant to obese children and adolescents.<sup>57,58</sup> Primary guidelines were aimed at primary and specialty care practitioners,<sup>59-64</sup> health care policy makers,<sup>60,62</sup> health care providers,<sup>60,61,64</sup> insurance companies,<sup>60</sup> and individuals and families providing self-care and provided recommendations for children and adolescents with obesity, although some guidelines also addressed adults.

### *Interventions and Comparators*

The two reviews of guidelines included primary guidelines that provided recommendations specifically on weight loss surgery,<sup>57,58</sup> or on general obesity management with specific recommendations regarding surgical procedures.<sup>57,58</sup> Some of the primary guidelines assessed multiple obesity interventions or primary prevention strategies, where others focused solely on bariatric surgery. Rather than formal comparators, guidelines often made recommendations regarding the clinical care process, indicating when various obesity related interventions would be appropriate. Evidence supporting guideline recommendations included limited comparative evidence, contrasting different types of bariatric surgery with non-surgical and alternative surgical interventions.

### *Outcomes*

Recommendations presented in the reviews of guidelines, as well as the primary evidence-based guidelines were made regarding selection or appropriateness criteria (e.g., age and physical maturity, BMI and comorbidity criteria),<sup>57-62,64</sup> exclusion criteria,<sup>57,58</sup> preferred surgical procedure,<sup>57,58</sup> peri-operative management (including preoperative assessment),<sup>57,58,64</sup> surgical setting and care team requirements,<sup>57,58,62</sup> and post-operative recommendations for education and management.<sup>57,58</sup>

## Summary of Critical Appraisal

A detailed summary of strengths and limitations of SRs, economic evaluations, and guidelines is provided in Table A5.

Primary Study Author, Publication Year	Systematic Review Author, Publication Year				
	Ollendorf, 201554	White, 201552	Göthberg, 201453	Black, 201351	Aikenhead, 201113
Abu-Abeid 2003					•
Aikenhead 2012 <sup>a</sup>			•		
Aldaqa 2013		•			
Al-Qahtani 2007					•
Alqathani 2012 <sup>d</sup>			•	•	
Ananthapavan 2010 <sup>c</sup>					•
Anderson 1980 <sup>d</sup>			•		
Angrisani 2005				•	•
Aslam 2010 <sup>d</sup>					•
Barnett 2005					•
Boza 2012 <sup>b</sup>	•			•	
Breaux 1995 <sup>d</sup>			•		•
Capella 2003					•
Carter 2009 <sup>c</sup>					•
Collins 2007		•			
Conroy 2011 <sup>b</sup>			•		
Cozacov 2014					
Dabbas-Tyan 2011				•	
Dan 2010 <sup>d</sup>					•
Dashkalakis 2010 <sup>d</sup>					•
De Filippo 2012				•	
De la Cruz-Munoz 2010				•	•
Dillard 2007 <sup>d</sup>			•	•	
Dolan 2004				•	•
Fatima 2006					•
Fielding 2005				•	•
Fowler 2009 <sup>d</sup>					•
Haby 2006 <sup>c</sup>					•
Holterman 2012		•			
Holterman 2007		•			
Holterman 2010		•		•	•
Inge 2007 <sup>d</sup>					•
Inge 2009			•		
Inge 2010			•	•	•
Jarvholm 2012		•			
Kaulfers, 2011 <sup>d</sup>			•		
Kim 2006	•				
Knerr 200 <sup>d</sup>					•
Lawson 2006			•		
Lee 2010	•				
Lennerz 2014	•				
Leon 2007 <sup>d</sup>					•
Leslie 2008 <sup>d</sup>					•
Loux 2008		•		•	
Marceau 2010				•	
Mason 1995					•
Messiah 2013 <sup>d</sup>	•		•		
Muller 2007 <sup>d</sup>					•
Nadler 2008	•				

**Table A5: Overlap Between Included Systematic Reviews**

Primary Study Author, Publication Year	Systematic Review Author, Publication Year				
	Ollendorf, 201554	White, 201552	Göthberg, 201453	Black, 201351	Aikenhead, 201113
Nadler 2009 <sup>d</sup>				•	•
Nadler 2012				•	
Nguyen 2011 <sup>d</sup>			•		
Nocca 2014 <sup>d</sup>	•				
O'Brien 2010				•	
O'Brien 2010	•	•	•	•	•
Olbers 2012		•	•	•	
Pallati 2012 <sup>d</sup>			•		
Papadia 2007 <sup>d</sup>			•		•
Ratcliff 2012		•			
Raziel 2014 <sup>d</sup>	•	•			
Rottembourg 2009 <sup>d</sup>					•
Silberhumer 2006		•			•
Silberhumer 2011 <sup>d</sup>	•	•	•	•	
Silva 2012				•	
Sinha 2013			•		
Stanford 2003					•
Strauss 2001				•	
Strauss 2001					•
Sugerman 2003				•	•
Sysko 2012 <sup>d</sup>		•	•		
Teepie 2012				•	
Till 2008					•
Tsai 2007 <sup>d</sup>			•		
Varela 2007 <sup>d</sup>			•		
Velhote 2010				•	
Velhote and Damiani 2008 <sup>d</sup>					•
Widhalm 2008					•
Yitzhak 2006 <sup>d</sup>			•		•
Zeller 2006					
Zeller 2009		•			
Zeller 2011		•			
Zitsman 2011 <sup>d</sup>			•		

<sup>a</sup>Not reviewed or critically appraised, discussed informally

<sup>b</sup>Case-series or case-report, non-comparative

<sup>c</sup>Cost-effectiveness study

<sup>d</sup>Concerns adolescent versus adult comparisons, not relevant to this report

### Clinical Evidence

None of the SRs provided or mentioned an a priori protocol, so it was unclear whether all study design elements were pre-planned.<sup>13,51-54,57,58</sup> Three SRs<sup>51-53</sup> included duplicate study selection, and two did not report the number of authors involved.<sup>13,54</sup> One study reported duplicate data extraction,<sup>52</sup> one reported extraction by one author and review by another,<sup>51</sup> and three did not report the number of authors involved.<sup>13,53,54</sup> In cases where less than two reviewers were involved, the risk of overlooking relevant studies or errors in data extraction occurring may have been higher. All SRs performed a comprehensive literature search using multiple databases, and searching of reference lists.<sup>13,51-54</sup> One SR also reviewed previous technology assessments and SRs.<sup>54</sup> No SRs reported a comprehensive grey literature search strategy increasing the risk of overlooking studies not indexed in the selected medical databases. There were restrictions made on search and selection based on language, publication date, and publication status. Included studies were published in English,<sup>13,51-54</sup> Swedish,<sup>53</sup> Norwegian,<sup>13,53</sup> Danish,<sup>13,53</sup> and

French.<sup>13</sup> All SRs either excluded unpublished studies or did not explicitly search for them. One SR limited search dates to 2000 onward and did not provide justification.<sup>54</sup> Four SRs included a list of included studies,<sup>51-54</sup> and one did not, but cited all studies in text.<sup>13</sup> One SR included a list of excluded studies and reasons for exclusion.<sup>53</sup> Detailed characteristics of included studies were provided by three SRs.<sup>51,52,54</sup> Some study characteristics presented included study design, withdrawals and dropouts, bariatric surgery type, gender, baseline age and BMI, and duration between intervention and assessment. SRs generally reported poorly on comorbidities or entry criteria to receive surgery. Two SRs formally assessed scientific quality of included studies.<sup>53,54</sup> They used the US Preventive Services Task Force Criteria,<sup>54</sup> and checklists from the Swedish Council on Health Technology Assessment.<sup>53</sup> The other SRs discussed strengths and limitations throughout the discussion, but did not conduct a formal systematic assessment of quality. This may have resulted in oversight or emphasis of specific quality concerns within the reports. All studies discussed scientific quality in the formulation of conclusions. Both SRs that conducted pooling<sup>51,52</sup> reported substantial statistical heterogeneity. Clinical and methodological heterogeneity was also apparent based on differences in procedures, patient populations, and follow-up periods. Differences at baseline and their influence on the effect estimates were not analyzed. Thus, pooling may have been inappropriate and the results should be interpreted with caution. Two SRs reported assessment of publication bias,<sup>51,53</sup> though the methods used in one case were unclear,<sup>53</sup> and results were not explicitly reported in the other (i.e., forest plot not presented).<sup>51</sup> All studies discussed funding sources and/or potential conflicts of interest. Authors of one review disclosed their involvement in one of the primary studies they included.<sup>53</sup> The primary author of the single RCT (O'Brien et al. 2010) reviewed by most SRs made a post-hoc disclosure of conflict of interest due to compensation by a clinical facility that treats obesity using gastric banding and from sales of a book that provides patient information on gastric banding.<sup>66</sup>

### Primary Cost-Effectiveness Evidence

Critical appraisal of the SR that evaluated primary economic studies,<sup>13</sup> is presented alongside the appraisal of other SRs in the previous section.

### *Study Design*

Both evaluations<sup>55,56</sup> stated research question(s) and viewpoints, and their economic importance. One provided sufficient rationale for choosing alternative programmes,<sup>56</sup> but one failed provide sufficient information about the alternative treatment path (it was only noted that

the base cohort included patients who did not receive bariatric surgery).<sup>55</sup> Both studies reported the form of evaluation used, which was justified based on the stated research questions.

### *Data Collection*

The sources of effectiveness estimates were provided in both cases. One study used primary data from a sample of 11 patients, and did not provide sufficient information about the patient characteristics or study design.<sup>55</sup> Synthesis of estimates for the other study were derived from a GRADE-based evidence review.<sup>56</sup> The primary outcome measures (cost/QALY<sup>55</sup> and cost/BMI unit reduction<sup>56</sup>) were provided. The cost-utility analysis presented the methods used to value benefits, but it is unclear whether the EQ-5D is an appropriate tool for assessing the specific patient population, particularly as there is an adolescent version (EQ-5D-Y) available for use. It was unclear whether valuations were obtained from the base population or an alternative source. Neither study accounted for productivity changes, which may have been relevant for the study that assumed the societal perspective.<sup>55</sup> Total costs were not presented separately from quantities, and methods to estimate quantities and costs were not described.<sup>55,56</sup> Both studies recorded currency and price data.<sup>55,56</sup> One study did not adjust for inflation or conduct any currency conversion.<sup>55</sup> The other study calculated costs in 2014 dollars and reported the method of adjusting for inflation (Consumer Price Index).<sup>56</sup> Neither study provided a visual representation of the model, but described model design in text.

### *Analysis and Interpretation of Results*

The time horizon was stated explicitly by one study (ten years),<sup>56</sup> and implied by the follow-up duration (seven years) of the base-study in the other.<sup>55</sup> These time horizons are appropriate for assessing immediate and long-term cost-effectiveness, but do not reflect the lifetime impact of bariatric surgery on adolescent patients. Both studies used a 3% discounting rate. One study did not provide justification for the discount rate,<sup>55</sup> and the other cited the US Panel on Cost-Effectiveness in Health and Medicine guidance. Details of statistical tests and confidence intervals were provided in both cases, and the approach to sensitivity analysis was described. Both studies conducted probabilistic and one-way sensitivity analysis. Justification for the ranges across which variables were varied was not discussed. Both studies reported incremental analyses. One study reported disaggregated results,<sup>55</sup> and the other presented only aggregated cost-effectiveness estimates.<sup>56</sup> Both studies presented answers to the study questions and the conclusions followed the data. Study limitations presented for one study<sup>55</sup> did not clearly explain the potential influence of confounding on the observed outcomes, and the results of sensitivity analyses were underreported by the other study.<sup>56</sup>

### *Reviews of Evidence-Based Guidelines*

None of the reviews of guidelines provided or mentioned an a priori protocol, so it was unclear whether all reporting was pre-planned.<sup>43,58</sup> Both reviews presented specific selection criteria. The number of authors involved in study selection or data extraction was unclear in both cases.<sup>43,58</sup> Both reviews conducted a comprehensive literature search, with truncated search dates; 2007 onward in one case,<sup>58</sup> and 2000 onward in another.<sup>57</sup> Concerns about overlooking older evidence may not apply to reviews of guidelines as guidelines are generally considered out of date once 3 years have passed without an update.<sup>67</sup> Both reviews included a list of included guidelines, but did not provide a list of excluded publications. Study characteristics were presented for both reviews including characteristics such as implementation guidance,<sup>57</sup> limitations of the evidence,<sup>57</sup> grading systems,<sup>57</sup> evidence synthesis methods,<sup>57,58</sup> intervention

and population of interest,<sup>57,58</sup> format, and issuing body,<sup>57</sup> as well as information about guideline authors and stakeholders.<sup>58</sup> Neither review systematically assessed the quality of included guidelines (e.g., using the AGREE II tool), but both discussed limitations throughout the discussion. Publication bias was not assessed and both sets of review authors declared no conflict of interest.

### Evidence-Based Guidelines

#### *Scope and Purpose*

Overall objectives were specifically described by four guidelines,<sup>61-64</sup> and two gave a general description but did not specifically state objectives.<sup>59,60</sup> Four guidelines<sup>59,61,62,64</sup> stated explicit health questions, while two did not.<sup>60,63</sup> All guidelines stated the patient population to whom the guideline is meant to apply.

#### *Stakeholder Involvement*

All guideline development teams included participants from relevant professional groups. No guidelines sought out patients preferences, but three<sup>61,62,64</sup> mentioned that patient preferences should be considered in treatment planning without providing details. The target users were defined by all but one<sup>64</sup> guideline.

#### *Rigor of Development*

All guidelines used systematic methods to search for the evidence, however the exact search strategy was unclear in one case.<sup>63</sup> Three guidelines provided information regarding criteria for selection of evidence,<sup>61,62,64</sup> and three did not.<sup>59,60,63</sup> Five guidelines described the strengths and limitations of the evidence<sup>59,61-64</sup> and one did not.<sup>60</sup> Methods for formulating recommendations were clearly described by all but one guideline.<sup>60</sup> Benefits and risks were considered by all guidelines in establishing recommendations, and all recommendations are clearly supported by the reviewed evidence. Four guidelines mentioned an external review process,<sup>59,61,62,64</sup> and the review process was unclear for two.<sup>60,63</sup> Three guidelines provided a procedure for updating the guideline,<sup>61,62,64</sup> and three did not.<sup>59,60,63</sup>

#### *Clarity of Presentation*

All guidelines provided specific and unambiguous recommendations and different options for the management of the condition or health issue. Key recommendations were easily identifiable.

#### *Applicability*

Three guidelines<sup>59,61,62</sup> provided information about barriers and facilitators to their application and four provided tools to put the recommendations into practice.<sup>59,61-63</sup> Potential resource implications were discussed by one guideline.<sup>62</sup> Two guidelines presented monitoring or auditing criteria.<sup>59,62</sup>

#### *Editorial Independence*

Four guidelines declared that authors had no conflict of interest.<sup>59-62</sup> One guideline stated potential conflicts of interest.<sup>63</sup> It was noted that many authors and stakeholders received

funding from industry sponsors, but it is unclear whether this influenced their recommendations.<sup>63</sup>

## Summary of Findings

A detailed summary of study findings of SRs and economic evaluations, as well as guideline recommendations is presented in APPENDIX 5.

### *What is the comparative clinical effectiveness of bariatric surgery versus alternative surgical procedures or non-surgical treatments for obese patients with a mean age of 18 years or younger?*

The SRs of clinical evidence identified a small number of comparative studies that addressed the research question. The same RCT by O'Brien et al., and several prospective and retrospective cohort studies were reported on by multiple SRs, but different reports addressed different outcome measures.

#### *Weight Loss*

Compared to conventional lifestyle interventions (diet and exercise), LAGB showed significantly greater weight loss versus non-surgical interventions (diet and exercise) at 2 years in a single RCT presented in one SR.<sup>54,68</sup> One SR<sup>53</sup> reported that based on the results of one RCT and three cohort studies, significant weight reduction at one and two years of follow-up occurred after surgery versus non-surgical interventions. No evidence was identified regarding long-term weight loss.

One SR,<sup>51</sup> of non-comparative studies assessing weight loss after bariatric surgery reported that the intervention led to significant weight loss at one year. This SR also reported subgroup analyses by surgery type. The results suggested that the reduction in BMI was largest in the RYBG group, followed by SG and then AGB. These results are indirect comparisons and should be interpreted with caution. Two retrospective non-randomized studies reported greater weight-loss after RYGB versus LAGB and VSG in the short-term.<sup>54,69</sup>

#### *Resolution of Comorbidities*

Patients who underwent LAGB also showed significantly greater rates of resolution of metabolic syndrome compared to the non-surgical intervention (diet and exercise).<sup>54</sup> One RCT<sup>68</sup> reviewed by one SR<sup>53</sup> reported that there were no significant differences in blood pressure and lipid profile between patients who received LAGB versus non-surgical intervention.<sup>53</sup> One SR<sup>53</sup> reported that based on a single RCT<sup>68</sup> significant improvements in insulin sensitivity were observed two years after LAGB versus non-surgical treatment.<sup>68</sup> A single cohort study reviewed by this SR observed reductions in fasting insulin, glucose, and glycated hemoglobin in the surgery group, but not the non-surgical control group; between group comparisons were not reported.<sup>53</sup>

Patients who underwent RYGB versus LAGB in one retrospective study showed greater rates of resolution of hyperlipidemia.<sup>54</sup>

#### *Complications*

One SR<sup>53</sup> reported that the single RCT observed no difference in adverse events between gastric banding and non-surgical treatment. Other non-comparative case series have reported incidents of bleeding, infection, depression, gallstone formation with cholecystectomies, internal hernia, ileus, micronutrient deficiencies, and excessive skin, but it is unclear what the population frequency and overall impact of these complications is.<sup>53</sup> No studies were identified to address long-term morbidity in patients.

### *Mortality*

In one retrospective cohort study reviewed by one SR,<sup>54</sup> a single death in the RYGB group occurred in follow-up due to cardiac failure,<sup>69</sup> while none were reported in the LAGB group. The SR authors did not discuss whether this death was treatment-related.<sup>54</sup> Based on nine non-comparative case-series, one post-operative death occurred 30 days after open surgery, and nine deaths occurred six months to four years after surgery for a variety of reasons (malnutrition, heart failure, infection, necrotizing pancreatitis, drug overdose).

### *Quality of Life*

Based on a single RCT, one SR<sup>52</sup> reported that at two years follow-up, based on the Child Health Questionnaire, individual domains of physical functioning and change in health scores significantly improved in the LAGB surgery group versus lifestyle intervention.<sup>68</sup> However, despite significant within group improvements demonstrated for family activities, general health, physical functioning, self-esteem and change in health in the LAGB group, and for general health in the lifestyle group, no between group differences between the surgical and lifestyle groups were observed for self-esteem, mental health, family activities, family cohesion, general behavior, or general health scores.<sup>52</sup> A single study comparing SG to no surgery in intra-familial non-weight-matched controls reported improvements in Pediatric Quality of Life Inventory domains at one year in the surgery group.<sup>52</sup>

### *Self-Esteem*

A single study comparing SG to no surgery in intra-familial non-weight matched controls reported significantly increased mean Rosenberg Self-Esteem Scale scores at one year in the surgery group.<sup>52</sup>

### *What is the cost-effectiveness of bariatric surgery for obese patients with a mean age of 18 years or younger?*

One SR<sup>13</sup> of economic evidence identified a single Australian cost-utility analyses. It reported that compared to alternative obesity treatment and prevention (non-surgical), LAGB was cost-effective (\$44 000 AU/disability adjusted life year).

One primary cost-utility analysis from the US healthcare system perspective<sup>55</sup> reported that up to 3 years post-surgery the cost of bariatric surgery versus non-surgical intervention was greater than \$100 000 USD/QALY, but that from year 4 onward to year 7 the ICER was below the threshold. As such, it was noted that the probability of cost-effectiveness is 75% over four years at the willingness to pay threshold of \$100 000 USD/QALY, and increased afterwards. When the assumed benefit of weight loss was lowered, intervention costs were increased, and medical costs savings were reduced in sensitivity analysis, the likelihood of cost-effectiveness was

reduced. Overall, they concluded that bariatric surgery was not cost-effective within the first three years after treatment, but became cost-effective from that point forward.

A primary cost-effectiveness analysis from the US modified societal perspective that compared increased access to bariatric surgery versus alternative obesity interventions and primary prevention strategies reported that surgery was substantially more expensive (\$1611 USD per reduction in BMI unit) compared to primary prevention strategies (\$0.66 to \$613 USD per reduction in BMI unit), and had the smallest reach of the interventions assessed. They concluded that primary prevention would be more cost-effective to implement and policy changes should focus on those areas.<sup>56</sup>

*What are the evidence-based guidelines regarding bariatric surgeries for obese patients with a mean age of 18 years or younger?*

Individual guideline recommendations and corresponding scores describing the quality of evidence and/or strength of recommendation where available are presented in APPENDIX 5.

*Eligibility Criteria*

Most identified guidelines put forth recommendations regarding age and physical maturity requirements. The majority recommended that patients be close to or at physical maturity prior to the procedure.<sup>28,57,58,60,62,64</sup> While there was not consensus on what constitutes physical maturity, some criteria included age cut-offs (ranging from age 11 to 15, varying by gender), Tanner stages 3 to 5, and near or at adult height and/or skeletal maturity.<sup>57,58</sup> One guideline<sup>59</sup> recommended that pediatric primary care physicians should not routinely refer for bariatric surgery.

Recommendations regarding pre-surgical weight were also inconsistent. Body mass index cutoff suggestions ranged from  $>35$  to  $>50$  kg/m<sup>2</sup> with or without comorbidities.<sup>28,57,58,60,62,64</sup> One guideline suggested being in the 99.5 percentile or greater for sex and age, based on pediatric growth charts.<sup>60</sup> Common obesity-related comorbidities that may qualify in this context included type II diabetes, sleep apnea, non-alcoholic fatty liver disease, dyslipidemia, poor quality of life, and hypertension. Several guidelines<sup>57,60,62</sup> state that the patient must have had a previous long-term (usually six month) attempt at weight loss using non-surgical interventions that has failed.

*Exclusion Criteria*

Based on the included guidelines, there are several circumstances under which bariatric surgery is contraindicated in adolescents. This includes: unstable psychiatric or psychological conditions, unstable eating disorders, pregnancy or intent to conceive, untreated endocrinopathies, inability to access long-term post-surgical support, metastatic cancer, life-threatening multi-organ failure, uncontrolled human immunodeficiency virus, active systemic infection, and medically correctable causes of obesity.<sup>57,60,62</sup> Prader-Willi syndrome is considered a contraindication by some guidelines, but others suggest that these patients may be eligible if their cases are reviewed by a team of medical, pediatric and surgical experts.<sup>60</sup>

*Preferred Surgical Procedure*

There was a lack of consensus regarding the preferred surgical procedure. In adults, RYGB is considered the gold standard, and some guidelines speculated that this procedure may be

preferable.<sup>58</sup> This is in line with some of the clinical evidence reviewed, which suggests greater weight loss with RYBG. One guideline suggested that there was insufficient data for all procedures with the exception of LAGB,<sup>62</sup> and another<sup>57</sup> discussed superiority of LAGB in the context of weight loss benefits, low complication rate, and potential reversibility, but other sources noted that LAGB is not yet approved for use in some regions.<sup>58,61</sup> Sleeve gastrectomy was considered by multiple sources to have insufficient data,<sup>58,61</sup> and only use in a research setting was suggested. The overall consensus of the guidelines was that there is insufficient evidence at this time to support the use of one bariatric procedure over others.

### *Pre-Operative Assessment*

There was general agreement among guidelines that an extensive pre-operative assessment be conducted. Clinical assessment of general medical health,<sup>26,60</sup> psychiatric health,<sup>58,60</sup> metabolic health,<sup>58</sup> nutritional status (including vitamin and mineral status),<sup>58</sup> eating disorders,<sup>64</sup> and genetic conditions associated with treatable obesity<sup>64</sup> were recommended. The guidelines recommended that the patient and family or caregiver be evaluated for knowledge and attitudes, and their willingness to adhere to medical guidance and post-operative care.<sup>58,60</sup> Patients and families should receive a debrief about the various procedures including relative risks and benefit.<sup>57,64</sup> The patient should also be assessed for willingness to adhere to adjunct lifestyle changes.<sup>58</sup> Patients should also receive pregnancy counseling, due to increased fertility post-surgery and risk of complications.<sup>58</sup> All patients should be able to provide consent during this period.<sup>57,58</sup>

### *Surgical Setting*

Some guidelines recommended that the surgical setting be a specialty centre with high volume and experience<sup>57,58</sup> and physical adaptations such as lifts, pressure-relieving mattresses, surgical tables, and access to emergency care that can accommodate the needs of adolescent bariatric surgery candidates.<sup>57,58</sup> Facilities should have the ability to monitor long-term follow-up and maintain databases of patient information.<sup>57,58</sup>

### *Care Team*

There was general agreement among guidelines that care should be administered by a multidisciplinary team.<sup>57,58,62,64</sup> This could include the bariatric surgeon, pediatric specialist, primary care physician, clinic coordinator, mental health specialist, and registered dietitian. Some guidelines recommended that the whole team be experienced with pediatric bariatric surgery, and that practitioners have specialty training and credentials.<sup>57</sup>

### *Post-Operative Care*

Extensive post-operative care was recommended by multiple guidelines.<sup>57,58,64</sup> Components of post-operative care might include specialty dietetic consultation and nutritional assessment,<sup>57,58,64</sup> psychological evaluation,<sup>57,58,64</sup> consultation about contraception and plastic surgery,<sup>58,64</sup> management of comorbidities and medication review,<sup>58,64</sup> and behavioral care.<sup>57</sup> One review of guidelines reported that post-operative surveillance be lifelong and at 4 to 6 week intervals.<sup>57</sup>

## **Limitations**

### *Generalizability*

There are some concerns with generalizability regarding the type of surgery, patient population, and context of care. As this review focused on GB, AGB, and SG, other types of surgery such as biliopancreatic diversion with duodenal switch, intragastric balloon, and vagal blocking therapy were not evaluated. Data from the types of surgery reviewed may not be applicable to these procedures. The majority of data focused on post-pubertal children. There are concerns regarding operating before a child has reached physical maturity. Effectiveness of bariatric surgery procedures in older children is not transferrable to younger children. Patients who underwent surgery were primarily morbidly obese or severely morbidly obese. There is interest in providing surgery to patients with lower BMI who meet other criteria, but caution should be taken as the findings of this review may not apply to these patients. The majority of care is provided in a research context, assuming high quality multidisciplinary care. In contexts where all aspects of care are not possible to provide, effectiveness of the procedures cannot be assumed. Lastly, the timeframe in which surgery was delivered may influence the effectiveness of the intervention. Several SRs noted wide timeframes for included studies. Procedures may have evolved and likely have improved over time, so findings from earlier studies may underestimate benefit.

### *Equity of Access*

The Canadian Institute for Health Information has reported that access to bariatric surgery varies across jurisdictions in Canada.<sup>7</sup> Varying wait times, limited numbers of trained surgeons, lack of funding, lack of hospital space, and lack of prioritization may limit access and lead to seeking surgery elsewhere, often paying out of pocket.<sup>7</sup> While guidelines reviewed in this report suggest that bariatric surgery may be indicated in specific circumstances, they stipulate that certain facility, staff, and family support components need to be in place. As this is not always possible, children across Canada may face unique barriers depending on their place of residence and the local circumstances. While they might meet the clinical criteria set by current guidelines, children may be excluded from receiving treatment on the basis of the aforementioned issues.

### *Differences in Eligibility Criteria and Measurement of Obesity in Youth*

Measuring obesity in children and adolescents is complicated by the availability of multiple classification systems, namely the traditional adult cut-offs, which may not account for variations in growth rate and represent the true association between childhood adiposity and chronic disease risk; the International Obesity Task Force has age/sex-specific classification cut-offs which may underestimate obesity<sup>70</sup> and can only be used at the population level; and the World Health Organization 2007 age/sex-specific cut-offs for children and adolescents aged 5 to 19, which are the current standard most commonly in use. Studies did not always report the eligibility criteria for surgery and which tool they used to assess patients for obesity. Thus, the patient population undergoing surgery may have been different from study to study limiting generalizability to the broader patient population.

## **CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING**

Fifteen publications — five SRs of clinical or both clinical and economic evidence, two economic evaluations, two reviews of guidelines, and six primary evidence-based guidelines — were

identified regarding the clinical and cost-effectiveness, and guidelines for use of bariatric surgery in adolescent and young adult patients requiring treatment for obesity.

Overall, the comparative clinical evidence identified by the systematic reviews was limited to a few studies that were narrow in scope and with relatively small sample sizes. The majority of evidence regarding bariatric surgery in adolescent patients is from observational case series. Current evidence suggests that there is significantly greater weight loss and clinical and quality of life benefits with surgery versus lifestyle interventions; however long-term complications and effectiveness remain unclear. Regarding cost-effectiveness, despite lacking empirical evidence to support predictive modeling, one primary cost-utility analysis suggested potential cost-savings over the long-term for patients who receive bariatric surgery; however, impact on a population level was perceived to be negligible compared to primary prevention strategies. Evidence-based guideline recommendations emphasize the importance of having set eligibility criteria as well as the availability of staff, facilities, programs, and family support systems that can cater to the requirement for lifetime surveillance, pre- and post-surgical care, and management of complications and comorbidities. The general consensus across guidelines was that while caution should be taken and strict criteria be met; there are likely certain circumstances under which specific patients who are able to access appropriate care may be candidates for bariatric surgery.

Research is needed to establish comparative effectiveness and harms of bariatric surgery versus alternative weight-loss methods, which may also help to inform future economic evaluations. Current ongoing studies and recently completed primary studies (see APPENDIX 6) may resolve some of the uncertainty, allowing future guidelines to establish stronger and specific recommendations. In conclusion, very limited evidence suggests that bariatric surgery is effective and cost-effective for weight loss in adolescents and young adults, but there is substantial uncertainty due to the limited scope and quantity of evidence, as well as substantial risk of bias. Current guidelines reflect this uncertainty in the strength of their recommendations, but also convey current clinical consensus that under the right circumstances and in the appropriate context, some patients may be eligible and may benefit greatly from bariatric surgery procedures.

**PREPARED BY:**

Canadian Agency for Drugs and Technologies in Health

Tel: 1-866-898-8439

[www.cadth.ca](http://www.cadth.ca)

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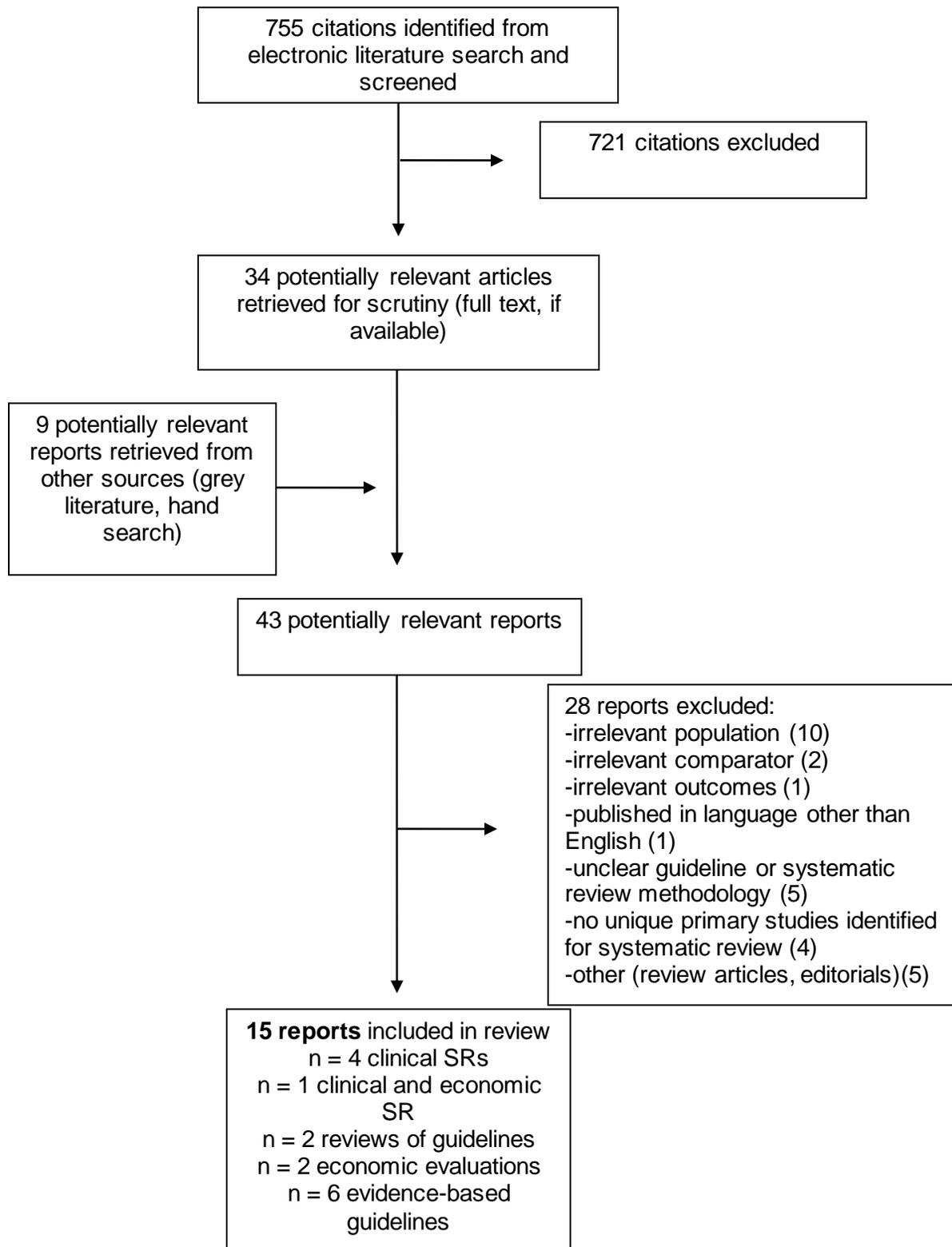
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APPENDIX 1: Selection of Included Studies



APPENDIX 2: Characteristics of Included Publications

Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses						
First Author, Publication Year, Country	Types and numbers of primary studies included; Search Timeframe	Population Characteristics; Criteria to Receive Bariatric Surgery	Intervention	Comparator(s)	Meta-Analysis (Y/N); Subgroup Analysis or Meta-regression (Y/N)	Clinical Outcomes, Length of Follow-Up
<i>Clinical</i>						
Ollendorf, 2015, US <sup>54</sup>	N = 275 studies (n = 3 comparative studies on adolescents)  2000 to current (date not specified)	Children (aged <21); Subgroups = 18 to 20 years, 13 to 17 years, and 12 or younger, mean BMI 41.4 to 51.4 kg/m <sup>2</sup>	LAGB, RYGB, VSG	Alternative surgical procedure or lifestyle intervention	No	Weight loss, resolution of comorbidities, morality,  Follow-up = Perioperative (within 30 days) to long-term
White, 2015, UK <sup>52</sup>	N = 15 studies (n = 10 cohorts, n = 3 comparative studies);  Inception to July 2014	Adolescents or young adults <21 years of age undergoing bariatric surgery (range = 9 to 20 years), mean BMI 42.3 to 63.5 kg/m <sup>2</sup>	Any type of bariatric surgery (RYGB, AGB, SG)	Non-surgical treatment;  Alternative bariatric surgery procedure;  No treatment (intra-family controls)	Yes (n = 4 for QOL, n = 2 for depressive symptoms)	Psychological and social outcomes (e.g., quality of life, depression);  Follow-up = 1 month to at least 5 years (some studies did not report follow-up times)
Göthberg, 2014, Sweden <sup>53</sup>	N = 4 studies (RCT and cohort), N = 17 case series;  Inception to March 2013	Children and adolescents 13 to 18 years of age with severe obesity (defined as BMI or Iso-BMI >35 kg/m <sup>2</sup> )	Bariatric surgery (majority on LAGB)	Non-surgical obesity treatment (diet and lifestyle changes, pharmacological treatment)	No	<i>Primary</i> <ul style="list-style-type: none"> <li>• Mortality (30 day and long term)</li> <li>• Suicide</li> <li>• Socialisation</li> <li>• QOL</li> <li>• Long-term morbidity (including bone mineralization, drug abuse, anaemia, and malnutrition)</li> </ul> <i>Secondary</i> <ul style="list-style-type: none"> <li>• Short term complications</li> <li>• Weight/BMI changes</li> <li>• Glucose</li> </ul>

**Table A1: Characteristics of Included Systematic Reviews and Meta-Analyses**

First Author, Publication Year, Country	Types and numbers of primary studies included; Search Timeframe	Population Characteristics; Criteria to Receive Bariatric Surgery	Intervention	Comparator(s)	Meta-Analysis (Y/N); Subgroup Analysis or Meta-regression (Y/N)	Clinical Outcomes, Length of Follow-Up
						metabolism/homeostasis <i>Tertiary</i> <ul style="list-style-type: none"> <li>Inflammatory markers</li> <li>Cardiovascular risk factors;</li> </ul> Follow-up = 6 months to 10 years
Black, 2013, UK <sup>51</sup>	N = 23 studies (n = 637 patients);  Inception to January 2013	Patients (mean age between 6 and 18 years) undergoing bariatric surgery (range 5 to 23 years), mean BMI 38.5 to 60.2 kg/m <sup>2</sup>	AGB, RYGB, BPD, SG;	Alternative surgical procedures	Yes (n = 11 for AGB; n = 3 for SG, n = 7 for RYGB, n = 2 for other);  Subgroup analysis (type of surgery)	BMI reduction;  Follow-up = minimum 6 months
<i>Clinical and Economic</i>						
Aikenhead, 2011, UK <sup>13</sup>	N = 37 clinical studies (n = 831 children), N = 1 economic study (Australian perspective);  Inception to September 2010	Patients ≤ 19 years of age, mean BMI 37.7 to 67 kg/m <sup>2</sup>	GB, RYGB, SG, VSG, BPD, or a combination of procedures	Alternative forms of treatment and prevention of obesity in childhood (non-surgical)	No	Harms, resolution or improvement of comorbid conditions, BMI reduction, cost-effectiveness;  Follow-up = minimum 1 year

AGB = adjustable gastric band; BMI = body mass index; BPD = biliopancreatic diversion with duodenal switch; GB = gastric banding; LAGB = laparoscopic adjustable gastric banding; QOL = quality of life; RYGB = roux-en-y gastric bypass; SG = sleeve gastrectomy; UK = United Kingdom; US = United States; VSG = vertical sleeve gastrectomy

**Table A2: Characteristics of Included Reviews of Guidelines**

First Author, Publication Year, Country	Number of primary guidelines included; Search Timeframe	Intended Users: Target Population	Intervention and Practice Considered	Major Outcomes Considered	Quality Assessment
Breij, 2014, US <sup>58</sup>	N = 7 Guidelines (only US and Canada) 2007 to April 2013 PubMed, Embase, and CINAHL	Medical practitioners providing care obese patients; Obese children and adolescents	Weight loss surgery or general obesity guidelines with specific recommendations regarding surgery	Age/physical maturity, BMI and comorbidity criteria, exclusion criteria, preferred surgical procedure, perioperative management, surgical setting/care team, postoperative recommendations	No formal quality assessment, limitations and guideline design discussed
Aikenhead, 2011, UK <sup>57</sup>	N = 15 guidelines; PubMed Inception to September 2010, clinical experts, systematic review references, focused internet search	Medical practitioners providing care obese patients; Obese children and adolescents	Interventions for pediatric obesity including bariatric surgery	Appropriateness criteria, selection criteria, exclusion criteria/major contraindications, surgical expertise, surgical facility/institution, preoperative assessment postoperative education, surgery type, postoperative management	No formal quality assessment, limitations discussed

AGB = adjustable gastric band; BMI = body mass index; UK = United Kingdom; US = United States

**Table A3: Characteristics of Included Cost Studies**

First author, Publication Year, Country	Type of Analysis, Perspective	Intervention, Comparator	Study Population	Time Horizon	Main Assumptions
Bairdain, 2015, US <sup>55</sup>	Cost utility analysis (Markov cohort model), cost/QALY; US Health care system perspective	Bariatric surgery (Roux-en-Y gastric bypass +/- concomitant hiatal hernia repair);  No surgery	Adolescent patients with obesity (n = 11) who attended a bariatric surgery multidisciplinary program over January 2010 to December 2013 who had at least 12 months follow-up at a single institution with no perioperative or postoperative complications	Pre-operative period to 12 months post-operative; Seven years	<ul style="list-style-type: none"> <li>Reduced BMI after surgery, 5% weight gain per year in the first five years, plateauing at 25%</li> <li>Assumed BMI remained unchanged in no surgery cohort (BMI = 48.7)</li> <li>Reduced medical care use associated</li> </ul>

**Table A3: Characteristics of Included Cost Studies**

First author, Publication Year, Country	Type of Analysis, Perspective	Intervention, Comparator	Study Population	Time Horizon	Main Assumptions
					with lower BMI determined using Medical Expenditures Panel Survey data <ul style="list-style-type: none"> <li>• 3% discount rate</li> </ul>
Gortmaker, 2015, US <sup>56</sup>	Cost-effectiveness analysis (Microsimulation using Monte Carlo simulations), cost/unit of BMI reduced assessing population-level impact of seven different interventions to address childhood obesity (including bariatric surgery) – Cost/BMI unit change; Modified <sup>b</sup> societal perspective	Increased access (4 fold nationwide) to adolescent bariatric surgery <sup>a</sup>	US youth population	Ten years (2015 to 2025)	<ul style="list-style-type: none"> <li>• Assumed that interventions took time (18 to 36 months) to decrease the BMI of individuals who received the intervention</li> <li>• Assumed that surgical change persisted over the 10 year time period</li> </ul>

BMI = body mass index; QALY = quality adjusted life year; US = United States

<sup>a</sup>Six other primary prevention or treatment strategies to address childhood obesity at the population level were also assessed

<sup>b</sup>Did not include several economic impacts such as productivity losses, transportation or value of time spent seeking or receiving medical care

**Table A4: Characteristics of Included Guidelines**

Objectives			Methodology			
Intended Users; Target Population	Intervention and Practice Considered	Major Outcomes Considered	Evidence Collection, Selection and Synthesis	Evidence Quality and Strength	Recommendation Development and Evaluation	Guideline Validation
Canadian Task Force on Preventive Health Care, 2015 <sup>59</sup>						
Primary care practitioners; Adolescents aged 2 to 17 years	Growth monitoring, prevention of overweight and obesity, overweight and obesity management (including bariatric surgery)	Referral for bariatric surgery	Systematic review	GRADE used to establish quality of evidence and strength of recommendations	Recommendations revised and approved by entire task force (panel of clinicians and methodologists)	External review by experts and stakeholders
Fried, 2014, International Federation for the Surgery of Obesity and Metabolic Disorders – European Chapter <sup>60</sup>						
Physicians, health care practitioners, health care policy	Treatment of obesity (including bariatric surgery)	Appropriateness criteria	Systematic Review	Oxford Centre for evidence-Based Medicine classification system	Best available evidence including expert opinion	NR

**Table A4: Characteristics of Included Guidelines**

Objectives			Methodology			
Intended Users; Target Population	Intervention and Practice Considered	Major Outcomes Considered	Evidence Collection, Selection and Synthesis	Evidence Quality and Strength	Recommendation Development and Evaluation	Guideline Validation
makers, health care providers, insurance companies;  Adult and pediatric populations						
National Institute of Clinical and Health Excellence, 2014 <sup>69</sup> (Update of 2006 Guideline)						
Clinicians providing care for obese patients;  Adult and pediatric populations	Treatment of obesity (including bariatric surgery)	Appropriateness criteria, pre-assessment	Systematic review	GRADE	Drafted by guideline development group on the basis of interpretation of available evidence, balance of benefits, harms and costs.	4-week public consultation and feedback
Institute for Clinical Systems Improvement, US, 2013 <sup>61</sup>						
Health professional and other experts providing care for obese children and adolescents;  Obese patients < 18 years of age	Preventive and interventional treatments for obesity	Use of bariatric surgery	Systematic review	GRADE	Consideration of the evidence as well as systems of care, resource variation, balance between benefits and harms, patient and community values, autonomy of clinicians – recommendations developed using consensus process	Group members and sponsors review guideline, final approval by ICSI's committee on evidence-based practice
National Health and Medical Research Council, Australia, 2013 <sup>62,63</sup>						
Primary and secondary care, Policy makers, individuals, families, and carers;  Adults and children with obesity	Interventions for the management of obesity	Appropriateness criteria; support requirements	Systematic review of evidence from 2007 onward	NHMRC additional levels of evidence and grades for recommendation for developers of guidelines	Developed by Obesity Guidelines Development Committee based on evidence presented	Revised following stakeholder, expert, and consumer input, public consultation
National Heart, Lung, and Blood Institute, 2012 <sup>65</sup>						
Primary pediatric care providers;  Children and Adolescents	Management strategies and interventions for cardiovascular health and risk reduction in children and adolescents (including bariatric surgery)	Appropriateness criteria	Systematic review of evidence from 1985 onward	Evidence given a quality grade, and strength of recommendation as per the American Academy of Pediatrics, Steering Committee on Quality Improvement and Management	Recommendations made based on the consensus of the Expert Panel upon review of the literature	NR

GRADE = Grading of Recommendations Assessment, Development and Evaluation; ICSI = Institute for Clinical Systems Improvement; NHMRC = National Health and Medicine Research Council; NR = not reported

APPENDIX 3 Overlap Between Included Systematic Reviews

Primary Study Author, Publication Year	Systematic Review Author, Publication Year				
	Ollendorf, 2015 <sup>54</sup>	White, 2015 <sup>52</sup>	Göthberg, 2014 <sup>53</sup>	Black, 2013 <sup>51</sup>	Aikenhead, 2011 <sup>13</sup>
Abu-Abeid 2003					•
Aikenhead 2012 <sup>a</sup>			•		
Aldaqa 2013		•			
Al-Qahtani 2007					•
Alqathani 2012 <sup>d</sup>			•	•	
Ananthapavan 2010 <sup>c</sup>					•
Anderson 1980 <sup>d</sup>			•		
Angrisani 2005				•	•
Aslam 2010 <sup>d</sup>					•
Barnett 2005					•
Boza 2012 <sup>d</sup>	•			•	
Breaux 1995 <sup>b</sup>			•		•
Capella 2003					•
Carter 2009 <sup>c</sup>					•
Collins 2007		•			
Conroy 2011 <sup>b</sup>			•		
Cozacov 2014					
Dabbas-Tyan 2011				•	
Dan 2010 <sup>d</sup>					•
Dashkalakis 2010 <sup>d</sup>					•
De Filippo 2012				•	
De la Cruz-Munoz 2010				•	•
Dillard 2007 <sup>b</sup>			•	•	
Dolan 2004				•	•
Fatima 2006					•
Fielding 2005				•	•
Fowler 2009 <sup>d</sup>					•
Haby 2006 <sup>c</sup>					•
Holterman 2012		•			
Holterman 2007		•			
Holterman 2010		•		•	•
Inge 2007 <sup>d</sup>					•
Inge 2009			•		
Inge 2010			•	•	•
Jarvholm 2012		•			
Kaulfers, 2011 <sup>d</sup>			•		
Kim 2006	•				
Knerr 2003 <sup>d</sup>					•
Lawson 2006			•		
Lee 2010	•				
Lennerz 2014	•				
Leon 2007 <sup>d</sup>					•
Leslie 2008 <sup>d</sup>					•
Loux 2008		•		•	
Marceau 2010				•	
Mason 1995					•
Messiah 2013 <sup>d</sup>	•		•		
Muller 2007 <sup>d</sup>					•
Nadler 2008	•				
Nadler 2009 <sup>d</sup>				•	•
Nadler 2012				•	

**Table A5: Overlap Between Included Systematic Reviews**

Primary Study Author, Publication Year	Systematic Review Author, Publication Year				
	Ollendorf, 2015 <sup>54</sup>	White, 2015 <sup>52</sup>	Göthberg, 2014 <sup>53</sup>	Black, 2013 <sup>51</sup>	Aikenhead, 2011 <sup>13</sup>
Nguyen 2011 <sup>o</sup>			•		
Nocca 2014 <sup>o</sup>	•				
O'Brien 2010				•	
O'Brien 2010	•	•	•	•	•
Olbers 2012		•	•	•	
Pallati 2012 <sup>o</sup>			•		
Papadia 2007 <sup>o</sup>			•		•
Ratcliff 2012		•			
Raziel 2014 <sup>o</sup>	•	•			
Rottembourg 2009 <sup>o</sup>					•
Silbehumer 2006		•			•
Silberhumer 2011 <sup>o</sup>	•	•	•	•	
Silva 2012				•	
Sinha 2013			•		
Stanford 2003					•
Strauss 2001				•	
Strauss 2001					•
Sugerman 2003				•	•
Sysko 2012 <sup>o</sup>		•	•		
Teeple 2012				•	
Till 2008					•
Tsai 2007 <sup>o</sup>			•		
Varela 2007 <sup>o</sup>			•		
Velhote 2010				•	
Velhote and Damiani 2008 <sup>o</sup>					•
Widhalm 2008					•
Yitzhak 2006 <sup>o</sup>			•		•
Zeller 2006					
Zeller 2009		•			
Zeller 2011		•			
Zitsman 2011 <sup>o</sup>			•		

<sup>a</sup>Not reviewed or critically appraised, discussed informally

<sup>b</sup>Case-series or case-report, non-comparative

<sup>c</sup>Cost-effectiveness study

<sup>d</sup>Concerns adolescent versus adult comparisons, not relevant to this report

APPENDIX 4: Critical Appraisal of Included Publications

**Table A6: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR<sup>22</sup>**

AMSTAR Item	Clinical				Clinical and Economic	Reviews of Guidelines	
	Ollendorf, 2015 <sup>54</sup>	White, 2015 <sup>52</sup>	Göthberg, 2014 <sup>53</sup>	Black, 2013 <sup>51</sup>	Aikenhead, 2011 <sup>13</sup>	Brei, 2014 <sup>58</sup>	Aikenhead, 2011 <sup>57</sup>
Was a priori design provided?	X	X	X	X	X	X	X
Was there duplicate study selection and data extraction?	Selection	?	•	•	•	?	?
	Extraction	?	•	?	X	?	?
Was a comprehensive literature search performed?	•	•	•	•	•	•	•
Was the status of publication used as an inclusion criterion?	•	•	•	•	•	•	•
Was a list of studies (included and excluded) provided?	Included	•	•	•	X	•	•
	Excluded	X	X	•	X	X	X
Were the characteristics of the included studies provided?	•	•	X	•	X	•	•
Was the scientific quality of the included studies assessed and documented?	•	X	•	X	X	X	X
Was the scientific quality of the included studies used appropriately in formulating conclusions?	•	•	•	•	•	•	•
Were the methods used to combine the findings of studies appropriate?	N/A	X	N/A	X	N/A	N/A	N/A
Was the likelihood of publication bias assessed?	X	X	•	•	X	X	X
Was the conflict of interest included?	•	•	•	•	•	•	•

N/A = not applicable;  
 • = yes; X = no, ? = unclear

**Table 7: Strengths and Limitations of Economic Studies using Drummond<sup>23</sup>**

Checklist Item	Bairdain, 2015 <sup>55</sup>	Gortmaker, 2015 <sup>56</sup>
<b>Study Design</b>		
The research question is stated	•	•
The economic importance of the research question is stated	•	•
The viewpoint(s) of the analysis are clearly stated and justified	•	•
The rationale for choosing alternative programmes or interventions compared is stated	X	•
The alternatives being compared are clearly described	X	•
The form of economic evaluation used is stated	•	•
The choice of form of economic evaluation is justified in relation to the questions addressed	•	•
<b>Data Collection</b>		
The source(s) of effectiveness estimates used are stated	•	•
Details of the design and results of effectiveness study are given (if based on a single study)	X	N/A
Details of the methods of synthesis or meta-analysis of estimates are given (if based on a synthesis of a number of effectiveness studies)	N/A	•
The primary outcome measure(s) for the economic evaluation are clearly stated	•	•
Methods to value benefits are stated	•	N/A
Details of the subjects from whom valuations were obtained were given	X	N/A
Productivity changes (if included) are reported separately	N/A	N/A
The relevance of productivity changes to the study question is discussed	X	X
Quantities of resource use are reported separately from their unit costs	X	X
Methods for the estimation of quantities and unit costs are described	X	X
Currency and price data are recorded	•	•
Details of currency of price adjustments for inflation or currency conversion are given	X	•
Details of any model used are given	X	X
The choice of model used and the key parameters on which it is based are justified	X	X
<b>Analysis and Interpretation of Results</b>		
Time horizon of costs and benefits is stated	X	•
The discount rate(s) is stated	•	•
The choice of discount rate(s) is justified	X	•
An explanation is given if costs and benefits are not discounted	N/A	N/A
Details of statistical tests and confidence intervals are given for stochastic data	•	•
The approach to sensitivity analysis is given	•	•
The choice of variables for sensitivity analysis is justified	•	•
The ranges over which the variables are varied are justified	?	?
Relevant alternatives are compared	•	•
Incremental analysis is reported	•	•
Major outcomes are presented in a disaggregated as well as aggregated form	•	X
The answer to the study question is given	•	•
Conclusions follow from the data reported	•	•
Conclusions are accompanied by the appropriate caveats	X	X

N/A = not applicable;  
 • = yes; X = no, ? = unclear

**Table A8: Strengths and Limitations of Guidelines using AGREE II<sup>24</sup>**

Item	Author					
	CTPH, 2015 <sup>59</sup>	Fried, 2014, <sup>60a</sup>	NICE, 2014 <sup>64</sup>	ICSI, 2013 <sup>61</sup>	NHMRC, 2013 <sup>62</sup>	NHLBI, 2012 <sup>63</sup>
<b>Domain 1: Scope and Purpose</b>						
1. The overall objective(s) of the guideline is (are) specifically described.	X	X	•	•	•	•
2. The health question(s) covered by the guideline is (are) specifically described.	•	X	•	•	•	X
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described	•	•	•	•	•	•
<b>Domain 2: Stakeholder Involvement</b>						
4. The guideline development group includes individuals from all relevant professional groups.	•	•	•	•	•	•
5. The views and preferences of the target population (patients, public, etc.) have been sought.	X	X	X	X	X	X
6. The target users of the guideline are clearly defined.	•	•	X	•	•	•
<b>Domain 3: Rigour of Development</b>						
7. Systematic methods were used to search for evidence.	•	•	•	•	•	•
8. The criteria for selecting the evidence are clearly described.	X	X	•	•	•	X
9. The strengths and limitations of the body of evidence are clearly described.	•	X	•	•	•	•
10. The methods for formulating the recommendations are clearly described.	•	X	•	•	•	•
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	•	•	•	•	•	•
12. There is an explicit link between the recommendations and the supporting evidence.	•	•	•	•	•	•
13. The guideline has been externally reviewed by experts prior to its publication.	•	X	•	•	•	X
14. A procedure for updating the guideline is provided.	X	X	•	•	•	X
<b>Domain 4: Clarity of Presentation</b>						
15. The recommendations are specific and unambiguous	•	•	•	•	•	•
16. The different options for management of the condition or health issue are clearly presented.	•	•	•	•	•	•
17. Key recommendations are easily identifiable.	•	•	•	•	•	•
<b>Domain 5: Applicability</b>						
18. The guideline describes facilitators and barriers to its	•	X	X	•	•	X

**Table A8: Strengths and Limitations of Guidelines using AGREE II<sup>24</sup>**

Item	Author					
	CTPH, 2015 <sup>59</sup>	Fried, 2014, <sup>60a</sup>	NICE, 2014 <sup>64</sup>	ICSI, 2013 <sup>61</sup>	NHMRC, 2013 <sup>62</sup>	NHLBI, 2012 <sup>63</sup>
application.						
19. The guideline provides advice and/or tools on how the recommendations can be put into practice	•	X	X	•	•	•
20. The potential resource implications of applying the recommendations have been considered.	X	X	X	X	•	X
21. The guideline presents monitoring and/or auditing criteria.	•	X	X	X	•	X
<b>Domain 6: Editorial Independence</b>						
22. The views of the funding body have not influenced the content of the guideline.	•	•	•	•	•	?
23. Competing interests of guideline development group members have been recorded and addressed	•	•	•	•	•	•

CTPH = Canadian Taskforce on Preventive Healthcare; ICSI = Institute for Clinical Systems Improvement; N/A = not applicable; NHLBI = National Heart, Lung, and Blood Institute; NHMRC = National Health and Medical Research Council; NICE = National Institute of Health and Care Excellence

<sup>a</sup>International Federation for the Surgery of Obesity and Metabolic Disorders – European Chapter

• = yes; X = no, ? = unclear

APPENDIX 5: Main Study Findings and Author’s Conclusions

<b>Table A9: Study Findings and Author’s Conclusions for Clinical and Economic Systematic Reviews and Meta-Analyses<sup>a</sup></b>			
<b>Outcome, Number of Studies</b>	<b>Intervention Group</b>	<b>Control Group</b>	<b>Findings; Interpretation or Author’s Conclusions</b>
<b>Ollendorf, 2015<sup>54</sup></b>			
<b>Weight loss</b>			
N = 1 RCT <sup>60</sup>	LAGB	Conventional weight-loss (calorie reduced diet and exercise program, monitoring)	78.8% versus 13.2% excess weight loss in the LAGB versus control group (p <0.001);  Generalizability to patients without barriers to insurance coverage unclear; small sample size limited power to detect non weight-loss outcomes; long-term benefits unclear
N = 1 retrospective cohort	LAGB	RYGB	48.6 versus 20.0 kg lost in the RYGB versus LAGB group (p < 0.001); controlling for selection bias and differences in baseline characteristics, no significant differences in weight outcomes were observed;  Long-term safety unclear, some missing follow-up data
N = 1 retrospective cohort	RYGB	VSG or LAGB	-32.9% reduction in BMI in the RYGB group versus -29.4% and -20.0% for VSG and LAGB, respectively (p <0.001);  Groups unmatched at baseline, high attrition rate during follow-up period
<b>Resolution of comorbidities</b>			
N = 1 RCT	LAGB	Conventional weight-loss (calorie reduced diet and exercise program, monitoring)	100% versus 60% metabolic syndrome resolution in the LAGB versus control group (p = 0.025)
N = 1 retrospective cohort	LAGB	RYGB	58.8% versus 23.3% hyperlipidemia resolution in the RYGB versus LAGB group (p < 0.05)
<b>Mortality</b>			
N = 1 retrospective cohort <sup>69</sup>	LAGB	RYGB	One death due to cardiac failure in the RYGB group
<b>White, 2015<sup>52</sup></b>			
<b>Quality of Life</b>			
QOL, N = 1 reported narratively <sup>68</sup>	AGB	Intensive lifestyle intervention	<ul style="list-style-type: none"> <li>Physical functioning, change in health scores significantly improved 2 years after surgery</li> <li>No significant between-group differences for self-esteem, mental health, family activities, family cohesion, general behavior or general health scores<sup>68</sup></li> <li>Significant within group differences in QOL related to family activities (p = 0.006), general health (p =</li> </ul>

**Table A9: Study Findings and Author's Conclusions for Clinical and Economic Systematic Reviews and Meta-Analyses<sup>a</sup>**

			0.003), physical functioning (p <0.001), self-esteem (p = 0.01) and change in health (p < 0.001)	
QOL, N = 1 reported narratively	Sleeve gastrectomy	No surgery in intra-familial non-weight matched controls	<ul style="list-style-type: none"> <li>No significant within group differences observed in general behavior, family cohesion, or mental health</li> </ul>	
Self-esteem, N = 1 reported narratively <sup>71</sup>			<ul style="list-style-type: none"> <li>At 1 year, improvement observed in all PedsQL domains</li> <li>Mean RSE scores significantly increased from pre to one year post-operation, indicating improved self-esteem</li> </ul>	
<b>Göthberg, 2014<sup>33</sup></b>				
<b>Weight loss/BMI changes</b> , n = 1 RCT, n = 3 cohort studies	Significant weight reduction at one and two years of follow up in surgical (28 to 38%) versus non-surgical groups (3% loss to 3% gain) based on the results of four studies; moderate quality of evidence based on 1 RCT and 3 cohort studies			
<b>Glucose metabolism/homeostasis</b>	<ul style="list-style-type: none"> <li>The RCT<sup>68</sup> reported a significant and clinically relevant improvement in insulin sensitivity at two years after LAGB versus non-surgical treatment</li> <li>The cohort study observed reductions in fasting insulin, glucose, and HbA1c, which decreased significantly after surgery, but there was no change in the control group – between group comparisons not reported</li> </ul>			
<b>Cardiovascular risk factors</b>	The single RCT <sup>68</sup> showed within group reductions in blood pressure, but no significant differences between groups (LAGB versus non-surgical); similar results for lipid profile			
<b>Mortality</b> , n = 9 case series (n = 2375 patients)	One post-operative death within 30 days after open surgery; 9 deaths 6 months to 4 years after surgery (due to malnutrition, heart failure, infection, necrotizing pancreatitis, drug overdose)			
<b>Short-term complications</b>	<ul style="list-style-type: none"> <li>Bleeding, infection, depression, gallstone formation with cholecystectomies, internal hernia, ileus, micronutrient deficiencies and excessive skin were common side-effects</li> <li>The single RCT reported similar frequency of adverse events after gastric banding and non-surgical treatment</li> <li>Evidence was considered of very low quality</li> </ul>			
<b>Long-term morbidity</b>	Insufficient evidence to draw conclusions			
<b>Black, 2013<sup>91</sup></b>				
Change in BMI (kg/m <sup>2</sup> ), weighted mean difference (95% CI)	AGB = -10.47 (-11.80 to -9.14), based on n = 11 studies; SG = -14.53 (-17.33 to -11.73), based on n = 3 studies; RYGB = -17.20 (-20.09 to -14.31), based on n = 7 studies			
<b>Economic</b>				
<b>Aikenhead, 2013<sup>136</sup></b>				
Cost-utility	LAGB	Alternative obesity treatment and prevention	\$44 000 AU per DALY	LAGB deemed cost-effective on the basis of ICER;
A SR reported that bariatric surgery was cost-effective versus non-surgical treatments; however, substantial variability in costs and outcomes and generalizability concerns were noted <sup>72</sup>				

AGB = adjusted gastric band; AU = Australian; DALY = disability adjusted life years; CI = confidence interval; ICER = incremental cost-effectiveness ratio; LAGB = laparoscopic adjustable gastric banding; PedsQL = Pediatric Quality of Life Inventory; QOL = quality of life; RCT = randomized controlled trial; RSE = Rosenberg Self-Esteem Scale; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; SR = systematic review; VSG = vertical sleeve gastrectomy

<sup>a</sup>Only comparative results are reported; where there was overlap in reporting on the same primary studies, the results are reported under the heading for the most recent systematic review

<sup>b</sup>Only cost-effectiveness outcomes reported due to overlap with clinical studies reported by later SRs

**Table A10: Study Findings and Author's Conclusions for Primary Economic Studies**

Clinical Population	Cost-Effectiveness Estimate	WTP Threshold	Sensitivity Analysis <sup>a</sup>	Interpretation or Author's Conclusions
Bairdain, 2015 <sup>55</sup>				
Obese adolescent patients	ICER = < 100 000 USD/QALY up to year 3  < 100 000 USD/QALY from year 4 to year 7 post-surgery	\$100 000 USD/QALY	Probabilistic and one-way <sup>a</sup> : <ul style="list-style-type: none"> <li>• ICER range based on assumed impact of BMI on HrQOL \$2700 to \$469333 USD/QALY; under assumption of no benefit on QOL, surgery became cost-effective after 9 years</li> <li>• \$24 828 to \$190 540 USD/QALY over four years when intervention costs were halved or doubled</li> <li>• \$110,922 to \$49,208 USD/QALY when medical costs savings varied per unit of BMI</li> <li>• \$76,191 (0%) to \$88,128 (6%) USD/QALY when discount rate varied</li> <li>• \$51,719 to \$93,185 USD/QALY when weight regain per year varied from 5 to 20%</li> </ul>	Probability of cost-effectiveness is 75% over 4 years, and increases afterwards  Lower assumed benefit of weight loss on QOL, higher intervention costs, and lower medical costs savings when assessed in sensitivity analysis influenced the ICER to suggest no cost-effectiveness at those inputs over 4 years  Bariatric surgery not cost-effective in the first 3 years, but becomes cost-effective afterwards
Gortmaker 2015 <sup>56</sup>				
US youth population undergoing bariatric surgery	\$1611 (95% UI = 1241 to 2337) per unit of BMI reduced	NR	<ul style="list-style-type: none"> <li>• Probabilistic sensitivity analysis (all parameter values varied over pre-determined distributions)</li> <li>• The 95% confidence interval for price per unit of BMI reduced was \$1241 to \$2337 USD</li> </ul>	<ul style="list-style-type: none"> <li>• Increasing access to bariatric surgery would reduce a BMI unit for \$1611 compared to eliminating tax deduction for advertising nutritionally for food to children which would cost \$0.66 per BMI unit</li> <li>• Reach of bariatric surgery was the smallest of the 7 interventions assessed, even assuming a fourfold increase in the number of patients nationwide receiving the procedure; highest costs per BMI unit reduced</li> <li>• Authors concluded that primary prevention strategies seemed more promising than treatment strategies like obesity and would be more cost-effective to implement</li> <li>• Uncertain if the interventions assessed in the study are relevant comparators</li> <li>• Authors state that Focus for policy makers should be on implementing cost-effective preventive interventions that have broad population impact</li> </ul>

<sup>a</sup>Probabilistic: Based on percent change in costs per unit of BMI (ranged from 0 to 100%); Varied based on intervention costs, medical costs, post-surgical weight loss, and QOL gains associated with BMI reductions; One-way: QOL gains, intervention costs, annual savings per unit of BMI lost, discount rate, and weight regain over time varied individually  
 BMI = body mass index; HrQOL = health-related quality of life; ICER = incremental cost-effectiveness ratio; NR = not reported; QALY = quality adjusted life year; QOL = quality of life; UI = uncertainty interval; USD = United States dollars; WTP = willingness to pay

**Table A11: Summary of Findings of Included Evidence-Based Guidelines and Reviews of Guidelines**

Recommendation	Grade/Strength of Recommendation or Interpretation
<b>Reviews of Guidelines</b>	
Brei, 2014 <sup>oo</sup>	
<p>Age/physical maturity criteria ranged across guidelines and included:</p> <ul style="list-style-type: none"> <li>• 12 to 18</li> <li>• Tanner stage IV</li> <li>• Near or adult height</li> <li>• Generally at least 15 for boys and 13 for girls</li> <li>• Skeletal maturity</li> <li>• 95% of adult stature with radiography (typically results in restriction of candidates to &gt; 12 years)</li> <li>• Based primarily on expert opinion and retrospective cohort studies</li> <li>• Overall consensus is that adolescents should have achieved, or nearly achieved physical maturity</li> </ul>	<p>Seven clinical practice guidelines were identified</p> <p>Most recommendations based on lower level evidence and expert opinion – well-conducted studies were not available to the guideline developers</p> <p>Current literature supports surgery as a treatment modality to be considered for morbidly obese adolescents who have had inadequate or no success with other weight loss efforts and who meets specific inclusion criteria with regarding to patient characteristics, staff and facility requirements</p>
<p>BMI and comorbidity criteria recommendations are generally based on expert opinion and retrospective cohort studies and varied across guidelines</p> <ul style="list-style-type: none"> <li>• One guideline recommended a BMI of greater than 50, and others recommended &gt;40 regardless of comorbidities, or conversely &gt;40 but only when severe comorbidities are present, &gt;35 with severe comorbidities</li> <li>• There is a lack of consensus regarding the severity of comorbidities and their need to justify surgery</li> <li>• Common comorbidities include type II diabetes, obstructive sleep apnea, pseudotumor cerebri, non-alcoholic fatty liver/steatohepatitis, dyslipidemia, and impaired quality of life</li> </ul> <p>Indicators of metabolic syndrome and cardiovascular disease are weaker indications for bariatric surgery in the adolescent population due to the comparatively lower body of evidence correlating these factors with clinically significant problems</p>	
<p>Exclusion criteria are informed by well-conducted cohort studies which provide strong evidence to suggest that uncontrolled depression and other psychopathology, unstable disordered eating, pregnancy, Prader-Willi syndrome, untreated endocrinopathies, inability to provide long-term post-surgical support</p>	
<ul style="list-style-type: none"> <li>• The preferred surgical procedure was not clear based on the reviewed guidelines though some strengths and disadvantages were discussed within the guidelines</li> <li>• RYGB is the gold standard for adults and some guidelines suggest that it may be suitable for younger patients</li> <li>• Adjustable gastric banding could be considered in the context of a research study as it is currently not approved by the FDA for use in patients under 18</li> <li>• Laparoscopic sleeve gastrectomy is only recommended as an investigational procedure</li> </ul>	

**Table A11: Summary of Findings of Included Evidence-Based Guidelines and Reviews of Guidelines**

Recommendation	Grade/Strength of Recommendation or Interpretation
<p>due to insufficient data</p> <ul style="list-style-type: none"> <li>At the time of publication, based on the 5 guidelines reviewed there was insufficient evidence to support one type of weight loss over another, and the consensus was that decisions should be made on an individual basis based on preferences and clinical opinion</li> </ul>	
<p>Pre-operative management recommendations included:</p> <ul style="list-style-type: none"> <li>Psychiatric evaluation of mental stability and maturity</li> <li>Metabolic, nutritional and vitamin screening</li> <li>Assessment of compliance with healthy lifestyle regimens</li> <li>Counseling regarding pregnancy (i.e., regarding increased fertility and risks of pregnancy in the first 2 years following surgery)</li> <li>Informed consent</li> </ul>	
<ul style="list-style-type: none"> <li>Surgical setting and care team recommendations were not consistent but included:</li> <li>Suggestions that care be provided at areas with high volume to ensure adequate surgical experience</li> <li>With necessary adaptations for bariatric patients and providers</li> <li>Settings that have proper maintenance of databases and ability to provide long-term follow-up</li> <li>Settings that are able to provide high quality multidisciplinary care (e.g., bariatric surgeon, coordinator, pediatric specialist, mental health clinician, registered dietician)</li> </ul>	
<ul style="list-style-type: none"> <li>Post-operative recommendations based on meta-analysis, case series, and retrospective reviews</li> <li>Nutritional follow-up assessment</li> <li>Psychological support</li> <li>Contraception</li> <li>Evaluation of chronic medications</li> </ul>	
<p>Aikenhead, 2011<sup>97</sup> International Association for the Study of Obesity</p>	
<ul style="list-style-type: none"> <li>Limited consensus regarding the lower limit for age with guideline recommendations ranging from 11 to 14 years, and the majority not providing age recommendations</li> <li>There is general consensus across guidelines that developmental maturity needs to be reached with guidelines suggesting criteria such as Tanner stage 3 to 5, final or near final adult height, post-pubertal, and physical maturity, or complete or near complete skeletal and developmental maturity, bone age &gt;13 for girls and &gt;15 for boys</li> <li>Inclusion criteria is often based on BMI with thresholds of &gt;35 or &gt;40 kg/m<sup>2</sup> suggested with or without the presence of comorbidities (such as type 2 diabetes, hypertension, non-alcoholic steatohepatitis, benign intracranial hypertension, obstructive sleep apnoea)</li> </ul>	<p>Majority of guidelines agreed that bariatric surgery is indicated for obese pediatric patients after previous failed attempts at weight loss who meet strict entry criteria</p> <p>Of 15 guidelines, 3 recommended against bariatric surgery except in exceptional circumstances, whereas 12 presented recommendations with tailored suggestions regarding selection criteria, surgical expertise, surgical facility, preoperative assessment, preoperative education, and postoperative management</p>

**Table A11: Summary of Findings of Included Evidence-Based Guidelines and Reviews of Guidelines**

Recommendation	Grade/Strength of Recommendation or Interpretation
<ul style="list-style-type: none"> <li>Most guidelines recommend previous attempts at weight loss for at least a 6-month duration, including a lifestyle modification component, formal supervision or organized weight loss and family involvement</li> </ul>	
<ul style="list-style-type: none"> <li>Patient assent or informed consent, and parent/guardian/caregiver consent is required by several guidelines</li> <li>Patient and family knowledge and attitudes may factor in to the decision to allow surgery. Patient knowledge and motivation, awareness of risks, availability of a supportive environment, emotional and cognitive maturity, and psychological stability are some common criteria.</li> <li>Patient and family may be required to undergo pre-operative psychiatric or psychological evaluations.</li> <li>Demonstrated capability and willingness to follow guidelines and submit for prolonged surveillance suggested</li> </ul>	
<p>Common contraindications among guidelines included patients with:</p> <ul style="list-style-type: none"> <li>Life-threatening multisystem organ failure</li> <li>Uncontrolled or metastatic malignancy</li> <li>Uncontrolled HIV</li> <li>Hypercarbic respiratory failure</li> <li>Active systemic infection or untreated endocrine dysfunction</li> <li>Plans to conceive</li> <li>Unresolved eating disorders</li> <li>Diseases threatening with likely short term morbidity</li> <li>Lack of available care (self or access to family or social support)</li> <li>Medically correctable causes of obesity</li> </ul>	
<ul style="list-style-type: none"> <li>Six of the guidelines mention requirements for surgical expertise; with most mentioning that the surgeon should be a bariatric surgery expert with specialized training and credentials. Other criteria include experience with adolescents, and ability to perform open procedures. Most publications suggest that a multidisciplinary team is needed as well as the availability of paediatric support. Surgeons may need to be capable in assessment and long-term follow-up of metabolic and psychosocial needs of patient and family. Some guidelines suggest that the entire team needs to be experienced.</li> </ul>	
<ul style="list-style-type: none"> <li>Some guidelines recommend that surgery be conducted at a specialty centre, with preference for those that focus on pediatric surgery or weight loss</li> <li>Some guidelines suggest that data be collected for publication or deposit in national registries, or that surgery only be conducted in the context of a</li> </ul>	

**Table A11: Summary of Findings of Included Evidence-Based Guidelines and Reviews of Guidelines**

Recommendation	Grade/Strength of Recommendation or Interpretation
<p>controlled clinical trial</p> <ul style="list-style-type: none"> <li>• Facilities should:               <ul style="list-style-type: none"> <li>○ Have experience with adult bariatric surgery</li> <li>○ Be able to accommodate the needs of bariatric patients and their providers</li> <li>○ Have staff with experience and sensitivity to bariatric surgery patients</li> <li>○ Have safeguards to protect staff against ergonomic and lifting injuries</li> <li>○ Have mechanisms to facilitate contact with primary care physicians</li> <li>○ Be able to meet guidelines for care described by the American Society for Metabolic and Bariatric Surgery and American College of Surgeons</li> <li>○ Provide 24 hour access to emergency services</li> </ul> </li> </ul>	
<ul style="list-style-type: none"> <li>• Pre-operative assessment should involve evaluation of the patients :               <ul style="list-style-type: none"> <li>○ General medical health</li> <li>○ Developmental status</li> <li>○ Psychological state</li> <li>○ Nutritional status</li> <li>○ Motivation and potential for adherence to postoperative care</li> <li>○ Knowledge of procedure and postoperative requirements</li> <li>○ Psychological/psychiatric status</li> <li>○ Capacity for care and knowledge of the operative procedure, and post-operative requirements</li> </ul> </li> <li>• Some guidelines recommend that pre-operative assessment include communication about:               <ul style="list-style-type: none"> <li>○ Outcomes, risks and potential complications</li> <li>○ Post-operative requirements and follow-up</li> <li>○ Alternative treatment procedures</li> </ul> </li> <li>• Some guidelines recommend that the family be involved in pre-operative education and that the process be documented for professional liability and risk-management</li> </ul>	
<p>Regarding type of surgery, one guideline recommended that laparoscopic adjustable gastric banding be used in the place of other procedures due to weight loss benefits, low complication rate, and potential reversibility – another guideline suggested that there was no evidence regarding the optimal surgical procedure</p>	
<p>Post-operatively, some guidelines recommended:</p> <ul style="list-style-type: none"> <li>• Management of nutritional deficiencies</li> <li>• Lifelong surveillance</li> <li>• Follow-up on 4 to 6 week basis</li> <li>• Multi-component multidisciplinary follow-up programmes involving nutritional, psychological,</li> </ul>	

**Table A11: Summary of Findings of Included Evidence-Based Guidelines and Reviews of Guidelines**

Recommendation	Grade/Strength of Recommendation or Interpretation
medical and behavioral care	
<b>Primary Evidence-Based Guidelines</b>	
Canadian Task Force on Preventive Health Care, 2015 <sup>59</sup>	
"For children and youth who are overweight or obese, we recommend that primary care practitioners not routinely refer for surgical interventions" (page 413)	Strong recommendation; very low quality evidence <sup>d</sup>
Fried, 2014, International Federation for the Surgery of Obesity and Metabolic Disorders, European Chapter <sup>60</sup>	
<p>In adolescents with severe obesity, bariatric surgery can be considered if the patient has the following:</p> <ul style="list-style-type: none"> <li>• Has a BMI &gt;40 kg/m<sup>2</sup> (or 99.5<sup>th</sup> percentile for respective age) and at least one co-morbidity</li> <li>• Has followed at least 6 months of organized weight reducing attempts in a specialized centre</li> <li>• Shows skeletal and developmental maturity</li> <li>• Is capable to commit to comprehensive medical and psychological evaluation before and after surgery</li> <li>• Is willing to participate in a post-operative multidisciplinary treatment programme in a unit with specialist paediatric support (nursing, anaesthesia, psychology, post-operative care)</li> <li>• Bariatric surgery can be considered in genetic syndromes such as Prader-Willi syndrome only after careful consideration of an expert medical, paediatric, and surgical team</li> </ul>	Oxford classification system of evidence levels C and D <sup>b</sup>
National Institute for Health and Care Excellence, 2014 <sup>64</sup>	
<p>See page 50</p> <ul style="list-style-type: none"> <li>• Surgical intervention is not generally recommended in children or young people</li> <li>• Bariatric surgery may be considered for young people only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity</li> <li>• Surgery for obesity should be undertaken only by a multidisciplinary team that can provide paediatric expertise in: <ul style="list-style-type: none"> <li>○ Pre-operative assessment, including a risk-benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s)</li> <li>○ Information on the different procedures including potential weight loss and associated risks</li> <li>○ Regular postoperative assessment, including specialist dietetic and surgical follow-up</li> <li>○ Management of comorbidities</li> <li>○ Psychological support before and after surgery</li> <li>○ Information on or access to plastic surgery when appropriate</li> <li>○ Access to suitable equipment, including scales, theatre tables, Zimmer frames, commodes, hoists, bed frames,</li> </ul> </li> </ul>	NR

**Table A11: Summary of Findings of Included Evidence-Based Guidelines and Reviews of Guidelines**

Recommendation	Grade/Strength of Recommendation or Interpretation
<p>pressure-relieving mattresses and seating suitable for children and young people undergoing bariatric surgery, and the staff trained to use them</p> <ul style="list-style-type: none"> <li>• Coordinate surgical care and follow-up around the child or young person and their family's needs.</li> <li>• Comply with the approaches outlined in the Department of Health's A call to action on obesity in England (2006, amended 2014)</li> <li>• Ensure all young people have had a comprehensive psychological, educational, family, and social assessment before undergoing bariatric surgery (2006, amended 2014)</li> <li>• Perform a full medical evaluation, including genetic screening or assessment before surgery to exclude rare, treatable causes of obesity</li> </ul>	
<p>Institute for Clinical Systems Improvement, 2013<sup>61</sup></p>	
<p>Stage 4 of a four stage model of obesity treatment terminates at tertiary care where "in some cases of severe obesity where there is no response to behavioral interventions there are specialty centers of excellence that may offer bariatric surgery." (page 32)</p>	NR
<p>Given limited evidence on long-term efficacy and safety, these conditions must be met for bariatric surgery to be given:</p> <ul style="list-style-type: none"> <li>• BMI <math>\geq 40 \text{ kg/m}^2</math> or <math>35 \text{ kg/m}^2</math> with severe comorbidities, noting lack of consensus in criteria for adolescent bariatric surgery</li> <li>• Tanner 4 or 5 pubertal development or bone age <math>\geq 13</math> for girls and <math>\geq 15</math> for boys</li> <li>• <math>\geq 6</math> months of failed attempts at weight management prescribed by the primary care clinician or a weight management program</li> <li>• Decisional capacity, demonstration of commitment to medical and psychological evaluations</li> <li>• Supportive family environment</li> </ul>	NR
<p>Surgery should not be given to:</p> <ul style="list-style-type: none"> <li>• Pre-adolescents</li> <li>• Patients who have not mastered principles of healthy diet and activity habits</li> <li>• Patients with unresolved eating disorders, psychiatric disorders or Prader Willi syndrome</li> <li>• Pregnant and breastfeeding adolescents, or individuals planning pregnancies within 2 years of surgery</li> </ul>	NR
<p>Surgery should be conducted in "regional bariatric centres of excellence" that are able to perform data acquisition, long-term follow-up and handle multidisciplinary issues</p>	High quality evidence
<p>A multidisciplinary team with the specific specialties (endocrine, gastrointestinal, cardiovascular, pulmonary, otolaryngological, surgical, nutritional, and psychological)</p>	NR
<p>LAGB has not been approved by the FDA for use in people &lt;18 years of age, because of a lack of both short-term and long-term safety and efficacy data for adolescent</p>	N/A

**Table A11: Summary of Findings of Included Evidence-Based Guidelines and Reviews of Guidelines**

Recommendation	Grade/Strength of Recommendation or Interpretation
patients	
Australian Government, National Health and Medicine Research Council, 2013 <sup>62</sup>	
For post pubertal adolescents with a BMI > 40 kg/m <sup>2</sup> (or >35 kg/m <sup>2</sup> with obesity-related complications), laparoscopic adjustable gastric banding via specialist bariatric/paediatric teams may be considered if other interventions have been unsuccessful in producing weight loss (Grade C) (Page 96)	Grade C <sup>c</sup>
“Bariatric surgery should only be undertaken by a highly specialised surgical team within the framework of a multidisciplinary approach for post-pubertal adolescents who require specialist intervention” (Page xv)	Practice point
No evaluative data are available for procedures other than LAGB – cost benefits for adolescents may be more significant than those for adults give the potential quality-adjusted life years gained by intervention in younger individuals. However, complication and revision rates are higher in adolescents. (Page 96) More intensive weight management interventions, such as very low-energy diets, weight loss medication and bariatric surgery may need to be considered as adjuncts to lifestyle approaches, especially when a person is obese and/or has risk factors or comorbidities or has been unsuccessful reducing weight using lifestyle approaches. The decision to use intensive weight loss interventions is made based on the individual situation	Endorsed other guidelines including the NICE guideline, ICSI guideline, and NHMRC guideline reviewed in this report
National Heart, Lung, and Blood Institute, 2012 <sup>62</sup>	
For adolescents with BMI far above 35 kg/m <sup>2</sup> and associated comorbidities, bariatric surgery on a research protocol, in conjunction with a comprehensive lifestyle weight loss program, improved weight loss, BMI, and other outcomes – such as IR, glucose tolerance, and CV measures – in a small case series	Grade D <sup>u</sup> ; strength of recommendation unclear

<sup>a</sup>The SR did not identify any comparative evidence comparing surgery to untreated control groups – the recommendation made is based on the absence of high-quality effectiveness evidence, potential for harm and irreversible nature of the procedure. Surgery may be best considered by interdisciplinary teams that specialize in obesity. The guideline did not assess comparative evidence that compared surgery to behavioral interventions and there is limited evidence<sup>68</sup> that surgery may be more effective than behavioral interventions in reducing weight and metabolic syndrome and improving quality of life

<sup>b</sup>Level C - Case series or extrapolations from level B studies (consistent retrospective cohort, exploratory cohort, ecological study, outcomes research, case-control study, or extrapolations from level A studies); Level D - Expert opinion without explicit critical appraisal or based on physiology, bench research or first experience/principles case reports

<sup>c</sup>Satisfactory – one or two level III studies (pseudorandomized controlled trial, comparative study with concurrent controls) with a low risk of bias, or level 1 (systematic review) or II (RCT) studies with a moderate risk of bias; some inconsistency reflecting genuine uncertainty around clinical question, moderate clinical impact

<sup>d</sup>Expert opinion, case reports, or reasoning from first principles

BMI = body mass index; CV = cardiovascular; FDA = United States Food and Drug Administration; HIV = human immunodeficiency virus; ICSI = institute for clinical systems improvement; IR = insulin resistance; LAGB = laparoscopic adjustable gastric banding; NHMRC = National Health and Medical Research Council; NICE = National Institute for Health and Care Excellence; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy;

**APPENDIX 6: Additional References of Potential Interest***Related CADTH Reports*

1. Bariatric surgery for the long-term treatment of obesity: a review of the clinical effectiveness and cost-effectiveness [Internet]. Ottawa: CADTH; 2015 Jul 20. [cited 2016 Aug 2]. (Rapid response report: summary with critical appraisal). Available from: <https://www.cadth.ca/sites/default/files/pdf/htis/july-2016/RC0789%20Bariatric%20Surgery%20Final.pdf>
2. Bariatric surgical procedures for obese and morbidly obese patients: a review of comparative clinical and cost-effectiveness, and guidelines [Internet]. Ottawa: CADTH; 2014. [cited 2016 Jul 8]. (CADTH rapid response report: summary with critical appraisal). Available from: <https://www.cadth.ca/sites/default/files/pdf/htis/jun-2014/RC0544-000%20Bariatric%20Surgery%20Final.pdf>
3. Bariatric surgery for obese patients with co-morbidities: a review of clinical and cost-effectiveness, and guidelines [Internet]. Ottawa: CADTH; 2013 Aug 8. [cited 2016 Jul 8]. (CADTH rapid response report: summary with critical appraisal). Available from: <https://www.cadth.ca/sites/default/files/pdf/htis/aug-2013/RC0468%20Bariatric%20Surgery%20Final.pdf>
4. Obstetric, neonatal, and child outcomes for women with previous bariatric surgery: a review of the clinical evidence [Internet]. Ottawa: CADTH; 2014 Sep 5. [cited 2016 Aug 2]. (Rapid response report: summary with critical appraisal). Available from: <https://www.cadth.ca/sites/default/files/pdf/htis/sep-2014/RC0578%20Bariatric%20Surgery%20and%20Pregnancy%20Final.pdf>

*Primary Studies – Recently Completed*

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- Pedroso FE, Gander J, Oh PS, Zitsman JL. Laparoscopic vertical sleeve gastrectomy significantly improves short term weight loss as compared to laparoscopic adjustable gastric band placement in morbidly obese adolescent patients. *J Pediatr Surg*. 2015 Jan;50(1):115-22.

#### *Ongoing Comparative Studies*

- Caprio S. Outcomes comparison between gastric band, laparoscopic sleeve gastrectomy and gastric bypass surgeries in obese adolescents. 2013 Nov 11 [cited 2016 Aug 2; updated 2016 Apr 6]. In: ClinicalTrials.gov [Internet]. Bethesda (MD): U.S. National Library of Medicine; 2000 - . Available from: <https://clinicaltrials.gov/ct2/show/NCT02004561>  
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