Alberta Health Technologies Decision Process

Synthesis Report 05-01S

Review of Laparoscopic Adjustable Gastric Banding: Synthesis Report

Review # 1
AHTDP# 03-20

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Alberta
HEALTH AND WELLNESS

This report has been prepared to support and inform the decision-making of Alberta Health and Wellness and its stakeholders regarding the provision of health technologies in Alberta's health care system and is based on the information available from public literature, expert opinion, and other sources at the time of preparation. Its conclusions are solely those of the review group and do not represent the policies or position of the Government of Alberta, Alberta Health and Wellness or any other agency.

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Executive Summary

- The review of the laparoscopic adjustable gastric banding (LAGB) device was undertaken in response to continued requests from Albertans for access to this surgery for treatment of clinically severe obesity. The review served as a pilot test of the new Alberta Health Technologies Decision Process.
- Obesity, considered epidemic throughout most of the world, is a complex metabolic condition in which the proportion of body fat begins to affect health. Clinically severe obesity is characterized by extreme obesity and/or the presence of co-morbidities.
- Obesity treatments range from nutrition and diet, exercise and behavioural modification to bariatric surgery (the surgical management of obesity). Obesity cannot be cured and effective management requires a lifetime commitment from the patient.
- LAGB is one type of surgical intervention; the other two are gastric by-pass, where the upper stomach is directly connected to the small intestine thus by-passing the rest of the stomach and the first part of the small intestine, and vertical gastric banding, or stomach stapling.
- LAGB surgery involves placing an adjustable band around the top part of the stomach. This creates a small stomach pouch, leading to an earlier feeling of fullness, and restricting the flow of nutrients to the rest of the digestive system. The band can be adjusted to further restrict or increase the flow of nutrients, altering the rate of weight loss.
- According to available evidence, with a trained and experienced surgical team, LAGB is as safe and effective as other bariatric surgeries. Effectiveness of all bariatric surgeries, including LAGB, is improved when provided as part of a comprehensive obesity management program. Although appropriate patient selection criteria for LAGB remain undetermined, this is the case with all bariatric surgeries and should not be a determining factor in the provision of LAGB.
- LAGB is as cost-effective as other bariatric surgeries, and there is no economic evidence for preferring one type of bariatric surgery over another. Nevertheless, the incremental cost for LAGB surgery over other laparoscopic gastric by-pass appears to be approximately $1,800 per case. Without significant increase in the capacity of the system, it is unlikely that more than 200 patients per year would receive LAGB. If so, total incremental costs would be approximately $360,000 per year. However moving to minimally invasive surgeries are expected to reduce current costs for hospital stays; these reductions would probably offset the increased costs of LAGB surgery.
- LAGB was assessed against the three screens set out by the Expert Advisory Panel. LAGB meets the safety and effectiveness criteria for the technical screen and most of the criteria of the socio-economic screen, failing only the alternative services test. LAGB may fail the criteria for the fiscal screen, if reductions in hospital stays do not offset incremental costs.
- Two funding policy options are provided:
    - do not provide;

  - provide as a standard good (insured service); encourage regions to coordinate service with comprehensive obesity management programs

- Funding would be re-allocated within RHA global budgets.

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Introduction

Purpose of Report

This report summarizes the findings and conclusions of the review of LAGB for public funding when used for the treatment of clinically severe obesity.

Objectives of Review

The LAGB review, part of the Alberta Health Technology Decision Process, was undertaken to provide government with appropriate evidence and information to make a decision on its public funding. Its three specific objectives,[1] representing the range of information required; were to review:

1. The effectiveness and safety of LAGB;
2. The social and economic considerations for the provision of LAGB. and
3. The fiscal considerations for the provision of LAGB.

The Alberta Health Technology Decision Process

In March 2003, the Expert Advisory Panel to Review Publicly Funded Health Services ("the Expert Panel") submitted its report *The Burden of Proof* recommending a three-screen decision framework—technical, socio-economic, fiscal—for the assessment of new technologies, along with the creation of an independent review agency. The government accepted the Expert Panel's recommended review process in principle, rejected the creation of a new agency in favour of strengthening existing processes to improve the rigour and timeliness of decisions, and decided to implement the process incrementally with stakeholders including the health authorities, the Alberta Medical Association and the Alberta Heritage Foundation for Medical Research (AHFMR). In September 2003, the Health Technologies and Services Policy Unit was established to coordinate the development and implementation of the Alberta Health Technologies Decision Process.

The full process involves eight broad phases or steps. Several steps have significant stakeholder involvement. Step 1 concerns setting priorities, once fully implemented, will see stakeholders canvassed annually to identify technologies needing review. A representative advisory committee will prioritize these technologies for review, based on established criteria. Steps 2 and 3 cover internal government processes, culminating in the project plan for a review of an identified technology.

Step 4, conducting the review, gathers and reviews the evidence and information required for the application of the three-screen process recommended by the Expert Panel and involves a broad range of stakeholders and agencies, such as AHFMR, the Institute for Health Economics, the University of Alberta and the University of Calgary, as well as medical and policy experts from relevant areas of the health system. In Step 5, consulting and formulating advice, health system decision makers and other stakeholders at all levels will be consulted on the results of the reviews before recommendations are finalized and submitted to government for approval (step 6). The health system community is again

[1] The Lap Banding Review Project Charter describes the purpose and approach to this review in full and detailed requirements of each analysis completed as part of this review.

significantly involved in implementing the decisions, which is Step 7. The final step, scheduled reviews, recognizes that follow-up reviews are required to maintain up-to-date evidence related to the technology.

Bariatric Surgery in Alberta

Bariatric surgery has been available within Alberta for many years. At the time of the review, only four general surgeons in Alberta performed bariatric surgery, one each in Edmonton, Red Deer, Medicine Hat and Cardston, with at least one nearing retirement. The average number of cases of bariatric surgery billed in the most recent five year span (1999/2000 to 2003/04) was 175. The annual number has fallen from a five-year high of 202 in 2001/02 to 149 in 2003/04.

During the course of the review, Capital Health began performing LAGB surgery; five cases have been treated since February 2005. These surgeries are not part of this review.

The Review Project

Prior to the review, LAGB had not been offered in Alberta, although the government had recently received several requests for coverage of the procedure on an out-of-province basis. With the increased interest in treatments for clinically severe obesity, the LAGB was chosen as the first technology to go through the complete decision process, partly as a test of the process.

The review (Appendix A: Project Charter) was structured to minimize elapsed time by dividing the work into five components performed by different organizations or teams:

- Technological effectiveness — Health Technology Assessment, AHFMR
- Population health — Surveillance Branch, Alberta Health & Wellness
- Implementation Issues — Capital Health
- Cost and Utilization — Institute for Health Economics (economics team)
- Government policy — Institute for Health Economics (policy team)

All analyses were intended to be done simultaneously where feasible, with coordination through the team leaders, the project manager and an advisory committee established and chaired by the Health Technologies and Services Policy Unit of Alberta Health and Wellness. Some analyses got underway before other analyses were fully resourced, leading to some discontinuities between components.

All teams prepared their own reports, which collectively serve as the basis for this synthesis report, prepared by Hummingbird Consultants. Appendix B provides a listing of all team and expert advisory group members. Analysis reports, with the exception of Implementation Issues, are available under separate cover[2] and should be consulted for further details on specific questions.

Every report written, every decision made necessarily refers to a point in time, but evidence is constantly accumulating. In some cases, important and useful information may only be produced after a report is written or after a decision is made. In these cases, the AHTDP step 8, scheduled review, will assist in ensuring that appropriate decisions are continually made in keeping with the latest information. Nevertheless, it sometimes happens that new

[2] Contact Alberta Health and Wellness for copies of the available reports. Contact information is on the inside of the cover page of this report. See Appendix C for a list of available reports.

information is available when the final report is being written and often can be incorporated in the process to ensure that decision makers have the most up-to-date information available. This is the case here. Between the end of the analyses on which this report is based and the finalization of this report, additional information came available in the technology effectiveness area and in the costs area. This report reflects this updated information, even though it may not be included in the background reports themselves.

Outline of Report

This report will discuss obesity and clinically severe obesity, including the demographics, quality of life issues and prevalence. The discussion will then move on to the effects and effectiveness of LAGB. Following the technological assessment, the report will provide an overview of the economics of providing LAGB in Alberta, implementation issues and some policy considerations. The discussion will end with the application of the three screens and policy options. This report is not intended to make recommendations.

Obesity and Its Effects

Obesity is a complex metabolic condition in which the proportion of body fat begins to affect health. Obesity is considered an epidemic throughout most of the developed and developing world and has been identified as a risk factor for a large number of chronic diseases.

Obesity has traditionally been measured by the body mass index (BMI), a calculation based on an individual's height and weight. A BMI between 18.5 and 24.9 is considered normal. Individuals with BMIs above 30 are considered obese. Clinically severe obesity (also called morbid obesity) refers to:

- BMIs of 40 or over, or
- BMIs of 35 or over when other serious medical conditions are also present and affected by the obesity (co-morbidities).

Co-morbidities usually considered as related to obesity include type 2 diabetes, hypertension, dyslipidemia (a metabolic disorder that leads to, among other things, elevated cholesterol levels), osteoarthritis, sleep apnea, certain cancers and increased risk factors for cardiovascular disease.

In Canada, prevalence rates of obesity have risen steadily over the past 30 years, with approximately 15% of Canadians now being considered obese. According to self-reported health information (which is likely to be an underestimate), an alarming number of adult Albertans are classified as overweight, obese or clinically severely obese. In 1996, it is estimated that there were over 28,000 adults, or 1.6%, in Alberta over the age of 20 with clinically severe obesity.[3] In 2000, the number of clinically severely obese adult Albertans has been estimated to be almost 40,000.[4]

The prevalence of overweight (BMIs of 25 to 30) and obesity increases markedly with age until the early sixties with a relative decline thereafter, which may be due to a higher death rate among the obese population than the population as a whole. Men are more likely to be

[3] Health Surveillance "Self-Reported Body Mass Index in Alberta", Alberta Health and Wellness, 2005, p. 14
[4] Jacobs, Philip et al "Costing of alternative interventions for the treatment of morbid obesity", Institute of Health Economics, p. 11

overweight than women, although both sexes have similar rates for obesity and clinically severe obesity.

There is a slightly larger proportion of individuals in the overweight, obesity and clinically severe obesity ranges among rural residents than among urban residents. Higher income is associated with being overweight, but lower income is associated with both obesity and being underweight.

Health status tends to decline with obesity, with increasing proportions of adults who are overweight, obese and clinically severely obese reporting only fair or poor health. Over four times as many individuals with clinically severe obesity report poor health than those with acceptable weight. Individuals with clinically severe obesity are twice as likely to be suffering from clinical depression as individuals in other weight categories and much more likely to have several co-morbidities. Clinically severe obese individuals are more likely to have long-term disabilities and to be relatively inactive.

Clinically severe obesity is associated with increased in-patient hospitalization and physician visits. Despite this increased use of the health system, clinically severe obese individuals are more likely to report an unmet health need.

Treatment of Clinically Severe Obesity: Laparoscopic Adjustable Gastric Banding

Management of Obesity

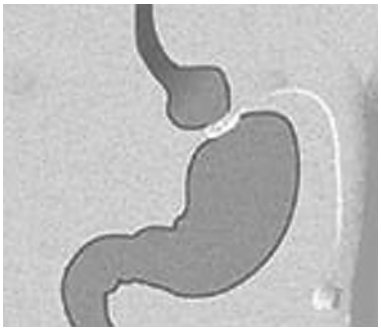
Treatments for obesity in general and for clinically severe obesity in particular vary from the nutritional to the surgical. In general, management of obesity begins with lifestyle changes such as diet, exercise and behavioural modification. For many people, especially those who are clinically severely obese, these strategies prove ineffective in producing and maintaining weight loss.

The second-line regimen is generally considered to be pharmacologic or drug therapy. These therapies involve more risks for the individual, but these risks are considered to be balanced by the potential for increased weight loss. Two drugs (sibutramine and orlistat) have been approved for this purpose, but their efficacy appears limited.

When both lifestyle changes and drug therapy prove unsuccessful in producing and maintaining sufficient weight loss to see improvements in co-morbid conditions, surgical interventions to manage the obesity may be considered. Along with the bariatric surgery, however, patients need to be followed by a multidisciplinary team, including the surgeon, nutritionists, psychological counsellors, health educators and fitness experts. Effective management of clinically severe obesity requires a lifetime commitment from the patient.

The types of bariatric surgeries include gastric restrictive, mal-absorptive, and a combination of restrictive and mal-absorptive. Restrictive procedures are intended to reduce caloric intake by reducing the volume of the stomach. These include gastric banding and vertical banded gastroplasty. Mal-absorptive procedures are intended to reduce the amount of calories absorbed. The present standard for bariatric surgery is the Roux-en-Y gastric bypass, which creates a small pouch in the stomach by sealing off the larger part with surgical division or stapling and re-directing processed stomach contents from the pouch to further down the small intestine. Although the Roux-en-Y has both restrictive and mal-absorptive features, it is believed that weight loss is primarily due to the restrictive element. All of these surgeries can now be done laparoscopically.

LAGB, is a restrictive method, involves inserting an adjustable/inflatable gastric band through a 1 cm incision in the abdomen and wrapping it around the upper part of stomach creating a very small gastric pouch (15cc). See figure. The surgery requires general anaesthesia and takes approximately 30 to 60 minutes. Lap-band surgery requires no cutting or stapling of the stomach. It is deemed major surgery by the College of Physicians and Surgeons of Alberta and may not be performed in a non-hospital surgical facility.



Source: Adapted from <www.obesitylapbandsurgery.com>

The small gastric pouch limits food consumption and creates an earlier feeling of fullness. With the use of a port placed just under the skin, a physician may control the constriction separating the upper pouch from the rest of the stomach by injecting saline into the hollow band or removing fluid and deflating the band. This alters the rate of food absorption.

The band is adjusted whenever the patient's rate of weight loss is greater or less than desired. If the patient is losing weight too fast, saline is withdrawn from the band through the port, the band is loosened, enlarging the passage and allowing nutrients to pass through faster. If the weight loss is too slow, saline is injected into the band through the port, tightening the band and restricting the size of the passage to the rest of the stomach. In addition to this adjustability, the procedure is thought to be reversible; that is, the band can be removed and normal stomach anatomy restored more easily than with the Roux-en-Y, for example. This reversibility has not however been tested over the long term.

With variations for individual manufacturers, the LAGB has been approved for use within Canada for managing weight loss in clinically severely obese adults for whom alternative weight loss regimens have not achieved significant results.

Effectiveness of LAGB

Influencing Factors

The effectiveness of LAGB in achieving good surgical outcomes and significant weight loss is influenced by several factors, the most important of which are the experience of the surgeon, the selection of patients and whether or not the surgery is integrated into an obesity management program.

LAGB is a complex procedure that takes some time and experience to perform effectively. Many studies report a steep learning curve effect, with significantly lower complications for the second 100 procedures performed by the same surgeon. During the first few surgeries performed by the same surgeon, the procedure will tend to take longer with a consequent increase in associated costs. These initial procedures are usually associated with higher mortality rates, perhaps because the medical staff are not familiar with the procedure. Maintenance of appropriate surgical skills and outcomes is also a function of the continuing number of surgeries performed; that is, surgeons and staff who continually perform a significant number of surgeries are more likely to maintain good outcomes than surgeons and staff who only do periodic surgeries.

Patient selection probably also affects the outcome of the surgery. Clinical guidelines recommend that bariatric surgery only be provided for carefully selected patients who are

clinically severely obese. Nevertheless, there is insufficient evidence to specify the patient characteristics of successful cases.

Unlike many surgeries, bariatric surgery is not a cure. Clinically severe obesity is a chronic condition requiring lifelong care. The most successful cases of LAGB, like other bariatric surgeries, are achieved when the patient is part of a comprehensive obesity management program involving nutritional, exercise and behavioural therapies.

Safety

Based on the evidence available to the technological effectiveness analysis team, LAGB appears to be as safe as or safer than open and laparoscopic Roux-en-Y and open vertical banded gastroplasty in terms of short-term (up to 5 years) mortality and morbidity. Evidence on longer term effects is not yet conclusive; however, reports of long-term postoperative complications and associated re-operations have raised significant concerns.

Weight Loss

Based on available evidence, it appears that LAGB is effective in reducing excess weight loss in patients with clinically severe obesity at least in the short term, with patients showing 40% to 60% excess weight loss over one to five years. Weight loss of this magnitude suggests that even successful patients may still be considered obese. Nevertheless, there is evidence that LAGB may be more effective than Vertical Banded Gastroplasty (VBG), but less effective than laparoscopic Roux-en-Y at reducing excess weight. As the length of time following surgery lengthens, however, the number of patients studied falls. Hence evidence for longer-term efficacy is not as solid as for shorter-term efficacy.

Effect on Co-morbidities

Although the effect of bariatric surgery on co-morbidities has not been fully researched, studies that did explore the effects concluded that LAGB (and open Roux-en-Y) results in the improvement of certain co-morbidities, notably diabetes, asthma, hypertension, hyperlipidemia and sleep apnea. LAGB also appears to result in an improvement in patient quality of life. Roux-en-Y, however, appears to result in higher scores on quality of life measures than LAGB or VGB.

Economics of LAGB

Because of the contradictory findings of the available economic research, whether bariatric surgery in general has a net savings effect on health care costs or, failing that, just how cost-effective it is, is difficult to determine. Moreover, there is little research comparing LAGB to other surgical interventions. Nevertheless, it appears that the economics of LAGB appears to be similar to other types of bariatric surgery, and there is little economic evidence to prefer one method over another.

Early in the learning curve, LAGB surgery requires additional surgery time with the consequence of increased costs over the usual bariatric surgeries. But once the surgical team is experienced, the costs of the procedure, leaving aside the cost of the device itself, are comparable to current surgeries. A 2003 study estimated the cost differential between LAGB and other bariatric surgeries to be approximately $2,000, or equivalent to the cost of the device.

Although there may be about 40,000 Albertans with clinically severe obesity, assuming that there is no significant increase in the capacity of Alberta's health system to manage obesity

within the next two or three years, it is not likely that the number of LAGB surgeries would exceed 200 cases annually for that period. Depending on the price at which Alberta RHAs can acquire LAGB devices, and assuming full implementation, this would mean an approximate incremental cost of $400,000 (in 2003 dollars) annually. In the first year or two of implementation, the costs may be higher due to the learning curve effect.

Implementation Issues

Surgeons and Operating Room Staff

Capital Health, in its report on implementation issues, anticipates that no special recruitment or retention strategies would be needed by any regional authority with on-site training capacity, access to experienced surgeons and a specialized multidisciplinary clinic team with research opportunities to attract and retain the two or three appropriately trained surgeons required to accommodate demand. Developing and maintaining such attractive conditions is never easy, for any medically specialized services. Some regional authorities may be better placed than others to implement an obesity management program and attract appropriate medical staff.

The operating and recovery room staff will require some additional training with new bariatric laparoscopic equipment and LAGB devices. Laparoscopic equipment, however, will be used for all laparoscopic surgery and not just LAGB procedures; hence, the investment in training can be spread across several different procedures. The majority of necessary skills have already been acquired in the Capital Health region. Its Outpatient Bariatric Clinic staff will require basic in-servicing and orientation to the LAGB device.

Infrastructure

Requirements for LAGB surgery can be incorporated within current plans for minimally invasive bariatric and general surgery, including digital OR technologies, cameras and other equipment and instruments that facilitate all laparoscopic procedures. Digital ORs are expected to cost approximately $250,000 each. These developments are already happening in hospitals across Alberta and will facilitate the implementation of the use of LAGB. Both LAGB devices presently available will be evaluated by Capital Health over a one-or-two-year period. The procedure will require:

- a bariatric laparascopic guiding device (one-time purchase);
- disposable trochars (continuing cost); and
- the lap-band device (continuing cost).

Incremental supply costs of LAGB compared to laparoscopic Roux-en-Y are estimated at $1,800 per case. This depends in part on the ability to negotiate favourable pricing for continuing supplies. Moving to minimally invasive surgeries such as LR-e-Y and LAGB is expected to reduce the length of stay (LOS) in hospitals. A reduction in LOS would free up beds for other uses and may reduce costs associated with the surgeries. Whether this makes LAGB affordable within present budgets needs to be tested.

Patient Management

Successful treatment of clinically severe obesity requires a comprehensive multidisciplinary team to coordinate the assessment, treatment (surgical and non-surgical), post-operative management when required, and continuing patient support. Capital Health's Bariatric Surgery Clinic presently provides this service and plans are already in place to expand these resources.

Post-operative care for all bariatric surgery (not just LAGB) requires eight follow-up visits within the first two years following the surgery and annual visits thereafter. Therefore, there would be no incremental care or costs associated with LAGB.

Policy Considerations

Legislative and Policy Framework

The provision and public funding of LAGB is governed by a complex framework of legislation, regulation and policy. The physician service component is governed in part by the Alberta Health Care Insurance Act (AHCIA) and its regulations, as well as the regulations and bylaws of the College of Physicians and Surgeons of Alberta. The facility component is governed by the Alberta Hospitals Act (AHA) and its regulations, the Regional Health Authorities Act (RHAA) and its regulations, and the Health Care Protection Act (HCPA) and its Regulation. Medical devices, like the lap band, require approval for use in Canada by Health Canada under the federal Food and Drugs Act. In addition to this legislative framework, the provision and funding of any medical device or service is subject to the policy directions of the Alberta government.

In order for physicians in Alberta to be paid with public funds, the service being provided must either be specifically identified on the Schedule of Medical Benefits (pursuant to a regulation of the AHCIA) or be defined as a medically necessary service that can fit under one of the more general provisions of the Schedule. At present, LAGB is not specifically identified on the Schedule. There is, however, a general service code for gastric partitioning for the treatment of obesity. It would appear that the LAGB procedure, in creating a small upper stomach separated from the larger lower stomach falls within the definition of gastric partitioning. This same code is presently used for the payment for VBG, as well. It would be difficult, therefore, to argue that the surgical procedure to fit the adjustable gastric band would not be an insured[5] service.

Nevertheless, although the surgical procedure itself is presently an insured service, the use of the LAGB device does not automatically follow. The decision whether to fund the device through public funds is a separate issue. The Hospitals Act, Regional Health Authorities Act, and their regulations provide for the management and funding of hospital services within Alberta. The RHAs are globally funded, for the most part, by the government of Alberta to provide appropriate services for Albertans. RHAs are also authorized by the Health Care Protection Act to charge patients for certain medical goods, provided as part of an insured service, that are deemed to be beyond the standard required for proper medical care, i.e.; generally accepted medical practice. Only medical goods listed in the HCPA regulations are deemed to be such enhanced goods. The LAGB device is not presently listed in the regulation.

[5] Within the definition of the Alberta Health Care Insurance Act and the Alberta Hospitals Act.

Arguing that the LAGB be designated an enhanced good would be difficult. First, what features would constitute the enhancement? For whom would these be an enhancement? Two features that proponents might point to are its reversibility and adjustability. If obesity management requires a lifelong commitment, it would be odd to consider the reversibility of the operation as an enhancement. In fact, opponents could argue that it might attract more patients who do not want to make the commitment required for successful treatment. Adjustability might be an enhancement, as it could be argued that the lap band device provides external (physician) control over the rate of weight loss when the patient can not or will not follow a diet. But this argument is undermined by the recognition that the surgery alone cannot control weight; continuing attention to diet and lifestyle is required in every case. Second, LAGB is unique among bariatric surgeries today in using a medical device. This makes it substantively different from other bariatric procedures, in turn making it difficult to determine what the standard good would be. Without a standard, good designating LAGB to be an enhanced good is more complicated.

Since LAGB is not significantly more effective than alternative bariatric surgeries, government policy directions are not relevant to the choices facing the government. For example, although government policy suggests that efforts be made to reduce waiting lists, expansion of any effective bariatric surgery would be compatible. In addition, any effective bariatric surgery would also support the government policy to increase efforts at disease prevention, in this case, obesity's co-morbidities. Providing LAGB would not have a significant effect on these policy goals.

The Three Screens[6]

Technical

The first, technical, screen proposed by the Expert Panel involves three main elements: safety, effectiveness and cost-effectiveness.

Health Canada has approved the device for use in Canada, deeming its use not to be harmful to patients. No safety issues, other than complications from surgery, have been noted in the evidence examined. Risk and severity of surgical complications, at least in the short-term, are in keeping with that of other bariatric surgeries.

Evidence has shown that LAGB is more effective than VGB, but less effective that Roux-en-Y. Nevertheless, LAGB has several elements not found in other bariatric surgeries: it is less invasive and adjustable, thus perhaps enabling better management of obesity, and apparently reversible.

LAGB appears to result in incremental costs of $1,800 per case, but its cost effectiveness is similar to other bariatric surgeries.

In sum, LAGB meets the criteria the Expert Panel has set out for the technical screen.

Socio-economic

The socio-economic screen involves five elements: importance for re-distribution; impact on specific, identifiable sub-populations; existence of other service options; existence of other payment options; and alignment with regulatory and policy frameworks.

[6] For ease of reference, the three screens are included in Appendix C.

Since cases involving LAGB would simply replace present alternatives, providing LAGB would not change relative access to bariatric surgeries. In fact, current medical thinking suggests that bariatric surgery should only be performed when long-term, multidisciplinary follow-up is available. Provision of LAGB would not have any effect on this trend.

Although clinically severe obesity is associated with some sub-populations, including rural residents and lower income groups, providing LAGB as an alternative to current bariatric surgeries would not affect any identifiable population. LAGB presents no more ethical dilemmas than the present alternatives.

There are alternatives to LAGB; one, Roux-en-Y gastric bypass, has been shown to be more effective than LAGB at less cost. Neither Roux-en-Y nor VGB offer adjustability and reversibility or the same degree of non-invasiveness. Nevertheless, these features do not appear to make LAGB more effective.

Since LAGB surgery is already an insured service, no other payment or insurance option is available. To make such options available, the Minister of Health and Wellness would have to declare that LAGB surgery was an uninsured service.

Alignment with regulatory and policy frameworks is not an issue for LAGB.

In sum, LAGB meets most, but not all, of the criteria established by the Expert Panel for the socio-economic screen. The existence of other, effective surgeries for clinically severe obesity raises the question of the need for LAGB.

Fiscal

The Expert Panel's third, fiscal, screen asks three questions:

- is LAGB affordable within current budget?
- would it be affordable with elimination of existing, less cost-effective treatment?
- would it be affordable only with new funding or revenue?

LAGB has incremental costs of $1,800 per case. Existing RHA budgets would appear to be fully committed; therefore, LAGB would seem not affordable within existing budgets. Hence, it does not appear that funds can be transferred from existing cases without reducing the number of surgeries performed.[7] If LAGB was significantly more effective at reducing health care costs for co-morbidities than alternative bariatric surgeries, a case might be made for a transfer of costs from the treatment of these diseases. However, LAGB appears not to have a significant incremental impact on these costs. It may be possible to transfer funds from other hospital expenses if the reduction in length of stay results in cost savings, but this does not normally happen. Without additional funding, an RHA would probably need to reduce the number of bariatric surgeries to free up sufficient funds to offer LAGB. This would increase the waiting list for these surgeries.

In sum, LAGB may fail the criteria established by the Expert Panel for the fiscal screen.

[7] Capital Health has already begun performing LAGB procedures to test the use of laparoscopic approaches for bariatric surgery to reduce the pressure on inpatient beds and to reduce in-hospital complications experienced with open surgical procedures. Additional funds were allocated for this budget year for this purpose. However, it is not clear whether there would be a continuing source of funds for implementation.

Policy Options

There are basically two options for the provision and public funding of laparoscopic adjustable banding.

1. Do not provide LAGB.

   Since LAGB may fail the second and third screens established by the Expert Panel and accepted by government as the basis for health technology decisions, this option might be the most appropriate. This option does not in itself declare LAGB as an uninsured or enhanced service.

2. Provide LAGB as a standard medical good; encourage regions to offer it as part of comprehensive obesity management programs.

   This option provides LAGB as another surgical treatment available to Albertans, both patients and providers, to be used in appropriate cases. As is the case with most insured medical services, appropriate patient selection would remain the responsibility of physicians.

   LAGB may offer several advantages to both patients and providers over existing services. Although not proved, the adjustability suggests that more appropriate weight loss regimens might be achieved, thus maintaining an optimum level of health while losing weight. Minimal invasiveness and reversibility suggest an easier surgery for the patient, although this has to be balanced against the risks of complications. Laparoscopic surgical techniques are being applied to many surgical interventions, LAGB is simply one more option in the array of interventions that physicians could use for appropriate patients.

   Since bariatric surgery in general and LAGB in particular appears to be more effective when used as part of a comprehensive obesity management program, RHAs should be encouraged to provide LAGB surgery only to appropriate patients who are able and willing to commit to long-term participation in such a comprehensive program. Patient selection within these programs would remain the responsibility of physicians. Nevertheless, this is an implementation question best left to the regional authorities.

   As a standard good, the cost of LAGBs would be covered by RHAs out of their global budgets, if they choose to provide it. Additional fees for LAGB would not be able to be charged to patients within the province.

Summary and Conclusion

The review of the LAGB device was undertaken in response to continued requests from Albertans for access to this surgery for treatment of clinically severe obesity. This technology was chosen to pilot the new Alberta Health Technology Decision Process; the results of the evaluation of the pilot test are the subject of a companion report.

Obesity, considered epidemic throughout most of the developed and developing world, is a complex metabolic condition in which the proportion of body fat begins to affect health. Clinically severe obesity is characterized by extreme obesity and/or the presence of additional diseases, termed co-morbidities, significantly affected by the obesity. Obesity treatments range from nutrition and diet, exercise and behavioural modification to bariatric surgery (the surgical management of obesity). Obesity cannot be cured and effective management requires a lifetime commitment from the patient.

LAGB is one type of surgical intervention; the other two are gastric by-pass, where the upper stomach is directly connected to the small intestine thus by-passing the rest of the stomach and the first part of the small intestine, and vertical gastric banding, or stomach stapling. LAGB surgery places an adjustable band around the top part of the stomach creating a small stomach pouch, creating an earlier feeling of fullness, and restricting the flow of nutrients to the rest of the digestive system. The band can be loosened or tightened to further restrict or increase the flow of nutrients, altering the rate of weight loss. According the available evidence, in a trained and experienced surgical team, LAGB is as safe and as effective as other bariatric surgeries.

Effectiveness of all bariatric surgeries, including LAGB, is improved when provided as part of a comprehensive obesity management program. Although appropriate patient selection criteria for LAGB remain undetermined, this is the case with all bariatric surgeries and should not be a determining factor in the provision of LAGB.

LAGB is as cost-effective as other bariatric surgeries, and there is no economic evidence for preferring one type of bariatric surgery over another. Nevertheless, the incremental cost of LAGB surgery appears to be approximately $1,800 per case. Over the five-year period from 1999/2000 to 2003/04, an average of 175 patients annually received some form of bariatric surgery. Capital Health forecasts 300 to 350 patients in that region may need bariatric surgery. Approximately 25% of these could be LAGB. Without significant increase in the capacity of the system, it is unlikely that more than 200 patients per year province-wide would receive LAGB. If so, total incremental costs would be approximately $360,000.

LAGB was assessed against the criteria set out by the Expert Advisory Panel to Review Publicly Funded Health Services in its March 2003 report, *The Burden of Proof*. LAGB meets the safety and effectiveness criteria for the technical screen. It meets most of the criteria of the socio-economic screen, failing only the alternative services test. However, although alternative services are available, there are features of this procedure that may be an improvement on current services. Finally, it is arguable that LAGB fails the criteria set out in the fiscal screen; however, Capital Health believes that reduction in costs associated with length of stay may offset the incremental cost of the procedure.

Two funding policy options are considered: do not provide and provide as a standard good encouraging regions to coordinate service with comprehensive obesity management programs. Funding for LAGB would be found within existing RHA global budgets, should they choose to provide it.

Appendix A

Member of the Expert Advisory Group and Project Leads

The members of the Lap Banding Review Expert Advisory Group were:

- Henry Borowski, Alberta Health and Wellness
- Joanne O'Gorman, Capital Health
- Nancy Guebert, Calgary Health Region
- Dr. Doug Davey, surgeon
- Dr. Richard Lewanczuk, specialist
- Marisa Bonuccelli, AMA representative

The project team leads were:

- Don Juziwishin, Alberta Heritage Foundation for Medical Research (technological effectiveness analysis)
- Dr. Donald Schopflocher (Ph.D.), Alberta Health and Wellness (population health analysis)
- Dr. Philip Jacobs, (Ph.D.) University of Alberta/ Institute of Health Economics (Costing and utilization analysis)
- Dr. Habib Fatoo (Ph.D.), Alberta Health and Wellness (data extraction)
- Joanne O'Gorman, Capital Health (implementation analysis)
- Dr. Devidas Menon (Ph.D.), University of Albera/Institute of Health Economics (public policy analysis)
- Dr. Raymond Howard, Medical Consultant, Alberta Health and Wellness
- Jon Brehaut, Hummingbird Consultants (project management and synthesis report)

Appendix B

List of Analysis Reports

1. Self Reported Body Mass Index and Its Correlates in Alberta: A portrait from survey and administrative data sources, D. Schopflocher, Health Surveillance Branch, Alberta Health and Wellness.
2. Laparoscopic adjustable gastric banding for treatment of clinically severe (morbid) obesity in adults: an update. B. Gao, C. Harstall, Alberta Heritage Foundation for Medical Research.
3. Costing of Alternative Treatments for Morbid Obesity: Institute of Health Economics Working Paper, P. Jacobs, A. Ohinmaa, S. Klarenbach, A. Chuck, R. Padwal, J. Varney, D. Lier, Institute of Health Economics.
4. Laparoscopic Adjustable Gastric Banding (LAGB) for Treatment of Patients with Clinically Severe Obesity, Capital Health.
5. Laparoscopic Adjustable Gastric Banding Policy Considerations: An Institute of Health Economics Working Paper. D. Menon, T. Stefanski, Institute of Health Economics.

Appendix C

Three-Screen Process (TSP)